INVESTIGATING FACTORS THAT IMPEDE SUCCESSFUL VACCINE MANUFACTURING BUSINESS IN THE KINGDOM OF SAUDI ARABIA: IMPERATIVES FOR HEALTHCARE SUSTAINABILITY

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Abstract

Vaccination is one of the most efficient methods for preventing and controlling dangerous and occasionally fatal viral diseases (World Health Organization (WHO), Report 2020, p. 266). Mass vaccination, surveillance, and campaigns have decreased morbidity and death from several infectious diseases, including SARS-CoV-2, and have helped eradicate diseases like smallpox. Technologies and systems for manufacturing vaccines have been developed over time to meet ongoing issues, address limitations, and reflect technological improvements. However, the worldwide need for vaccines is increasing because of several factors, which include the growing global population, the impending acceptance of newly licensed or advanced-stage vaccines into healthcare systems, and ongoing global immunization campaigns to combat new infectious diseases. Several researchers and the WHO Immunization Report (2020) have emphasized that to meet the surge in demands for vaccines, there is a vital need for nations around the world to intensify efforts through the collaboration of the government and private sector to manufacture vaccines to meet local and international needs. In the Kingdom of Saudi Arabia (KSA), economic diversification has become a top priority on the national agenda, and the manufacturing sector has experienced tremendous growth over the years, geared towards playing a crucial role in realizing Saudi Vision 2030 and is anticipated to be the country's largest economic driver in line to meet the Sustainable Development Goals (SDGs). Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), known as COVID-19, which necessitated the vaccination of the KSA populace, revived the need for locally manufactured vaccines as WHO-approved vaccines in other countries around the world had to be imported, creating

additional medical costs and logistics challenges. Hence, investigating factors that impede successful local vaccine manufacturing businesses in KSA is crucial for enhancing primary healthcare services as well as meeting the KSA Vision 2030, which emphasized economic diversification and less reliance on pharmaceutical products. This research employed a cross-sectional quantitative survey method to gather data from 265 respondents (entrepreneurs, healthcare practitioners, academicians, and government workers in KSA). Data gathered through the survey questionnaire were encoded into the Statistical Package for Social Sciences (SPSS version 20.1). Descriptive statistics were used to establish the mean and standard deviation of the demographic variables, and inferential statistics (Regression analysis, One-way ANOVA) were utilized to test the stated hypothesis statements. Findings from regression analysis showed that the independent variables: cost of investment ($b = .313$, $t = 4.483$, $p < .001$), lack of adequate infrastructure ($b = -.131$, $t = -1.956$, $p < .052$), and government regulations and policies ($b = .316$, $t = 6.302$, $p < .001$), are significant. However, the independent variables lack of research and development (R&D) capability ($b = -.057$, $t = -1.211$, $p = .227$), low revenue ($b = .048$, $t = 1.176$, $p = .241$), lack of technical knowledge ($b = -.011$, $t = -.180$, $p = .857$), lack of government support ($b = .026$, $t = .626$, $p = .532$), lack of partnership opportunities ($b = .011$, $t = .185$, $p = .854$), were not significant. Findings from One-way ANOVA conducted to evaluate the perception of the participants according to the work sector regarding vaccine manufacturing business in KSA, indicated statistical significance at ($p = 0.05\%$) confidence level [$F (3 = 3.157, p < .025)$]. This research demonstrated that the study independent variables are factors that impede vaccine manufacturing business in KSA.

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List of Abbreviations

CINs	Critical Infrastructure Networks
DCVMN	Developing Countries Vaccine Manufacturers' Network
DTaP	Diphtheria, Tetanus, and Acellular Pertussis
EID	Emerging Infectious Diseases
EMA	European Medicines Agency
EPI	Expanded Program on Immunization
EUA	Emergency Use Authorization
EID	Emerging Infectious Diseases
BMGF	Bill & Melinda Gates Foundation
FDA	Food and Drug Administration
IPV	Inactivated Polio Vaccine
LMIC	Low- and Middle-Income Countries
mRNA	Messenger Ribonucleic Acid
NGO	Non-Governmental Organization

SARS-CoV-2	Severe Acute Respiratory Syndrome Corona Virus 2
SPSS	Statistical Package for Social Sciences
UNICEF	United Nations International Children's Emergency Fund
US	United States
WHO	World Health Organization
CDMO	Contract Development and Manufacturing Organization
TPB	Theory of Planned Behavior
SCT	Social Cognitive Theory
FDA	The Food and Drug Authority
RNA	Ribonucleic Acid
COVID-19	Coronavirus disease 2019
SFDA	Saudi Food and Drugs Authority
VPDs	Vaccine-Preventable Diseases
EPI	Expanded Program on Immunization
SAGE	Strategic Advisory Group of Experts
KAAUH	King Abdullah University Hospital

ADE	Antibody-Dependent Enhancement
VAERD	Vaccine-Associated Enhanced Respiratory Disease
RSV	Respiratory Syncytial Virus
SARS	Severe Acute Respiratory Syndrome
R&D	Research and Development
USA	United States of America
UK	United Kingdom
GDP	Gross Domestic Product
SA	Saudi Arabia
DoV	Decade of Vaccines
MENA	Middle East and North Africa
GMP	Good Manufacturing Practices
CEPI	Coalition for Epidemic Preparedness Innovations
GSK	GlaxoSmithKline PLC
MSD	Merck & Co., Inc
SIDF	Saudi Industrial Development Funds

USD	United States Dollar
RDIF	Russian Direct Investment Fund
GAVI	Global Alliance for Vaccines and Immunization
ACT	Access to COVID-19 Tools
GCC	Gulf Cooperation Council
CEPI	Coalition for Epidemic Preparedness Innovations

Chapter One: Introduction

Introduction to the Research

Vaccination is one of the most efficient methods for preventing and controlling dangerous and occasionally fatal viral diseases (World Health Organization (WHO), Report 2020, p. 266). Mass vaccination, surveillance, and campaigns have decreased morbidity and death from several infectious diseases, including SARS-CoV-2, and have helped eradicate diseases like smallpox (Haas et al., 2021, p. 221; Plotkin et al., 2017, p. 122). See Table (1.1).

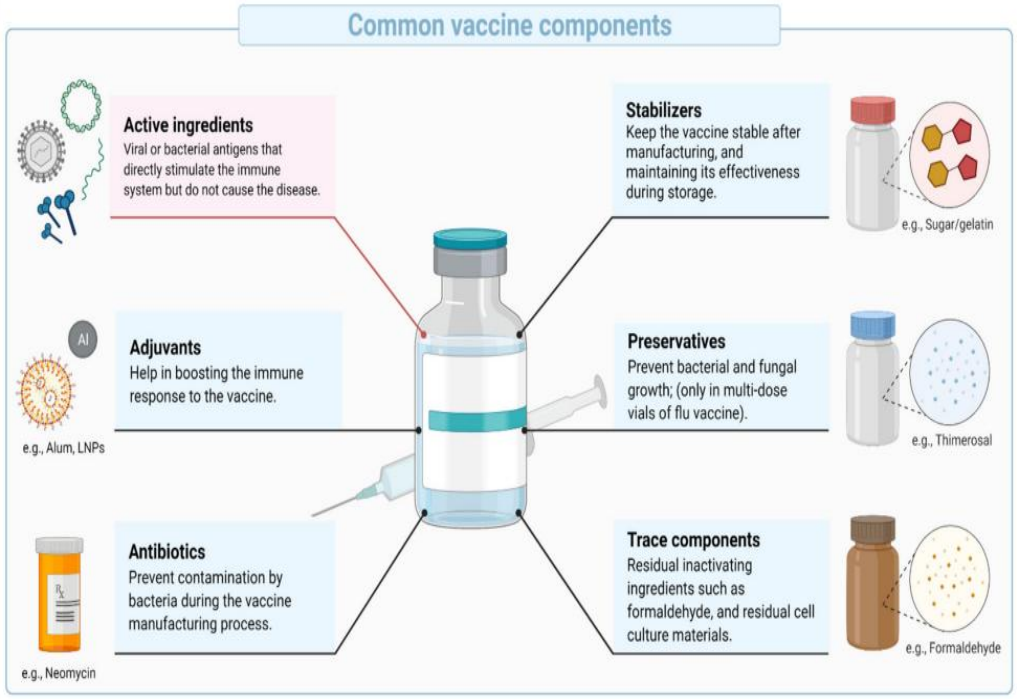
Vaccines are biological substances created by modifying genetic material of living organisms, such as cultures of yeast, bacteria, insect cells, or animal cells (Aars, Clark, & Schwalbe, 2021, p. 212; Nguyen & Schwalbe, 2019, p. 302; Plotkin et al., 2017, p. 122). As biological compositions, vaccines are designed to boost and prime the immune system to fight against illness or infection by making use of the highly developed mammalian immune system's capacity to identify, react to, and recognize pathogens (Ghattas et al., 2021, p. 31; Plotkin et al., 2017, p. 122). See figure (1.1).

Vaccines differ from small-molecule medications in many ways, in terms of development, production, regulatory restrictions, and patent structure (Lurie, Saville, Hatchett, & Halton, 2020; Azimi et al., 2019).

Most vaccines made with the same active ingredients are in fact a new entity, in contrast to generic medications that are chemically identical (Nguyen & Schwalbe, 2019, p. 302; Plotkin et al., 2017, p. 122; Azimi et al., 2019, pp. 233-235).

Figure 1.1

Schematic Representation of Common Vaccine Components



Note. Adapted from Ghattas et al., 2021, p. 3.

Generally, vaccines have been successful in eradicating serious illnesses like poliomyelitis, haemophilus influenzae type-b (Hib), rotavirus enteritis, hepatitis, parotitis (mumps), pertussis, varicella (chickenpox), tetanus, measles, and diphtheria in many nations throughout the world, despite the significant discrepancy in access to vaccines, particularly in low- and middle-income countries (WHO Vaccination and Immunization Report 2020, p. 266; Ghattas et al., 2021, p. 32). See Table (1.1).

Table 1.1

Emerging Viral Infectious Diseases

Year of first Description	Name	No of deaths	Comments
1918	'Spanish influenza'	In the range of about 50 million to 100 million	1918: H1N1; other pandemics in 1957–1958 (H2N2), 1968 (H3N2) and 2009 (H1N1)
1931	Rift Valley Fever	Overall CFR < 1%; ~50% for hemorrhagic fever	Contact with blood or organs of infected animals and mosquito-borne; several outbreaks in 1977, 1997–1998,
1937	West Nile fever	CFR ~5%	Mosquito-borne; worldwide outbreaks (most recent 1999–2010, USA)
1967	Marburg hemorrhagic fever	~470; very high CFR (24–88%, WHO)	Contact with African green monkey; numerous outbreaks in Africa 1969–2018
1969	Lassa fever	~5,000 deaths annually; CFR 1–2%; Nigerian CFR 25%	Contact with rodents or contaminated food or items; mostly in West Africa (Nigeria 2018)
1976–2020	Ebola hemorrhagic fever	>15,000; CFR 75%	First identified in 1976; first major outbreak in 2013–2016 in West Africa and in 2018 in Democratic Republic of Congo; 29 regional epidemics in 2020 in West and Central Africa
1981	HIV/AIDS	~37 million	Ongoing pandemic
1996	Avian flu	High CFR (60%)	H5N1 and H7N9 viruses from poultry; several outbreaks worldwide; last outbreak in China in 2018

1999	Nipah fever	<1,000. very high CFR	Outbreaks in Malaysia, Singapore, Bangladesh, and India
2002	SARS	813; CFR ~ 10%	Contained—did not turn into pandemic
2009	H1N1; H7N9 'swine flu'	284,000. CFR 2.9–9%	Pandemic
2012	MERS	935; CFR 34.4%	Major outbreak in 2012–2019; ongoing (camels, humans); detected in 27 countries but mostly in Middle Eastern countries
2014	Chikungunya	Rare	Mosquito-borne
2015	Zika	Unknown	Mosquito-borne
2019–ongoing	COVID-19 (SARS-CoV-2)	>2.3 million;	2019–ongoing

Note. Adapted from Excler et al., 2021, p. 595.

WHO Vaccination and Immunization Report (2020, p. 266) estimates that immunizations prevent between 2-3 million deaths annually. Monitoring, pandemic preparedness programs, government and non-government cooperation, national policies, and current technology and platforms for vaccine production and distribution are among the many variables that affect capacities to respond to threats quickly (Nguyen & Schwalbe, 2019, Pagliusi, 2013, p. 231).

Although technologies and systems for manufacturing vaccines have been developed over time to meet ongoing issues, address limitations, and reflect technological improvements (Jacob et al., 2020, p. 112). However, the worldwide need for vaccines is increasing because of several factors, which include the growing global population, the impending acceptance of newly licensed or advanced-stage vaccines into healthcare systems, and ongoing global immunization campaigns to

combat new infectious diseases. Several researchers (Shuman et al., 2020, p. 23; Badreldin & Atallah, 2021, p. 2; Yu et al., 2010, p. 11), as well as the WHO Vaccine and Immunization Report (2020, p. 189), have emphasized that to meet the surge in demands for vaccines, there is a vital need for nations around the world to intensify effort through the collaboration of government and private sector to manufacture vaccines to meet the local and international needs. Vaccine manufacturing serves to facilitate levels of revenue and capital investment in healthcare facilities and systems that are in proportion to KSA economic status and are appropriately distributed to reflect domestic primary healthcare (KSA-MoH-VRO, 2017, p. 113).

Table 1.2

Vaccine Platforms and Vaccines Currently Developed

Vaccine Platforms and Vaccines Currently Developed or Under Development for Emerging Viral Infectious Diseases

Vaccine Platform	Other Specifications	Developed For	Under Development or Stopped For	Shortcomings And Advantages
Live attenuated		Influenza; yellow fever; poliomyelitis	COVID-19; rvf (veterinary and human use) Lassa fever; chikungunya	Biosafety level 3 manufacturing plant for handling dangerous viruses
Whole inactivated	With or without adjuvant	Influenza; poliomyelitis; COVID-19	Sarsa; zika; rvf (veterinary use); chikungunya	Biosafety level 3 manufacturing plant for dangerous viruses; needs adjuvant; hpb regimens possible

DNA	Electroporation; adjuvant		Sars; mers; zika; lassa fever; COVID-19	Poorly immunogenic; electroporation requires device; difficult use for Rollout; hpb regimens possible
Mrna		COVID-19	Lassa fever; disease x	Rapidly adaptable to new emerging viruses; hpb regimens possible; ultracold chain currently unpractical for large-scale use in resource-limited settings
Recombinant vectors				
Nonreplicating				
Ad5			COVID-19	Preexisting immunity to ad5
Chad3			Ebola	Cell-line-produced.
Chadox1		COVID-19	Mers; rvf; lassa fever; Nipah; zika; chikungunya	Adaptable construct to emerging virus in 5–6 months; hpb regimens possible
Ad26		Ebola; COVID-19		
Live attenuated				
Mva		Ebola	Mers	
Vsv		Ebola	COVID-19a; lassa fever; nipah	

Measles			Mers; lassa fever; Nipah; chikungunya; COVID-19a	
Protein based				Requires more time to adapt to new
Virus-like particle	With adjuvant	COVID-19	COVID-19	Emerging viruses; needs adjuvant;
Monomer; dimer; trimer	With adjuvant		COVID-19; rfv; nipah	Hpb regimens possible
Molecular clamp	With adjuvant		Influenza; mers; COVID-19a	

a vaccine development stopped.

Note. Adapted from Excler et al., 2021, p. 592.

In the Kingdom of Saudi Arabia (KSA), economic diversification has become a top priority on the national agenda, and the manufacturing sector has experienced tremendous growth over the years, geared towards playing a crucial role in realizing Saudi Vision 2030 and is anticipated to be the country's largest economic driver in line to meet the Sustainable Development Goals (SDGs), which were declared by the global community in 2015 (KSA Vision 2030, p. 29; Rahman & Al-Borie, 2020, p. 20).

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which necessitated the vaccination of the KSA populace, revived the need for locally

manufactured vaccines as WHO-approved vaccines in other countries around the world had to be imported, creating additional medical costs and logistics challenges (WHO, 2020, p. 241). Hence, investigating factors that impede successful local vaccine manufacturing business in KSA is crucial for enhancing primary healthcare services as well as meeting the KSA Vision 2030 that emphasized economic diversification and less reliance on pharmaceutical products (Jacob et al., 2020, p. 112).

Background of the Research

KSA is the largest country on the Arabian Peninsula and has a well-established free health care system for all residents (KSA-MOH-VRO, 2017, p. 113). The Ministry of Health (MOH) is the primary provider of healthcare services via a network of 287 government hospitals and 2257 primary healthcare institutions (Ministry of Health, Statistical Yearbook (2020, p. 2). Other ministries, such as Defense and Aviation, Human Resources and Social Development, and Interior, as well as organizations like the National Guard and ARAMCO, are responsible for financing and delivering healthcare services to their employees and their families (Hasanov, Javid, & Joutz, 2021, p. 4). Other government agencies currently operate 50 hospitals in the Kingdom. The private health sector operates 267 hospitals, 3005 medical complexes, 49 private doctor clinics, and 174 laboratories (KSA Ministry of Health Annual Statistical Report, 2021, p. 2), as shown in Table (1.3).

KSA nationals, as well as foreigner workers, are all subject to known infectious viral diseases and newly emerging ones (Kashte et al., 2021, p. 23). As emphasized by Beach et al. (2022, p. 11), there are many synergistic and interlinked

aspects that also take under its ambit high-density urbanization, demographic trends, modernization that favors high mobility of individuals through all transportation mediums, mass gatherings, modifications in human behaviors, environmental modifications with changes in ecosystems and insufficient global mechanisms for public health, etc. These factors have accelerated the emergence and spread of viruses as existing threats for humanity.

Table 1.3

KSA Health Services Sector Statistical Report

Health services providers	No. of hospitals	No. of hospital beds	No. of doctors	Population served
Public health sector				
Ministry of Health (MOH)	287 (56.9%)	45180 (57.48%)	50065 (52.5%)	All Saudi nationals and expatriates working in government services
Other Government Sectors		13989 (17.79%)	20234 (21.2%)	
Armed Forces Medical Services		5689	8242	Employees and their families
National Guard Services	50 (99.9%)	2669	4751	Employees and their families
Ministry of Interior		855	1100	Employees and their families
King Faisal specialist hospital & research center		1817	1859	Referred Saudi Nationals
Royal Commission Hospitals		455	498	RCJY's Employees
ARAMCO Hospitals		424	760	ARAMCO Employees
Ministry of Human Resources and Social Development		2080	147	University Students and Employees

Private Health Sector	167 (33.1%)	19427 (24.71%)	25037 (26.3%)	Saudi Nationals and Expatriates
Total Hospitals and Beds	504 (100%)	78596 (100%)	95336 (100%)	

Note. Adapted from KSA Ministry of Health Annual Statistical Report, 2021, p. 2.

During the emergence of the Spanish flu in 1918, as per estimates, the global population was around 1.8 billion (WHO Report, 2020, p. 241; Beach et al., 2022, p. 11). As per recent estimates, the global population has been anticipated to reach around 9.9 billion by the year 2050, which would mark an increase of more than 25 percent from the prevailing global population of 7.8 billion as recorded during 2020 (Worldometer, 2023).

The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which was said to be responsible for the coronavirus (COVID-19) in 2019, that swept over the whole world in a period of less than six months with a high rate of mortality among the elderly and those with interlinked comorbidities, caused a healthcare pandemic and disrupted the world economy (Wang et al., 2020, p. 2; Zhu et al., 2020, p. 1). Other than lockdowns, the only measure of control was restricted to an array of mitigation strategies like wearing masks, avoiding large gatherings, and self-distancing, which was not only imperfect but also had its own limitations (WHO Vaccine and Immunization Report, 2020, p. 189).

As more than 100 million individuals around the world were infected with the disease and caused deaths across nations, it has been widely acknowledged that the development of vaccines to supplement the current countermeasures was the best option to control the COVID-19 pandemic (WHO Vaccine and Immunization Report

(2020, p. 189). Therefore, factors that drive policymakers and researchers to maintain vigil and reevaluate their steps towards surveillance and management of threats from infectious diseases that might emerge in the future while reassessing the global mechanisms to control similar pandemics need to be facilitated and investigated (Friedler, 2021; Gully, 2020, p. 164).

Throughout the millennia, the emergence of new infectious diseases has been well-recognized and acknowledged, much before causative agents were discovered (Sharma et al., 2020, p. 2). Irrespective of the advancements in countermeasure development (therapeutics, diagnostics, and vaccines), global travel and increased inter-reliance globally have extended the intricacies in terms of containing such infectious diseases (Bedford et al., 2020, p. 12; WHO-GHO, 2019, p. 17). Hence, emerging infectious diseases (EIDs) have been identified as major threats to stability around the world and also to the health of humans (IFPMA, 2019, p. 15; Pier et al., 1980).

A review of emergent pandemic diseases over the course of history presents a perspective on the emergence and attributes of coronavirus epidemics, with much stress on the SARS-CoV-2 pandemic (Morens et al., 2020; Morens & Fauci, 2020). With the growth of human societies in size and complexity, there is an endless variety of opportunities that present themselves for infectious agents to rise into the vacant ecological spaces that are being continuously created by humans (WHO-GHO, 2019, p. 17). Therefore, adhering to a conventional pipeline for research and development, the time usually taken for vaccine development for an infectious agent range between five and ten years (IFPMA, 2019, p. 15; WHO-GHO, 2019, p. 17). An approach such as this is not appropriate for the requirements as imposed through

the rise of a new pathogen in the time of a pandemic. For instance, the outbreak of the Ebola virus in West Africa during 2014 lasted for around two years, caused around 11,325 deaths, and was adequately extended to facilitate the development and testing of vaccines for Ebola (WHO Ebola Situation Report, 2020, pp. 110–112). In this case, the level of efficacies was revealed for one vaccine among several, towards the end of the pandemic (Wolf et al., 2020, p. 11; Feldmann et al., 2018, p. 25). However, the remarkable aspect of the COVID-19 pandemic was that the entire pipeline for research and development, right from the very initial SARS-CoV-2 viral sequenced for interim analysis of trials on vaccine efficacy, was finished within just around 300 days (Ball, 2020, p. 15; Schwartz, 2020, p. 2).

Amid growing concerns pertaining to unmitigated transmission over the 2013-2016 Ebola outbreak in Western Africa during 2014, the World Health Organization (WHO Ebola Situation Report, 2020, pp. 110–112) stressed speeding up the development and assessment of candidate vaccines. To make sure that manufacturers would take the Ebola vaccine to complete development and implementation, the Vaccine Alliance (GAVI) announced a support of around $300 million for the purchase of the vaccine, which was followed by an announcement on an advance purchase agreement. But the irony was that there were previously developed and tested Ebola vaccines for defense purposes within non-human primates (Jacob et al., 2020, p. 122). However, this earlier work was not prepared for clinical trials at the time of the epidemic nor deemed commercially viable to facilitate its development (Feldmann et al., 2018, p. 25).

Vaccines have been considered the keystone in terms of managing outbreaks of infectious diseases (WHO Vaccine and Immunization Report (2020, p. 189).

Vaccines have also been acknowledged as one of the firmest mediums to placate the risk of an epidemic or a pandemic (Puri et al., 2020, p. 25). The faster the deployment of a vaccine is, the faster it would be to control a disease outbreak (WHO Vaccine and Immunization Report (2020, p. 189; Feldmann et al., 2018, p. 25). As is evident, the standard cycle for vaccine development is not appropriate to tackle explosive pandemics such as COVID-19 (WHO Ebola Situation Report, 2020, pp. 110–112; IFPMA, 2019, p. 15).

Nonetheless, new vaccine platform technologies have the scope to reduce the standard cycle and present the scope for several vaccines to be developed at a rapid pace, tested, and manufactured (van Riel & de Wit, 2020, p. 141). There are several significant technical platforms for vaccines that have been developed or are in the process of development to tackle emergent infectious viral diseases (Polack et al., 2020, p. 75; Kumar, Meldgaard, & Bertholet, 2018). Two vaccines for COVID-19 have been evidenced to be developed with the help of Messenger Ribonucleic Acid (mRNA) technology, viz., Pfizer-BioNTech and Moderna, both of which indicated high levels of efficacy and safety (Polack et al., 2020, p. 75; Baden et al., 2021, pp. 104-106).

Furthermore, the emergency use authorization (EUA) now prompted by the United States (US) Food and Drug Administration's (FDA) (2020) and the European Medicines Agency’s (EMA) authorization for conditional marketing have now made the process simpler. However, there are clear costs linked to any programs for vaccinations (Polack et al., 2020, p. 75). This would be inclusive of infrastructure needed to execute the program and cold-chain sustenance, personnel for healthcare

administration, and the purchase of vaccines (Polack et al., 2020, p. 75; Baden et al., 2021, pp. 104-106).

Several governments, with requisite support obtained from non-governmental organizations (NGOs) and charities, invest in vaccine manufacturing with the objective of facilitating health improvements (IFPMA, 2019, p. 15). This has resulted in the reduction in morbidity and mortality rates associated with impactful vaccination programs, with a blend of direct and indirect safeguards, which has led to a drop in the existence of diseases and costs related to healthcare (Wouters et al., 2021, p. 932; Du et al., 2022, p. 455). Such noticeable reductions have major implications for the growth of the economy, with minimum amounts being spent as costs are avoided with a smaller number of medical tests, treatments, and procedures and less time off from work by patients (Wouters et al., 2021, p. 932; Du et al., 2022, p. 455).

Based on an analysis of the cost-effectiveness of vaccination programs, it has been reported that it is immensely worth the investment, as several programs are known to have costs lower than US$50 for every life gained (IFPMA, 2019, p. 15; Troja, 2020, p. 20; Bloom et al., 2017). As indicated by IFPMA (2019, p. 15), return on investments (ROI) for vaccines given its growing provisions has been estimated at 12–18 percent.

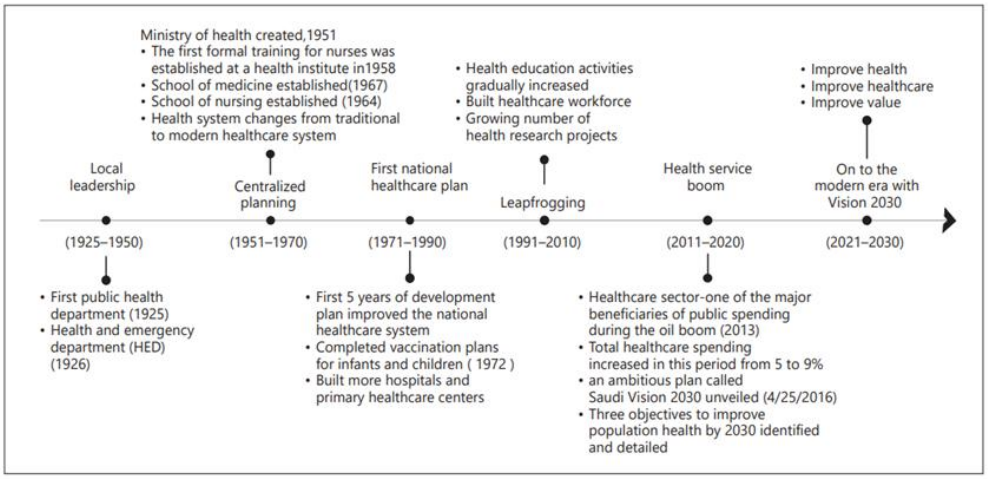
Zimmermann et al. (2019, p. 221) mention that economic gains from the elimination of diseases such as smallpox and polio are commendable. For instance, costs associated with the elimination of smallpox were estimated at US$100 million, but it led to savings estimated at around $1.35 billion, while the eradication of polio

was expected to save around $1.5 billion per year. Economic gains that were not very much taken into consideration about cost-effectiveness or analysis of cost benefits emerged through prevention of long-term morbidity following acute infections. For example, hearing impairments after pneumococcal meningitis infection or limb amputation following meningococcal disease, in tandem with extensive productivity gains, could have massive impacts on low- and middle-income countries (LMIC), as far as adoption of vaccination programs were concerned (Zimmermann et al., 2019, p. 221; Troja, 2020, p. 20).

The COVID-19 pandemic has been a check on reality regarding the fragile nature of supply of vaccines around the world and an absolute absence of extensive expertise in vaccine manufacturing in many countries, including KSA (Troja, 2020, p. 20). Particularly in KSA, the government is heavily focused on the provision of healthcare services, which is one of the top priorities of Vision 2023 (KSA Vision 2030, p. 29). As compared to the past, a large-scale enhancement in healthcare services has been observed regarding quantity and quality (Ibid., p. 29). Though many nations have observed major improvements within their healthcare system, compared to KSA, which has a large population as well as a large geographical area, none of these other nations have succeeded in healthcare development at an extensive national scale in a short time span (Young et al., 2021, p. 94). See Figure (1.2).

Figure 1.2

Evolution of the Health System in Saudi Arabia (1925–2030)



Note. Adapted from Young et al., 2021, p. 95.

Despite the massive enhancements within the KSA healthcare system, there are still challenges at the primary healthcare system, such as population growth, high costs of healthcare, emergent infectious diseases, chronic ailments, inequitable access, and a healthcare system that is highly centralized (Aljuaid et al., 2016; Asmri et al., 2020). During the outbreak of the COVID-19 pandemic, KSA was prompt to order vaccine supplies, wherein the first batch of vaccines reached in February 2021 (KSA-MoH-VRO, 2017, p. 213).

The vaccines delivered were distributed in phases, wherein the first phase focused on healthcare workers who had the highest exposure to risk of infection from COVID-19. The second phase involved the delivery of vaccines to frontline workers, such as military and security personnel, and other essential workers in the public and private sectors (transportation, energy, education, communication, etc.).

It also included people who were suffering from chronic medical conditions. The third phase focused on ensuring delivery of vaccines to the rest of the population (KSA-MoH-VRO, 2017, p. 213). In all three phases, vaccine delivery was facilitated and delivered to citizens and residents free of cost (Assiri et al., 2021). Such priorities were planned by the KSA government as they anticipated a shortage in supply of vaccines to cover their entire population (Dooling et al., 2021, p. 31; Thanh Le et al., 2020, p. 20).

Vaccine manufacturing involves an intricate procedure along with many challenges in the implementation as well as a safe and effective vaccine manufacturing process lifecycle (IFPMA, 2019, p. 31). The intricacies are further accentuated as the techniques used for analyzing the biological processes and antigens emerging from the production of vaccines often have a high inherent variability, and failure in managing such risks could result in enormous cost implications (Thanh Le et al., 2020, p. 20; IFPMA, 2019, p. 31). Based on the annual reports as presented by the United Nations International Children's Emergency Fund (UNICEF) between the periods of 2015-2019, there is an indication that most of the goods that were obtained from diverse nations were either biologicals or vaccines (UNICEF, 2015, 2017, 2019).

GAVI, the vaccine alliance, commenced with six vaccines from five suppliers across five nations, and as of date, they have 430 vaccine launches to their credit. Their existing vaccine portfolio comprises 17 suppliers within 11 nations and focuses on 18 diseases, which makes an impact on supply security and affordability. DCVMN that contributes to GAVI markets has increased from four to 10 during the periods between 2012 and 2018. In addition, 55 percent of the overall doses were

supplied by DCVMN to GAVI within the said period (Pagliusi et al., 2020, p. 2). Even at the time of the COVID-19 pandemic, there were only a handful of nations with exceptions who were actively engaged in the process of vaccine development and manufacturing. This has added much stress upon localization of vaccine production. Local production would need interested nations to work towards the transfer of technology, its assimilation, capacity building, and innovation.

Interventions on capacity building specifically could assume diverse forms that encompass detailed consultations, online learning options, technical support, in-person and web-based trainings, skills-based courses like mentoring and coaching, and guidance materials in the form of knowledge products (DeCorby-Watson et al., 2018, p. 12). However, KSA was not among the nations that were contributing to the overall vaccine production. During the COVID-19 pandemic, the nation was heavily dependent on the acquisition of vaccines from other countries that were manufacturing and marketing them. This extreme reliance cannot be considered an issue unless the KSA market is affected by a shortage of essential vaccines for any epidemic or pandemic-like situations in the future. For the fact that KSA depends on imports, it will be affected in the event of a shortage of vaccine imports or any disruption in the global supply chain (Dooling et al., 2021, p. 31). This renders the need for KSA to consider localizing their vaccine production. It is vital that the challenges and opportunities presented by vaccine manufacturing be investigated (Thanh Le et al., 2020, p. 20; Thanh Le et al., 2020, p. 20).

Statement of the Research Problem

The vaccine market within low and middle-income countries (LMIC) is dominated by foreign vaccine manufacturers, which creates challenges such as logistics and delivery schedule issues, vaccine storage, and the viability of vaccines (El-Chaarani, 2019, p. 7). Hence, these immediate challenges necessitate interventions through local or regional groupings of nations for vaccine manufacturing businesses (Ortiz-Prado et al., 2021, p. 32). Basically, such a novel investment approach results in maintaining rigid control over sustainability and scheduling during production, security of supply, socio-economic development, cost control, and prompt response to local epidemics, which encompass infectious diseases that are emerging (Ortiz-Prado et al., 2021, IFPMA, 2019, p. 31). Considering the importance of vaccines in public health programs, the KSA government and donors have made huge investments in research and development on vaccines in low-resource contexts (Lakdawalla, 2018).

During the COVID-19 pandemic, there was massive demand for vaccination as the spread of the disease increased, and this was matched with an unprecedented response in terms of research and development, accelerating the development of many vaccine platforms that immediately received approvals within a year of the virus being identified (Ahnert et al., 2021, p. 20). This necessitated the requirement for scaling up production at a faster pace than is usually known in the domain of pharmaceutical development (Ibid., p. 20). Furthermore, the challenge of the COVID-19 pandemic was further aggravated by massive vaccine demand worldwide and suppliers of vaccine components and manufacturers of vaccines aimed at collective supply targets of around 14 billion COVID-19 vaccines by the end of

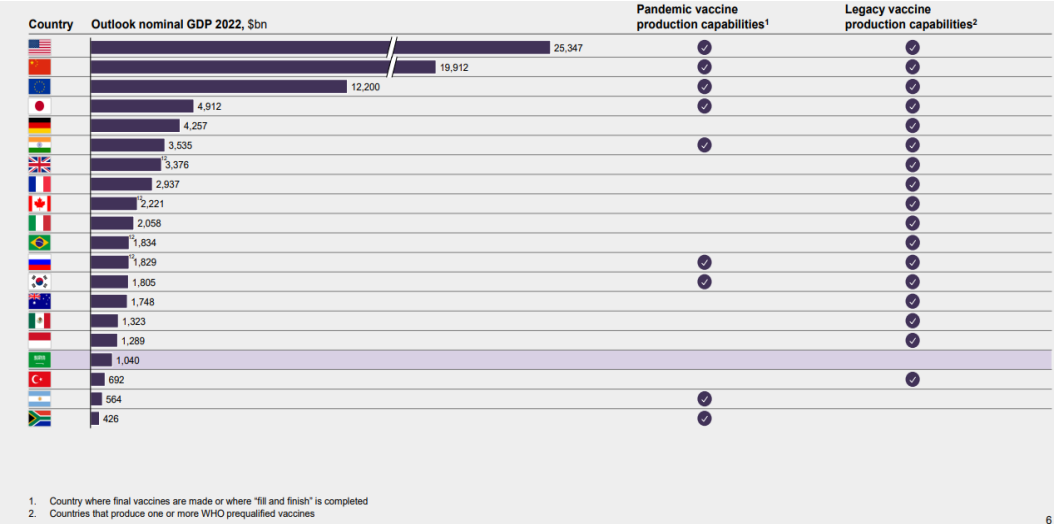
2021, which was three to four times larger than the anticipated annual global demand for all vaccines prior to COVID-19 (IFPMA, 2019, p. 24).

In Saudi Arabia, the first case of COVID-19 was reported on March 2nd, 2020, and the number of cases witnessed a peak on the 18th of June 2020, when KSA recorded the highest single-day infection of 4,919 individuals. The number of cases confirmed by laboratories on 13th January 2021 was 364,096, with around 6,300 fatalities (Barry & BaHammam, 2021, p. 22). Robust steps were undertaken by KSA-MoH to restrict the spread of the disease, which included restrictions on travel, mandatory use of masks, and lockdowns (Barry & BaHammam, 2021, p. 22). During the COVID-19 pandemic, KSA was confronted with several issues related to vaccine delivery and operations, communication, patient experience, vaccine quality assurance, vaccine education, supply chain, and clinical care (Bashir et al., 2021, p. 6; Shuman et al., 2020, p. 1; Badreldin & Atallah, 2021, p. 2). Since there are no locally manufactured vaccines for COVID-19 in the country, a highly integrated process that involved ensuring a consistent track of vaccine supply was maintained. However, several challenges continue to emerge (KSA-MoH Report, 2020; Kis et al., 2020, p. 22; Tawfik et al., 2022, p. 1).

Among the G20 countries, KSA is the only country that is not locally manufacturing vaccines (International Monetary Fund, WTO, WHO, WITS, Team analysis, 2022, p. 6). See Figure (1.3). As mentioned by Tawfik et al. (2022, p. 1), KSA depended largely on other countries to cater to their vaccine requirements. Generally, KSA is known for restriction in terms of biopharmaceutical manufacturing (Tawfik et al., 2022, p. 1; Badreldin & Atallah, 2021, p. 2).

Figure 1.3

Vaccines Manufacturing and Supply Countries



Note. Adapted from IMF, WTO, WHO, WITS, Team analysis, 2020, p. 6.

As such, currently, there are a few pharmaceutical manufacturers, and among these are 19 pharmaceutical organizations involved in secondary packaging of biopharmaceuticals products and six organizations involved in executing aseptic filling and secondary packaging of biopharmaceuticals drugs (Alzahrani & Harris, 2021, p. 12; Tawfik et al., 2022, p. 1).

In KSA, some organizations are planning to setup start-up organizations for vaccine manufacturing, as the government favors vaccine manufacturing and has also invested around US$3.4 billion to the economy for boosting vaccine manufacturing businesses locally (Abd-Alaziz, 2022, p. 21). Furthermore, there are also some organizations that have shown interest in licensing their pharmaceutical products in developing a vaccine portfolio that lowers the high fixed costs associated

with production and volatility of the market (Alruthia et al., 2018, p. 22). It is evident that the incident of the COVID-19 pandemic in KSA exposed challenges that were previously never witnessed or experienced, such as large-scale reliance on global pharmaceutical markets and vaccine imports (Tawfik et al., 2022, p. 1; Badreldin & Atallah, 2021, p. 2). Hence, the KSA government is now compelled to seriously consider localization of vaccine manufacturing businesses to avoid being affected whenever there are any severe disruptions in global vaccine supply chains while strengthening their capabilities in domestic manufacturing (Alzahrani & Harris, 2021, p. 12; Tawfik et al., 2022, p. 1; Consulting, 2022, p. 1).

One way through which the KSA government is considering localization of vaccine manufacturing is through the establishment of partnerships and joint ventures between global vaccine manufacturers and local organizations as an outcome of routine immunization and disease outbreaks (Alzahrani & Harris, 2021, p. 12). Reputed multinational companies have an enhanced understanding regarding complex manufacturing processes, entry barriers arising from high technology, research and development, and cost associated with vaccine production (Biopolis Biomedical Research Initiative, 2021, p. 22; Narayana et al., 2019, p. 214; Surya et al., 2019, p. 15). Alliance with organizations such as the developing countries vaccine manufacturers network (DCVMN) with headquarters in Switzerland is among the ways through which vaccine manufacturing business can be achieved. DCVMN is an innovative global alliance that brings together public and private organizations to work toward a common aim of producing and distributing affordable, high-quality vaccines to protect people from known and emerging infectious diseases (Hotez & Bottazzi, 2022, p. 13). Notably, the network is a

voluntary public health-driven alliance of manufacturers with facilities established in developing countries and majority ownership by those countries' stakeholders and excludes multinational corporations and their subsidiaries with manufacturing facilities in developing nations (Mascarenhas, 2021, p. 17).

In KSA, decision-makers, donors, and investors do not have empirical information locally relating to factors that impede vaccine manufacturing and have frequently resulted in consolidation and attrition within current manufacturers. Therefore, investigating further the complexities and factors related to vaccine manufacturing is deemed to be vital in making intricate business decisions (Saudi Industrial Development Fund, 2020, p. 21; Tawfik et al., 2022, p. 1; Alzahrani & Harris, 2021, p. 12; Tawfik et al., 2022, p. 1). Therefore, this research is conducted to investigate factors that impede successful vaccine manufacturing business in KSA for the enhancement and sustainability of the health care sector.

Research Objectives

1. To assess if there is a relationship between lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, and government regulations and policies on vaccine manufacturing business in KSA.
2. To analyze the moderating effect of government regulations and policies in the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA.
3. To evaluate if there are any significant differences in the perception of respondents according to work sector regarding vaccine manufacturing business in KSA.

Research Questions

1. To what extent do lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, and government regulations and policies impede vaccine manufacturing business in KSA?
2. To what extent do government regulations and policies moderate the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA?
3. Is there any significant difference in perception of respondent according to work sector regarding vaccine manufacturing business in KSA?

Significance of the Research

This research is significant and beneficial as factors identified have the capacity to further and advance the development of local vaccine manufacturing while strengthening manufacturing firms within KSA to harness their entire potential and capacity in terms of vaccine manufacturing capabilities (Alzahrani & Harris, 2021, p. 12; Tawfik et al., 2022, p. 1).

In addition, the research finding has the potential to also enable the KSA manufacturing sector, especially in biomedical products, to understand current challenges in terms of production capabilities and supply chain aspects and thereby prepare the nation for any global pandemic or local epidemic in the future. Furthermore, findings from this research are instrumental in helping manufacturing organizations and government agencies to entirely develop their competencies in terms of tackling issues in vaccine discovery, manufacturing, and distribution within the country (Consulting, 2022, p. 23; Beach, Clay, & Saavedra, 2022, p. 12). Similarly, findings from this research provide a much-needed impetus to the KSA government to provide extra support to local vaccine manufacturing investors by developing an environment that facilitates vaccine manufacturing firms to entirely develop their capacities in full. At the same time, encourages the government to conserve earnings from foreign reserves that can later be funneled into other predominant areas like infrastructural development (Ahnert, Dhulesia, & Roper, 2021, p. 2).

This research finding also provides the necessary grounds for stimulating the KSA government to take an active lead by encouraging investors and manufacturers

through providing and supporting financial assistance and favorable policies that would lead to the development of environments that are largely beneficial for local vaccine manufacturing. Similarly, such findings have the capacity to draw attention to the opportunities for market present within the vaccine manufacturing business while encouraging new players to venture into the market and create feasible business in the domain of vaccine manufacturing (Bloom et al., 2017, p. 55; Huang & Kuan, 2022, p. 8).

The availability of vaccines within the country for general vaccination of the population against emerging diseases can prevent death of young and old (Huang & Kuan, 2022, p. 22). Nonetheless, there is no equitable access to vaccines within low and middle-income nations, including KSA. While it is a fact that manufacturing vaccines locally does offer an opportunity for manufacturers in the biopharmaceutical domain, at the same time, it is also confronted with several challenges (Spadaro, 2021, p. 34). A stable and robust process of vaccine manufacturing with a consistent supply of raw materials is of utmost importance (IFPMA, 2019, p. 24). The vaccine manufacturing is undergoing continuous evolution, and given current circumstances, it is necessary that nations like KSA manufacture their own vaccines instead of relying on imports to cater to their vaccine requirements. KSA also needs to maintain control over security in terms of supply, sustainability, production, costs, scheduling, socio-economic development, and rapid response to global pandemics or even local epidemics. Furthermore, there is also a need for building capacity in terms of workforce development, financial support, and technology transfer (Ahnert, Dhulesia, & Roper, 2021, p. 2).

Definition of Terms

Vaccines - defined as preparations that are biological in nature for deriving a particular immune response among people against a targeted microorganism.

Vaccination - a process through which an individual or a group of individuals can be inoculated with the objective of eliciting immunity.

Communicable diseases are those that can spread from one individual to another, from an animal to an individual, or from the surface to a food.

Non-communicable diseases are those that arise from unhealthy behaviors such as smoking and alcoholism. These are diseases that cannot spread from one person to another by common mediums like food or air.

Healthcare access refers to an individual's or society’s capability to acquire health related services like diagnosis, prevention, treatment, and disease management.

Disparities in Healthcare Access - refers to a situation where the entire population in a particular region does not have equal healthcare access. For instance, a rural region in a particular nation might not have a healthcare facility that can be availed by the residents, and residents might have to travel a long distance to urban areas for their healthcare needs. While those in urban regions might have several healthcare facilities to choose from, this creates disparities in healthcare access.

Pandemic - refers to a situation where the whole world is impacted by the outbreak of a communicable disease.

Clinical trials - a process where a new drug (or vaccine) is tested on animal or human subjects to determine its effectiveness against a specific disease.

Public health programs - refer to programs established and intended towards safeguarding and enhancing the health of people and their communities.

Localization - refers to the process of locally producing or manufacturing a product, or it could also mean conducting an activity locally within a nation.

Scope of the Research

The main objective of this research is to investigate the factors that impede successful vaccine manufacturing business in the KSA: imperatives for health care sustainability.

Therefore, this study focuses on gathering pertinent data and necessary information from employees in the healthcare sector, or KSA, pharmaceutical entrepreneurs, and government employees responsible for pharmaceutical products in all the regions of KSA.

Organization of the Research

This dissertation is organized into six chapters, which are inclusive of introduction, literature review, research procedures and methods, results findings and discussion, case study and implication, and summary, implications, and recommendations for further research.

Chapter One: Introduction - This chapter presents the background of the research, highlights the statement of the problem, research objectives, and research

questions, and specifies the significance of the research, organization of the research, definition of terms, and summary of the chapter.

Chapter Two: Literature Review - this chapter conducts an extensive review of existing literature relating to factors that impede the vaccine manufacturing business as well as critical analysis of previous research that has been carried out previously by other researchers. This chapter also examines underlying theories, identifies key variables for this research, and eventually identifies the gap in existing research.

Chapter Three: Methods and Procedures - this chapter discusses the procedure and methodology that was adopted for this research in data gathering, which involves research philosophies, research design, research methods, research population, sample size determination, data collection and analysis procedures, and ethical statements.

Chapter Four: Results and Discussion - in this chapter, the data that has been collected for this research was analyzed and the findings are presented.

Chapter Five: Case Study and Implications - this chapter presents a case study conducted to validate the finding presented in Chapter 4.

Chapter Six: Summary, Implications, and Recommendations for Further Research: - this chapter presents the overall summary of the research findings as well as the theoretical and practical implications of the findings, limitations of the research, and finally, providing recommendations for future research.

Summary of the Chapter

This introductory chapter presented a detailed insight into the background of this research regarding factors that impede the vaccine manufacturing business in KSA. This chapter also presented the background with regards to the importance of vaccines and vaccination in primary healthcare, which facilitates a reduction in mortality rates, the challenges of regularly importing vaccines, and the benefits of manufacturing vaccines locally for domestic and international needs.

This chapter also highlighted the research problems, research objectives, research questions, significance of the research in the context of the KSA business environment, and the organization of the research. This introductory chapter is the basis for the next chapter (Chapter Two: Review of Literature).

Chapter Two: Literature Review

Introduction

This chapter presents a review of related literature as well as critical analysis and synthesis of previous studies related to vaccine manufacturing. This chapter also presents the theoretical background of the study, emphasizing pertinent theories that underpin the research in general.

Theoretical Background of the Research

In every research endeavor, stating a theory or theories is critical because they give guidance to research through knowledge and understanding (Bradbury-Jones, Taylor, & Herber, 2014, p. 10).

According to Nkuda (2017, p. 31), theory is the root, and empiricism is the product of scientific endeavor. Gioia and Pitre (1990, p. 4) defined theory-building as “any logical description or justification of observed or experienced phenomena." Colquitt and Zapata-Phelan (2007, p. 21) state that theories can emerge from a new notion or a metaphor, which leads to the construction of a conceptual model that then aids in the reconsideration of theoretical methods.

Underpinning Theories

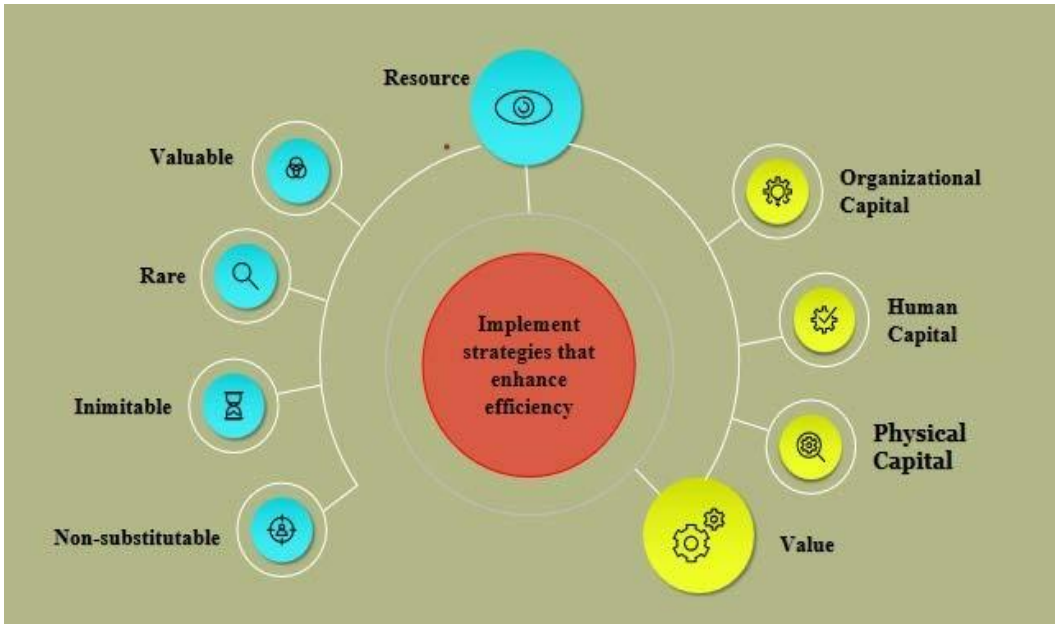
Research is primarily concerned with the pursuit of knowledge founded on truth discovered using acceptable methods. Therefore, this research is underpinned by the following theories:

Resource-Based View Theory (RBV): The Resource-Based View (RBV) theory is a managerial framework that assists organizations in identifying strategic resources that may be used to obtain a long-term competitive advantage (Barney 1991, p. 10; McIver & Lengnick-Hall, 2018). RBV posits that having unique resources and skills that are valued and unmatched enables a business to gain a sustainable competitive advantage, such as better performance and efficiency in productivity (Bodlaj & Čater, 2022; Dogbe et al., 2020). Gunasekaran et al. (2017, p. 3) state that firm resources are essential for performance and survival in a competitive environment and must be harnessed and utilized to meet set goals and objectives. These resources encompass an organization's internal assets, inherent skills, and abilities. According to Wernerfelt (1984), as cited by Azeem et al. (2021, p. 5), resources are assets that might be viewed as the organization's strength or weakness, and these include assets, both tangible and intangible, that are linked, such as organization names and services, internal knowledge and technology, skilled labor, machinery, and effective processes that can be used to compete in the market (Reimann et al., 2022; Dogbe et al., 2020, p. 4). Regarding manufacturing organizations, RBV theory emphasizes that sustainability and competitive advantage depend on the ability to use highly valuable, rare, and indispensable organizational resources in settings where policies and procedures for resource exploitation are in place (Furr et al., 2021; Gerhart & Feng, 2021). Barney (1991) posits that resources that are valuable, scarce, unique, and non-replaceable might provide organizations with a competitive edge. Therefore, physical capital, human capital, and organizational capital, all of which are the controllable resources of an organization, create value and facilitate efficiency and effectiveness. See Figure (2.1).

Application of RBV theory and concepts in the manufacturing industry necessitates focusing on knowledge and skills possessed by individuals, both employers and employees, thus contributing to an overall competitive advantage to facilitate performance and productivity (Safari & Saleh, 2020; Assensoh-Kodua, 2019). Similarly, RBV theory incorporates traditional strategies into unique corporate competencies called heterogeneous abilities (Collins, 2021; Gerhart & Feng, 2021), as shown in Figure (2.1) below:

Figure 2.1

Illustration of Resource Based View Theory Concepts



Note. Adapted from Rishi, Dwivedi, & Ghosal, 2022, p.139.

Knowledge-Based View (KBV) Theory: Knowledge-Based View (KBV) Theory integrates knowledge assets that are significant, distinctive, rare, and reliant on the resource-based perspective of organizations (Grant, 1996). In KBV,

knowledge is regarded as an organizational strategic resource, a key to value, and a long-term competitive advantage (Grant, 1996; Seleim & Khalil, 2007). In this regard, manufacturing organizations can only achieve superior performance if they effectively manage and use their knowledge and intelligence to better care for their internal establishment, which is only feasible through efficient and successful coordination resources (Yildiz & Kara, 2017, p. 4).

Generally, researchers assert that using knowledge and skills gives a business a competitive edge since having access to these resources helps in fostering innovation of new services and products as well as processes to enhance productivity (Ipek, 2020, p. 4; Arbelo, Arbelo-Perez, & Pérez-Gomez, 2020; Varadarajan, 2020).

Knowledge, according to KBV, is the company's most important resource and the main factor in determining its competitive advantage (Hock-Doepgen et al., 2021; Bamel et al., 2021). This perspective has a significant impact on the applicability of the absorptive capacity construct since it is crucial to growing and expanding a firm's knowledge base (Bamel et al., 2021; Keat et al., 2018). Learning at the organizational and individual levels is crucial for knowledge-intensive businesses. As a result, absorptive ability affects individuals, groups, and organizations (Iqbal et al., 2019; Akram et al., 2018).

Knowledge flow refers to the process of imparting knowledge to the recipient (Mehrez et al., 2021; Sanchez et al., 2015). According to scholars, the sender and receiver's ability to absorb information, the receiver's prior experiences, and the degree of relevant knowledge are the most crucial variables that affect the success of knowledge transfer (Keat et al., 2018; Akram et al., 2018). In the case of vaccine

manufacturing, available knowledge and the capacity to receive and utilize such knowledge are fundamental to successful vaccine manufacturing (Azeem et al., 2021; Pereira et al., 2021; Plotkin et al., 2017).

Healthcare in KSA

According to the World Health Organization (WHO Primary Health Care Report 2020), the Saudi health care system is ranked 26th among 190 of the world's health systems and comes before many other international health care systems such as Canada (ranked 30), Australia (32), New Zealand (41), and other systems in the region such as the United Arab Emirates (27), Qatar (44) and Kuwait (45).

Despite these achievements, the Saudi healthcare system faces many challenges, such as a lack of sufficient drugs and vaccines, a lack of necessary laws, regulations, and policies by the KSA Ministry of Health (MOH), and a lack of effective cooperation with other sectors of the economy (Al-Shahrani et al., 2020; Al-Kubaisi & Shahbal, 2021).

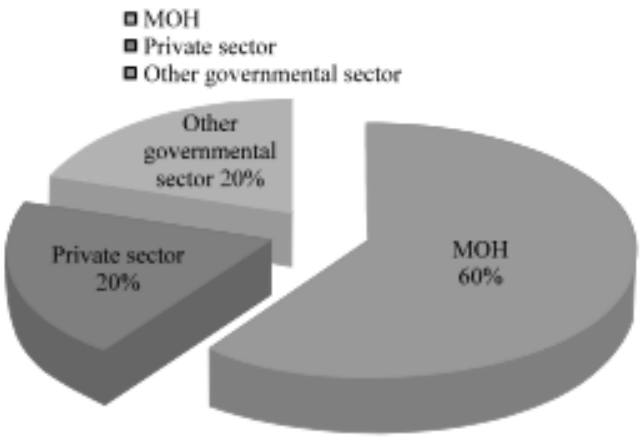
Gallagher (2002, p. 182) stated that, "Although many nations have seen sizable growth in their health care systems, probably no other nation (other than Saudi Arabia) of large geographic expanse and population has, in comparable time, achieved so much on a broad national scale, with a relatively high level of care made available to virtually all segments of the population.

The estimated cost of healthcare worldwide in 2017 was USD 7.8 trillion (World Health Organization 2019). Between 2017 and 2022, it was anticipated to expand at a pace of (5.4%) per year. KSA is considered the leading spender on

healthcare in the Middle East, with nearly USD 37 billion in spending across the Ministry of Health and the private and semi-government sectors (Aitken et al., 2019; Dash et al., 2019; KSA-MoH, 2010). The average cost of healthcare worldwide (excluding the US) is USD 677 per person; however, in Saudi Arabia, it is more than USD 1,120 per person, which is 66 percent more than the average cost worldwide. In Saudi Arabia, the medical sector is the third subsidized sector, following the military and educational sectors, with funding of over USD 46 billion in 2019. See Figure (2.2), from International Trade Administration 2019, as shown below:

Figure 2.2

Beds in Various Sector of KSA Healthcare System



Note. Adapted from MOH, 2010, p. 10.

The KSA economy is largely dependent on oil revenue, being the world's largest producer and exporter of oil (KSA Profile, 2011; Aldossary et al., 2008). However, KSA has recently introduced programs to diversify its economy, and today it produces and exports a variety of industrial goods all over the world (KSA Vision,

2030). The sound economy and well-established industry base affect the Saudi community by increasing their income as well as impacting positively on its various services, including healthcare services (Saudi Version 2030, National Transformation Program, 2020). The first public health department was established in Mecca in 1925 based on a royal decree from King Abdulaziz (Alharthi et al., 1999). This department was responsible for sponsoring and monitoring free healthcare for the population and pilgrims through establishing several hospitals and dispensaries. While it was an important first step in providing curative health services, the national income was not sufficient to achieve major advances in health care; most people continued to depend on traditional medicine, and the incidence of epidemic diseases remained high among the population and pilgrims (Al Otaibi, 2017).

The next crucial advance was the establishment of the MOH in 1950 under another royal decree (Rahman, 2020). Twenty years later, the 5-year development plans were introduced by the government to improve all sectors of the nation, including the Saudi health care system, and since then, substantial improvements in health care have been achieved in Saudi Arabia (Alasiri & Mohammed, 2022; Al-Hanawi et al., 2020).

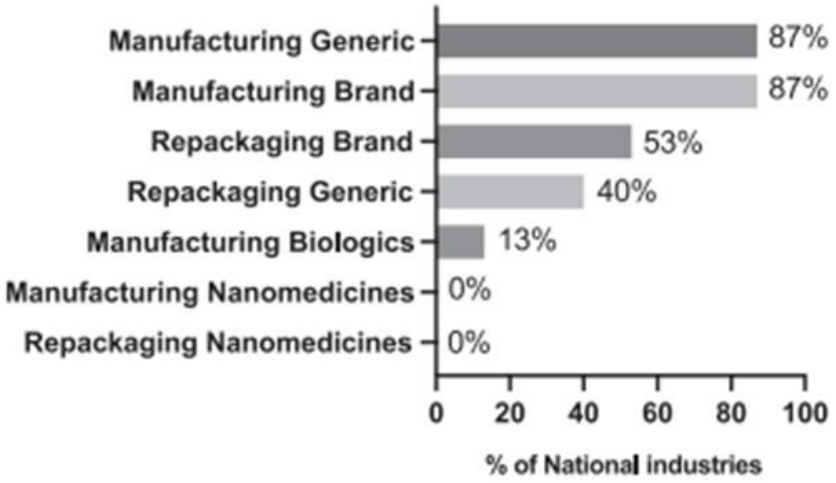
Pharmaceutical Manufacturing Industry in KSA

More than 82 percent of the national pharmaceutical industries do not manufacture biological products, while less than 14 percent manufacture not more than 10 biological products in the KSA market (Halwani et al., 2023). More than 80 percent of the national pharmaceutical industries do not manufacture biosimilar products,

while 20 percent of the sectors manufacture between (1 and 5) biosimilar products in the Saudi market. None of the KSA pharmaceutical manufacturing companies produce or repackage nanotechnology-based medicines (see Figure 2.3).

Figure 2.3

General View of Pharmaceutical Manufacturing in KSA



Note. Adapted from Halwani et al., 2023, p. 4.

The pharmaceutical market in KSA is worth USD 8.3 billion. Forecasts applied by the Pharmaceuticals Export Promotion Council of India (pharmexcil 2020) showed that the KSA pharmaceutical market would reach USD 10.89 billion by 2024 with a compound annual growth rate (CAGR) of 5.4 percent. This made the pharmaceutical market in KSA the largest in the region, attracting several international pharmaceutical companies to localize their drug manufacturing

technologies as part of the KSA long-term development plan, “Vision 2030” (Saudi Version 2030, National Transformation Program 2020).

KSA has successfully promoted local pharmaceutical manufacturing development during the last decade to become the leading manufacturer and innovator in the MENA region by accelerating the transition of pharmaceuticals into products with higher complexity. The KSA pharmaceutical market is expected to grow at a 5 percent rate each year until 2025 to reach USD 10 billion. The contribution of KSA to the MENA region is expected to increase and get 30 percent by 2025 (IQVIA 2019). Most pharmaceutical companies started as importers and distributors of drugs, and some have developed into pharmaceutical industries. Locally manufactured products cover only a small amount (i.e., 30%) of the current market demand (Tawfik et al., 2022), with a primary focus on producing generics, which means there is growth potential, but this will require a significant capital investment.

The KSA pharmaceutical drugs market is expected to exhibit a CAGR of 7.3 percent during the forecast period (2020–2027), owing to increasing launches and approval of drugs. Among drug types, the branded drugs segment is expected to hold a major revenue share in 2027, owing to increasing launches of branded medicines in the local market, which is expected to accelerate the Saudi Arabia pharmaceutical drugs market growth soon (Coherent Market Insights 2021). For instance, in December 2015, SAJA Pharmaceuticals announced that it signed a contract with Novartis AG to launch SAJA, the first antidiabetic drug (Jalra and JalraM), as a second brand of Novartis AG blockbuster (Galvus and Galvus met). However, increasing the production of pharmaceutical products locally by foreign

players will also put more competitive pressure on smaller local companies that can fight to compete on their costs with international competitors (Pharmexcil, 2020, p. 2).

The size of the pharmaceutical market in KSA has grown massively in the past few years; however, most national pharmaceutical industries still focus on manufacturing generics. In contrast, the major worldwide manufacturers focus on developing and launching advanced pharmaceutical drugs such as vaccines. This effort of developing new advanced medicines could gain a significant economic impact on both the pharmaceutical drugs market and the overall healthcare system (Tawfik et al., 2022; World Health Organization, 2019).

Related Literature and Hypothesis Development

Factors that Impede Vaccine Manufacturing Business

The COVID-19 pandemic, which impacted all segments of the world economy due in part to the fact that there was no readily available vaccine, attests to the need for research and development initiatives in pharmaceuticals, as vaccination is considered one of the most effective schemes to control the pandemics (WHO, 2022 report; Khalifa et al., 2020). This has led to widespread attention in both the biomedical manufacturing industry and other related industries (Yiu et al., 2020; Wang et al., 2020).

One of the biggest advances in medical research history is vaccination against disease, and it is now regarded as essential for improving life expectancy,

reducing mortality at a reasonable cost, and spurring economic growth (Ulmer, Valley, & Rappuoli, 2006).

The World Health Organization (WHO) estimates that licensed vaccines save two to three million lives annually, and that number would rise by at least six million if every child received vaccinations in accordance with the recommended schedule (Delany, Rappuoli, & De Gregorio, 2014).

Patil and Shreffler (2019, p. 20) point out that due to lack of access to basic vaccinations, 19.5 million infants globally remain at risk of vaccine-preventable illnesses (VPDs), and the main cause of this is because low- and middle-income developing countries do not have fair access to essential immunizations.

The process of manufacturing vaccines is fraught with difficulties, such as adequate production facilities, machinery, lead times, product portfolio management, life cycle management, intellectual property (IP), process development, and maintenance in general (Plotkin et al., 2017). Furthermore, to maintain an extended vaccination life cycle in a market, a strong and stable production process and consistent raw material supplies over decades are essential.

(a) Research and Development (R&D) Capability

The manufacture of an effective vaccine is complicated; hence, extensive research and development (R&D) must be established, and this includes facilities, technology, and skills (Makenga et al., 2019; Plotkin et al., 2017).

Lack of adequate R&D for vaccine manufacturing has been recognized as a challenge for local manufacturers in the developing countries. In a study conducted

by Kumraj et al. (2022, p. 5), the authors outlined the main challenges to vaccine manufacturing to include:

i. Vaccine manufacturers from over (70%) of developing countries face inadequate R&D capacity to support technology transfer.
ii. Lack of experience in R&D staff.
iii. Resource prioritization at the company level.
iv. License negotiation skills and training.
v. Evaluation and assessment of quality of technologies.

Researchers have argued that the great majority of vaccines that are presently available were created using conventional research techniques; therefore, the next generation of novel vaccines will be far more difficult, challenging, expensive, and risky to manufacture because of the complexities associated with the targets set for vaccine development, which demand significant financial investment and expertise, making R&D capability indispensable (Black et al., 2020; Makenga et al., 2019, p. 34).

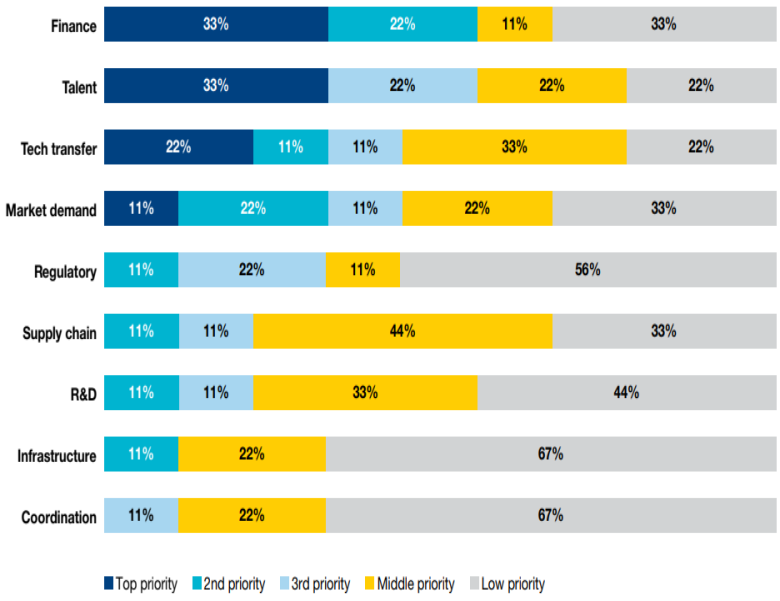
Hollis (2019, p. 2) posits that for any pharmaceutical organization, the spending on research and development (R&D) can be influenced by multiple factors, which are controlled mainly by the expected revenues, expenses, and policies that are required to produce and market vaccines and other drugs (Hollis, 2019; Austin, 2006).

According to researchers, several factors contribute to the overall cost of vaccine research and development. These include timeline, costs, sectoral affiliation (i.e., public or private sectors with commercial or non-commercial orientations), the

licensure track record of vaccine developers, the licensure track record of vaccines for a specific disease, and the complexity of platform technology, etc. See Figure (2.4) Altman et al., 2023; Walkinshaw et al., 2023; Chandra et al., 2023.

Figure 2.4

Vaccine Manufacturers' Ranked Assessment of Priority Challenges



Note. Adapted from Boston Consulting Group (BCG) Survey 2022, p. 37.

Vaccine portfolios have different industrial challenges that manufacturers must scale through in the process of development. See Table (2.1). In this case, a well-established research and development strategy is of paramount importance to effectively achieve a successful vaccine manufacturing business.

Table 2.1

Classes of Vaccines and the Industrial Challenges Associated

	Vaccine Active Component	Main Manufacturing Challenge
Oral Polio vaccine	Live-attenuated viruses x3	Maintaining phenotypic and genotypic stability of each of the 3 strains
Rabies	Inactivated cell culture grown virus (e.g., on Vero cells)	Ensuring complete inactivation while maintaining immunogenic potency and avoiding reactogenicity. Appropriate BSL containment of live virus steps.
Acellular Pertussis	Purified proteins from B. pertussis	Consistency of production, detoxification of components. Stability and
Multivalent Pneumococcal conjugate vaccines	Multivalent Pneumococcal conjugate vaccines	Multivalent Pneumococcal conjugate vaccines
Hepatitis B Vaccine	Recombinant protein	Consistency of manufacturing, with reproducible immunogenicity and Minimal host protein contaminant profiles
Japanese Encephalitis e.g., Immuno Jev	Vectored vaccine	Need to demonstrate absence of potential for reversion or genetic rearrangement. Robustness of process. Freeze drying process and stability of product.

Note. Adapted from Smith et al., 2011, pp. 428–438.

In KSA, local drug producers have good capabilities to produce conventional dosage forms within the generics market, i.e., tablets and capsules, but cannot produce non-conventional forms, such as biologicals and plasma-derived products (Shuman et al., 2020). Therefore, an innovative drug development scheme could be the foundation of a successful pharmaceutical market, which would require a well-established R&D capability and patent protection through reliable intellectual

property policies. This scheme will improve the return on investment in R&D for developed vaccines and other essential drugs (Roland Berger Strategy Consultants, 2014).

However, Alzahrani and Harris (2021) posit that despite the government's financial support for R&D in general, most of the research projects that are related to pharmaceutical development are scattered and have no true outcome, majorly due to a lack of new domestic 'branded' medicines (Alzahrani & Harris, 2021).

These poor R&D investments, with poor outputs, are due to factors such as lack of skilled personnel, lack of technical knowledge, lack of adequate R&D infrastructure, tight regulations and policies that hinder drug market accessibility, and the emergence of patent cliffs (expired or inefficient drug patents) (Badreldin & Atallah, 2021; Alzahrani & Harris, 2021).

Aljadhey et al. (2015, p. 4) argued that factors such as lack of adequate R&D facilities and technical knowledge have caused the local pharmaceutical companies to depend on drug importing and repackaging. The authors added that the lack of local vaccine manufacturers and other drugs might be due to the inefficient cooperation strategies between academia, research institutes, and pharmaceutical companies in developing new pharmaceutical products that can be registered as patents and produced locally (Aljadhey et al., 2015; Shankar & Jha, 2015).

Shankar and Jha (2015, p. 11) assert that there is an unprecedented need to manufacture and distribute enough safe and effective vaccine to immunize an extraordinarily large number of individuals to protect the entire global community

from the continued threat of morbidity and mortality from severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2).

Furthermore, Shuman, Fox, and Unguru (2020) stress that the global need for vaccines and the wide geographic diversity of pandemics require more than one effective vaccine approach (Horner, 2020), and collaboration for research and development programs is essential among biotechnology and pharmaceutical companies, many of which are bringing forward a variety of vaccine approaches.

Régnier and Huels (2013) previously pointed out that vaccine portfolios in many pharmaceutical companies have decreased in the last decades due to the cost and time involved in vaccine development compared to the development of other drugs. However, pharmaceutical companies as well as academic institutions are continuously investing in vaccine research. For example, it has been noted that the number of vaccines in pipeline development has increased tremendously over the years (Davis et al., 2010). This fact can be explained, in part, by the advancement of alternative technologies, such as baculovirus-based recombinant vaccines, virus-like particles, viral vectors, and RNA or DNA vaccines (Buckland et al., 2014; Chung et al., 2016). Moreover, with a world population projected to be 10 billion by 2050, 90 percent of it is estimated to live in developing countries (United Nations projection), which will continue to encourage vaccine research and development (Sparrow et al., 2021; DeSA, 2015).

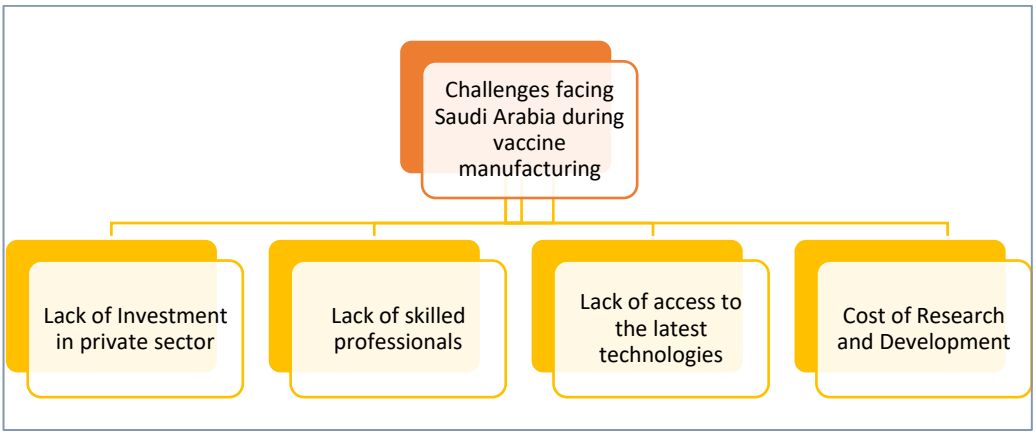
The KSA government, in its capacity, has intensified its effort to enhance the nation's vaccine manufacturing, as evidenced by the number of infrastructures in the country and in the research institutions, although there is still a long way to go

before these national institutions can effectively produce vaccines of the highest quality for its people (Alzahrani & Harris, 2021).

According to Kumar et al. (2022), a primary hindrance is the insufficient investment by the private sector in the industrial infrastructure. Specifically, the nation still needs state-of-the-art vaccine production facilities that can quickly and efficiently produce vast quantities of vaccines. Another obstacle is the dearth of qualified experts who possess the necessary understanding and proficiency in vaccine production procedures. See Figure (2.5). Moreover, the development of effective vaccine production in the nation has been hampered by the lack of access to cutting-edge technology. As mentioned by Badreldin and Atallah (2021, p. 6), another important issue that must be resolved is the expense of doing research and developing new vaccine technologies.

Figure 2.5

Challenges to Manufacturing Vaccines in KSA



Note. Research compilation.

As stated by Li (2019, p. 6), KSA is a wealthy and rich country, except for the healthcare sector. KSA highly relies on international imports of medicines from the USA and European countries when it comes to public vaccination at a high cost. Moreover, it has been highlighted that not only during the COVID-19 pandemic, KSA has also suffered from a shortage of vaccines during the surge in hepatitis in the past years (Aldossari et al., 2021, p. 8). Therefore, it is critically important for KSA to establish vaccine manufacturing facilities instead of relying on other countries (Ibid., p. 20).

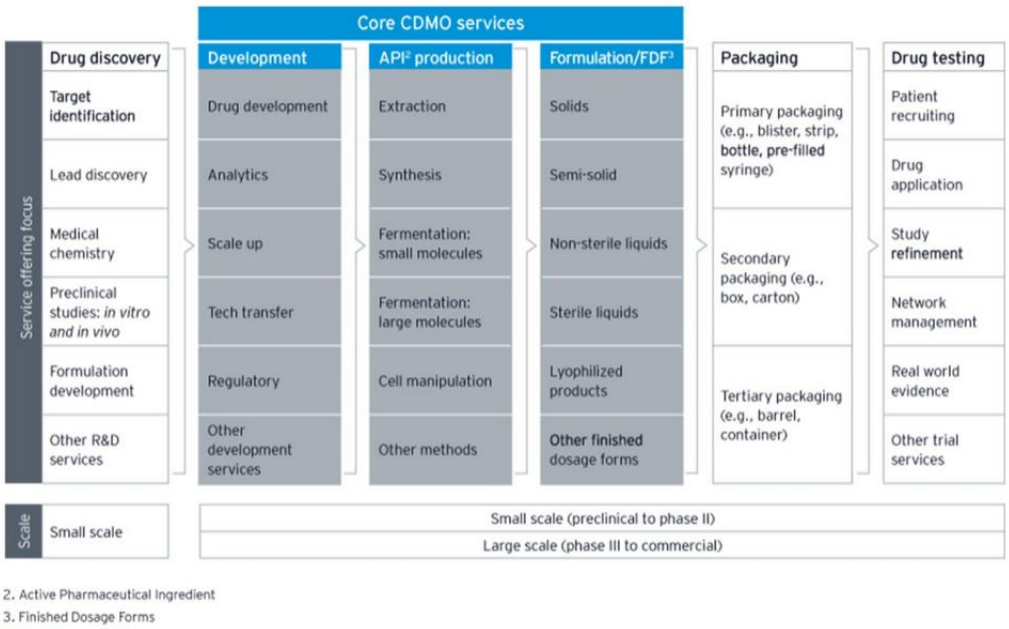
Ahmed et al. (2020, p. 12) emphasized that as the population of KSA is increasing day-by-day, thus, to meet the future demand of the upcoming generation, it is essential for KSA to develop local vaccine manufacturing factories, which can be done through the Contract Development and Manufacturing Organization model (CDMO). This model will help both government and private sector local manufacturers to develop and manufacture the most needed vaccines.

Price Waterhouse Coopers GmbH (2019) states that a pharmaceutical business organization may hire a CDMO to assist with one or more stages of the research and manufacturing process of a vaccine or other pharmaceutical product. Specifically, CDMO is a model that encompasses various healthcare strategies, such as enabling healthcare professionals to better understand and capture clinical data to improve outcomes. It is also relevant for the health sector as it provides a framework for healthcare data management, which can be used to improve the accuracy and efficiency of medical records, as well as the quality of care provided to patients. The model also helps healthcare organizations to better analyze and use data to optimize performance and patient outcomes (Ibid., p. 40).

Ahmed et al. (2020, p. 12) further posit that the rationale behind the application of CDMO modalities is appropriate for the health sector in general and vaccine localization initiatives as it consists of processes starting from drug discovery and development to marketing and sales of the products. See (Figure 2.6) Bown and Bollyky (2022, p. 476) stress that CDMO in the pharma industry acts as a sequence of interaction that delivers plug-in and oversight that is capable of providing multiple facilities under a single roof, such as access to multiple technologies, availability of multiple pharmaceutical companies, products from various pharma companies, the ability to identify different CDMOs, provide concentration on the volumes, enable smaller production batches, and also helps to provide an efficient mechanism for pooling professional talents.

Figure 2.6

Modalities for Manufacturing Categories for CDMOs



Note. Adapted from EY-Parthenon, 2023, p. 2.

The implication of CDMO models has helped numerous developed and developing countries such as Brazil, Morocco, South Africa, South Korea, and Italy, South Africa. Furthermore, it has been foreseen that leading global CDMOs have covered all major vaccine technology platforms and have also helped to be key technological transfer centers (Bown & Bollyky, 2022, p. 476; Kurata et al., 2022). See Table (2.2).

Table 2.2

Top CDMOs Manufacturing Organizations and Sales Revenue 2020.

Revenues (millions of dollars)/firms	Headquarters
3,000–5,000	
Lonza	Switzerland
Catalent	United States
Thermo Fisher Scientific (Patheon)	United States
1,000–3,000	
Fareva	France
Recipharm	Sweden
Wuxi AppTec/Bio	China
Siegfried	Switzerland
Delpharm	France
750–1,000	
Cambrex	United States
Albany Molecular Research (AMRI)	United States
Vetter	Germany
Aenova Group	Germany
Boehringer-Ingelheim	Germany
Fujifilm Diosynth Biotechnologies (FDB)	Japan
500–750	
Ajinomoto	Japan

Note. Adapted from *Bown & Bollyky, 2022, p. 476.*

Based on the report of Fitch Solutions (2023, p. 3), a strong corporate governance structure is crucial if KSA is to get past the historical challenges that provide impediments to the production and manufacturing facilities for local

vaccines. Accordingly, research indicates that implementing an effective corporate governance structure might facilitate the dissemination of information to the public, government, and other relevant authorities in KSA on the availability of local vaccines and the significance of having local vaccine manufacturing facilities in as the recent allocated healthcare budget has decreased by 4.5 percent from the previous years (Ibid., p. 15).

According to the statistics from the World Bank, the health expenditure of the KSA was highest in 2017, which is 6.26 percent of the GDP, and decreased to 5.69 percent in 2019, with about 25–35 percent of the total health budget spent on the treatment of cardiovascular diseases, diabetes, and obesity (World Bank Report, 2022). Generally, vaccination programs have helped in reducing the prevalence of VPDs (vaccine-preventable diseases) such as poliomyelitis, measles, and pertussis in developed countries. However, a large proportion of KSA citizens are still hesitant to receive vaccines.

According to the studies by Alaamri, Okmi, and Suliman (2022, p. 10), approximately 20 percent of parents in KSA showed vaccine hesitancy, while 17 percent of the people are hesitant to take the influenza vaccine. This indicates that people in KSA are still not aware of the advantages of vaccination programs and their impact on preventing VPDs. This has also created the hesitancy among common people; hence, the lack of social awareness that has also been identified among the factors that impede the vaccine manufacturing program significantly. These occurring incidences and the low healthcare budget impede research and development activities in the pharmaceutical sector and restrict vaccine manufacturing significantly (Ibid., p. 10). It is evident that the lack of proper

pharmaceutical R&D infrastructure and the frequent reduction in healthcare budget hinder vaccine manufacturing initiatives and have resulted in the reliance on foreign pharmaceutical companies such as Pfizer-BioNTech and Moderna during the COVID-19 pandemic for vaccines needed for the citizens vaccination (Aldossari et al., 2021, p. 6).

According to the WHO Report (2022), manufacturing of quality vaccines needs international standardization, beginning with quality control testing, materials, and the production process. Therefore, vaccine manufacturing requires setting the overall manufacturing procedure from start to finish, keeping in mind that the field of vaccine technology is ever evolving. Hence, R&D infrastructure elements such as

Manufacturing procedures, testing tactics, standards, and reagents have to comply with all the standards defined for "Good Manufacturing Practices (GMP)". These requirements include implementing "hoc pharmaceutical quality systems" for quality assurance and processes, implementing various quality controls at each stage, and establishing a sufficient infrastructure that separates all activities to ensure vaccine purity, identity, safety, sterility, and efficacy (WHO, 2023).

Alaamri, Okmi, and Suliman (2022) emphasized that to encourage the increasing rate of vaccine manufacturing, all companies that are manufacturing vaccines need to maintain these above measures and quality controls. Hence, it can be stated that, to increase the rate of vaccine production, it is necessary to bring technological advancements up to date, which are among the imminent challenges of developing countries such as KSA.

Furthermore, biotechnology can help with the manufacture of vaccines, starting with the design and exploration processes. This calls for an effective R&D development for the enhancement of every step of the vaccine production process, which involves the presence of immunogenic and antigenic components to ensure the vaccine's overall efficacy when it enters the recipient's body (Aldossari et al., 2023, p. 4; Alhowaymel et al., 2022, p. 7).

In terms of R&D for vaccine manufacturing, the European Union (EU) has a robust industrial infrastructure and a long history of conducting R&D and producing vaccines (Medaglini et al., 2018). It is estimated that more than 80 percent of vaccine doses from the top research manufacturers are made in Europe and exported for usage internationally, according to Vaccines Europe (2017). Leading authorities on vaccines have come together to form the Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE), whose mission is to create a roadmap outlining the best ways for Europe to invest in the science and technology necessary for vaccine innovation (Laigle et al., 2021).

This FP7 project, started in December 2013, brought together more than 130 key public and private stakeholders from academia, public health institutes, regulators, industry, and small and medium-sized enterprises to determine and prioritize the gaps and challenges to be addressed to bolster innovation in vaccines and vaccination in Europe (Almond & Medaglini, 2017, p. 20).

More than 130 important public and private stakeholders from academia, public health institutes, regulators, industry, and small and medium-sized businesses came together for this FP7 project, which began in December 2013, to identify and

rank the gaps and obstacles that need to be filled to support innovation in vaccines and vaccination in Europe (Boulton et al., 2015, p. 5). The seven issues that shaped the structure of the IPROVE consultation process were: research and development of vaccines, manufacturing and quality control, infrastructure, therapeutic vaccines, needs of small and medium-sized businesses, acceptance of vaccines, and training requirements. The IPROVE consortium consists of four leading European vaccine-related organizations: Vaccines Europe, European Vaccine Initiative, Sclavo Vaccines Association, and European Infrastructure for Translational Medicine. Europe is well-positioned to spearhead the development of the upcoming vaccine generation due to the many centers of expertise in vaccination and related fields that are already established (Bermejo et al., 2023; Sargin et al., 2022). There are additional non-governmental organizations (NGOs) operating globally that support the development of vaccine manufacturing capacity. See Table (2.3).

Table 2.3

List of NGOs Supporting R&D Vaccine Development

Name	Task Description
Bill & Melinda Gates Foundation (BMGF)	The Vaccine Development and Surveillance team of BMGF invests in expertise and platform technologies that helps in making vaccines faster, better, and affordable. The aim of the team is advancing public goods for global health through novel technology by accelerating the development and commercialization of innovative vaccines, sustainable manufacturing of existing vaccines, utilizing primary data and world-class modeling to define global disease burden, and using innovative tools to reduce the threat of epidemics.
Gavi, the Vaccine Alliance (GAVI)	GAVI, a public-private partnership, helps in vaccinating half of the world's children against some of the world's deadliest diseases. It also plays a crucial role in improving global health security by supporting

	health systems, as well as funding global stockpiles for Ebola, cholera, meningitis, and yellow fever vaccines.
Clinton Health Access Initiative, Inc. (CHAI)	The CHAI is a global health organization that works toward saving lives and reducing the disease burden in LMICs. It partners with other organizations to strengthen the capabilities of governments and the private sector to create self-sustained high-quality health systems.
International Vaccine Access Center (IVAC)	Based at the Johns Hopkins Bloomberg School of Public Health, IVAC has served as a trusted partner for governments, international agencies, research groups, and non-profit organizations seeking to advance access to life-saving immunizations for all people. It accelerates equitable access to vaccines through the generation, synthesis, and use of evidence to inform decision-making and action.
Coalition for Epidemic Preparedness Innovations (CEPI)	CEPI, a Norwegian Association, is an innovative global partnership between public, private, philanthropic, and civil society organizations CEPI accelerates the development of vaccines to prevent emerging infectious diseases and enables equitable access to these vaccines for people during outbreaks.
International Vaccine Institute (IVI)	IVI is a nonprofit international organization established in 1997 as part of the United Nations Development Program (UNDP) initiative. It is headquartered in Seoul and hosted by the Republic of Korea with 36 member countries and the WHO on its treaty. It is among the few organizations in the world dedicated to vaccines and vaccination for global health. Its mission is to discover, develop and deliver safe, effective, and affordable vaccines for global public health.
Netherlands Vaccine Institute (NVI)	NVI facilitates in the development and transfer of vaccine technology to vaccine manufacturers in both developing as well as developed countries.
The COVID-19 Vaccines Global Access Facility (COVAX)	COVAX is co-led by CEPI, GAVI, and WHO, alongside key delivery partner UNICEF. COVAX. aim is to accelerate the development and manufacturing of COVID-19 vaccines as well as ensure fair and equitable access of these vaccines to every country across the globe.

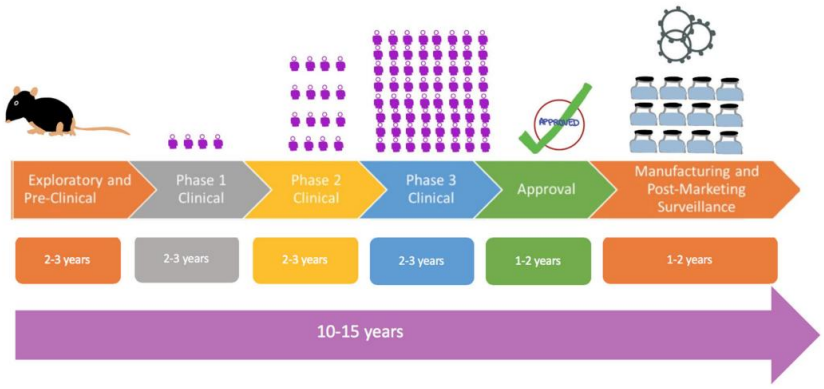
Note. Adapted from Kumraj et al., 2022, pp. 11-12.

(b) Cost of Investment and Revenue for Vaccine Manufacturing

Vaccine manufacturing constitutes an elaborate process that takes 10 to 15 years to complete (Sharma et al., 2020, p. 4; Pronker et al., 2013). See Figure (2.7). In accordance with established conventions, the multiphase vaccine development process, spanning from vaccine discovery to advanced clinical development in Phase three efficacy trials, generally necessitates financial investments ranging from $0.5 billion to $1 billion, coupled with the likelihood of less than 10% vaccine candidates entering the market (Pronker et al., 2013; Pronker et al., 2011). As a result, the number of vaccine investors has decreased, and this has contributed to the existing productivity disparity in vaccine development (Rappuoli & Hanon, 2018; Pronker et al., 2013; Pronker et al., 2011).

Figure 2.7

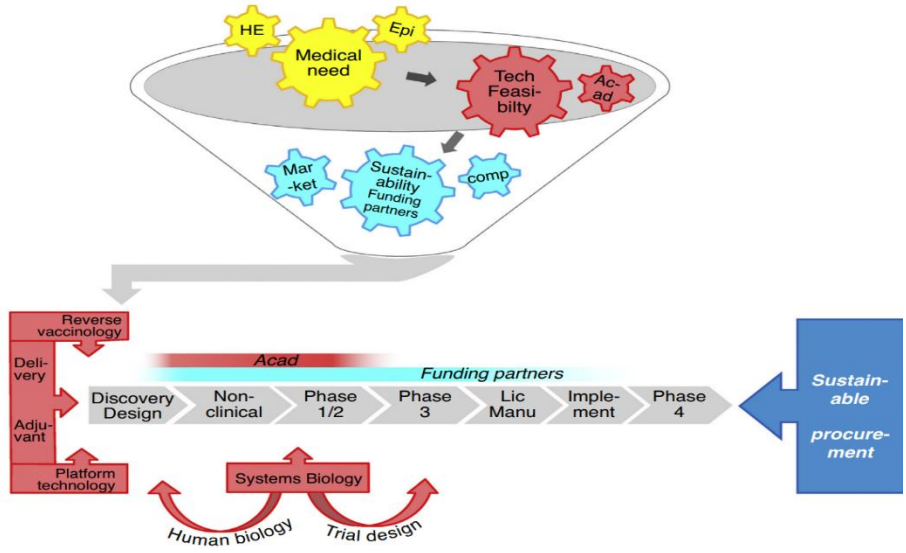
Traditional Process of Vaccine Development



Note. Adapted from Sharma et al., 2020, p. 4.

Figure 2.8

Sustainable Vaccine Development and Collaborations



Note. Adapted from Rappuoli & Hanon, 2018, p. 112.

A fundamental objective of an entrepreneurial business is to make profit to sustain the business and facilitate business operations in general (Mokbel et al., 2022, p. 12; Hong et al., 2023; Hikmah, Ratnawati, & Darmanto, 2023; Ramoglou, Zyglidopoulos, & Papadopoulou, 2023, p. 17). Therefore, profit remains a fundamental principle and concurrently the objective of contemporary business, despite the emergence of social entrepreneurship, which aims at social value creation and quality of life improvement. Hence, it is indisputable that profit is indispensable for the attainment of other objectives (Mokbel et al., 2022, p. 12; Hong et al., 2023).

A similar opinion is also shared by Pronker et al. (2013), stressing that vaccine manufacturing requires a significant financial investment and carries a high

failure rate. Studies indicate that vaccine development programs that progress from discovery to licensure typically entail substantial financial investments, exceed a decade in duration, and carry a 94 percent failure rate on average (Pronker et al., 2013; Gouglas et al., 2018).

In as much as addressing domestic, regional, or worldwide infectious disease crises is an essential aim of the vaccine manufacturing industry in terms of public health, the inherent risks in the development of vaccines in most cases often exceed the potential return on investment that is made in the production of vaccines (Taghvaee & Talebi, 2022). Therefore, there is a possibility that entrepreneurs and shareholders will not consistently approve the necessary investments or undertake the necessary actions necessary to commence vaccine manufacturing (Emami and Klein (2020, p. 5).

In business perspectives, entrepreneurs are more likely to take appropriate actions when they have a firm grasp of the market's requirements, technical opportunities, and challenges, according to Emami and Klein (2020, p. 5), and perceived market insights, in other words, present entrepreneurs with the task of determining whether or not they are inclined to take action in response to situations such as the scenarios posed by vaccine manufacturing.

According to GEM (2022, p. 3), there is a correlation between perceptions of entrepreneurs' ability to take on challenges and the technical feasibility of products and services. As per Taghvaee and Talebi (2022), it stands to reason that if entrepreneurs find out they know a lot about closing a market gap, that knowledge will spur them on to the next step and a test of confidence. But if the market gap

widens, businesses may face more difficulties and become aware of increasing ambiguity and uncertainty (Taghvaee & Talebi, 2022).

Cost of investment versus revenue generation is a paradox that constantly prompts attention and consideration for entrepreneurs. Ratnasih (2017) argues that organizations net profit can rise if the management can reduce expenses; on the other hand, if the business incurs expenses carelessly, net profit will drop. In this case, Risyana and Suzan (2018) posit that operational expenses have an impact on net profit; as a result, a company's net profit will fall when its operational costs rise and vice versa. However, Vina et al. (2021) contend that operational expenses can be characterized as any commercial costs incurred to support business operations or activities to meet predefined goals; also, operational expenses can be considered as expenses incurred in relation to business operations to maximize business objectives.

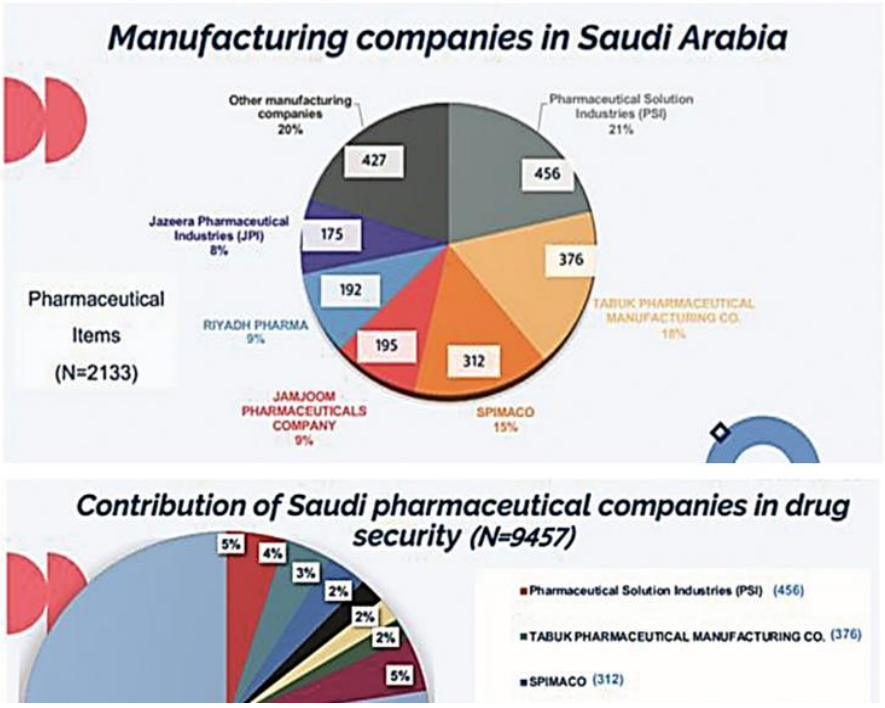
According to studies by Hidayanti et al. (2018) and Wulandari (2016), operational costs have an impact on net income. On the other hand, a study by Aditya and Yulianti (2019) indicated that operational expenses significantly influence net income to a part extent. Moreover, Rostianti and Ferliyanti's (2019) findings showed the contrary, suggesting that operating expenses had little bearing on net profitability.

Pharmaceutical businesses play a significant part in a nation's healthcare sector reform, and in addition to reflecting corporate and economic growth and development of a nation, pharmaceutical businesses operate in a very complicated industry; hence, investment requires a consolidated corporate of diverse stakeholders to attain a successful establishment (Alruthia et al., 2018, p. 4).

In KSA, it is estimated that there are over forty licensed drug manufacturers that hold good manufacturing practice (GMP) certification. Among these are Tabuk Pharmaceuticals Company, Al Jazeera Pharmaceutical Industries, and Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO) (Alzahrani & Harris, 2021; Alruthia et al., 2018; Oxford Business Group, 2018), and most of these local pharmaceutical enterprises began by repackaging completed dosage forms, importing medications, and engaging in distributing (Saleh, 2012, p. 2).

Figure 2.9

Pharmaceutical Companies in KSA



Note. Adapted from Alshehri et al., 2023, p. 608.

At this level of pharmaceutical business engagements, these organizations have experienced an increase in their return on investment (ROI) based on the recorded growth rate of 14 billion Saudi Riyal (SAR) in 2012 to 28 billion SAR in 2016 and 40 billion SAR in 2023, indicating a favorable pharmaceutical business in KSA (Assad, 2007; Vasisht et al., 2016; Alzahrani & Harris, 2021).

In view of the Saudi Vision 2030, local research institutes, such as King Abdulaziz City for Science and Technology (KACST), King Abdullah University of Science and Technology (KAUST), and King Abdullah International Medical Research Center (KAIMRC), have started to concentrate on pharmaceutical research, development, and innovation (RDI). These research facilities have been tasked with carrying out R&D projects related to vaccine manufacturing to increase interest in the vaccine manufacturing business (Almotiry, 2022; Alruthia et al., 2018; Oxford Business Group, 2018). These research institutes could be able to carry out several R&D projects related to drug development, but the difficulty lies in translating the outcomes from these facilities into reliable output. Translating the outcome of the R&D initiatives to the market may require the backing of the regional pharmaceutical industries (Tawfik et al., 2022, p. 6; Alzahrani & Harris, 2021, p. 4).

(c) Infrastructure for vaccine manufacturing

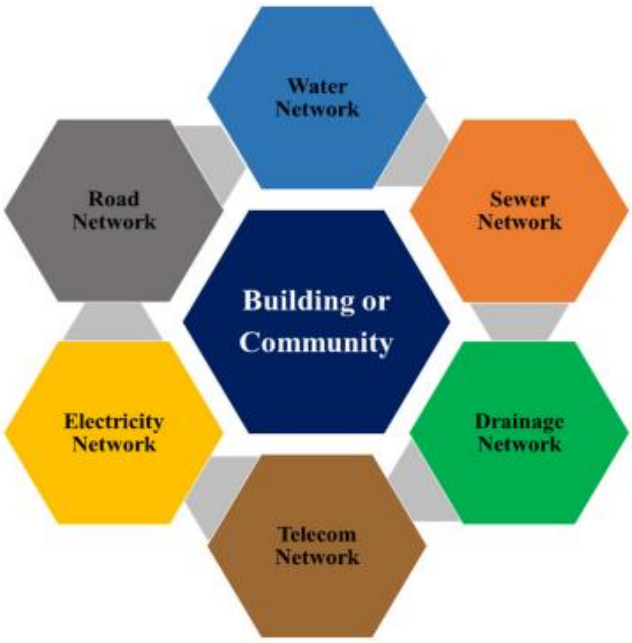
The development and growth of the manufacturing sector of every economy depends on its infrastructure (Ramli et al., 2022; Popoola et al., 2022). In general, the importance of infrastructure as a major driver of growth and development of the economy has been emphasized by classical and neoclassical schools of thought such as Adam Smith (1723-1790); David Ricardo (1722-1823); Thomas Robert Malthus

(1766-1834); John Stuart Mill (1806-1873); and Karl Marx (1818-1883), to name a few (Dolderer, Felber, & Teitscheid, 2021; Raworth, 2017).

As stated by Serre and Heinzlef (2018), by definition, critical infrastructure networks (CINs) are the collection of assets, networks, and systems that are so vital to a country's security, economy, public health, and safety necessary for steady maintenance business operation (Serre & Heinzlef, 2018; Ramli et al., 2022). See Figure (2.10).

Figure 2.10

Critical Infrastructure Networks (CINs) in a Society



Note. Adapted from Heinzlef, 2018, p. 51.

Researchers such as Ibahimov et al. (2023); Bekhti et al. (2022); Felber and Titchier (2021); and Tirole (2018) argue that the development of the manufacturing industry in every economy depends on its infrastructure, and infrastructure is a major driver of economic growth.

Infrastructure Monitor (2022, p. 22) highlights that public and private infrastructure investment strengthens economic resilience and promotes sustainable development performance. Public infrastructure investment, which consists of highways, airports, mass transit, etc., is modeled as important sources that generate external economies and facilitate private sector productivity and growth (Ramli et al., 2022; Popoola et al., 2022; Ji et al., 2019; GI Hub, 2022).

Diewert (1986, p. 12) defined core infrastructure as resources provided by the public sector, such as roads, railroads, ports, electrical, and communication infrastructure. Accordingly, public infrastructure is regarded as non-marketable products as its services are provided at no cost, which is consistent with earlier studies by Morrison and Schwartz (1996), Nadiri and Mamouneas (1994), and Lynde and Richmond (1992) stressing the importance of infrastructure as a key component in industrial development. Furthermore, previous empirical findings suggest that infrastructure is a significant source that has the potential to produce external economies (Barro & Sala-i-Martin, 1995; Anwar, 1995; Lucas, 1988).

Aschauer's (1989) study elaborated on the importance of infrastructure in the manufacturing industry by looking at production elasticity in relation to public capital stock. Findings reveal a favorable correlation between output and infrastructure. In support of the Aschauer (2000) report, another study conducted by Eisner (1993) provided evidence grounded on aggregate economic statistics that investment in public infrastructure plays a major role in driving productivity development.

Pereira and Roca-Sagales (2001, p. 10) also looked at the impact of infrastructure on productivity in the private sector in Spain. Findings reveal that a one percent (1%) increase in public capital raises private production by 0.055 percent. Zegeye (2000, p. 3) extended the discussion by utilizing the trans log production function technique to investigate the effect of public infrastructure investments on the manufacturing sector's productivity with a sample of more than 1,500 counties from 50 US states. Findings revealed that while infrastructure affects output, it has little effect on productivity.

However, recent studies such as those from Nworji and Oluwalaiye (2012, p. 31) and Nnyamzi et al. (2022, p. 21) demonstrated that infrastructure may have a major effect on productivity as building infrastructure can foster industrialization, which is a necessary step toward achieving long-term development. Studies have also shown that infrastructure, particularly soft infrastructure, promotes economic and industrial development by creating an atmosphere conducive to business growth (Omimakinde, 2022) and can support economic diversification (Ebi & Eke, 2018).

Anyanwu (2018, pp. 14-16) found that social infrastructure had varying effects on the manufacturing industry. Azolibe and Okonkwo (2020), in their study using panel least squares estimation, found that the most significant factor influencing productivity in the industrial sector is the quantity and quality of telecommunication infrastructure. According to Bekhti et al. (2022) and Ramli et al. (2022), the quality of infrastructure should be considered a determining factor in addition to the quantity of infrastructure needed for industrial development.

In Ghana, however, Abokyi et al. (2018) found that infrastructure development in terms of electric consumption negatively impacts the manufacturing sector output, and according to Ogunjimi and Amune (2019, p. 22), the deployment of technology facilitates the use of capital for investment, growth, and development. Alrasheedy (2020) and Alruthia et al. (2018) added that a nation with strong infrastructure, such as electric power, is more appealing to foreign direct investment than one with weak infrastructure development.

As indicated in table (2.4), KSA has in recent years implemented various significant infrastructure projects in line with its 2030 vision for economic growth. This quickening pace of infrastructure development is promoting investment, job creation, and economic growth. However, it is noted that before companies can take advantage of these growth prospects, they need to know what the operational and financial ramifications of these changes are, which are paramount to an efficient vaccine manufacturing business in KSA (Alrasheedy, 2020; Alruthia et al., 2018).

Table 2.4

Notable Infrastructure Projects in KSA

Projects	Description
King Salman International Airport	A new hub for international travel based in Riyadh.
The Riyadh Metro	One of the largest urban transport projects in the world.
The Red Sea Project	A massive tourism, leisure and residential development planned for the western coast of Saudi Arabia.
The Makkah Public Transport Program	A comprehensive system designed to reduce congestion in the holy city of Makkah.
The Riyadh-Dammam Expressway	A major highway project that is expected to reduce travel times between the two cities.
Al Widyan	A new city located in the north of Riyadh is being built with an eye towards encouraging economic growth.
Al Widyan	A new city located in the north of Riyadh is being built with an eye towards encouraging economic growth.
Jabal Omar Development Project in Makkah	A massive urban project, which aims to develop the area into one of the most luxurious residential, business and leisure districts in the Middle East.

Note. Compiled by the Researcher.

In a report by Global Infrastructure Hub (2023, pp. 3-6), the findings indicated that KSA has been putting up major economic changes as part of its Vision 2023 strategy. See Table (2.5).

These reforms have included making it easier to establish business, obtaining building permits, gaining access to financing, resolving insolvency, and streamlining the procurement and permission procedures. These changes and implementations are boosting competition, stimulating the entry of new companies, and enhancing the openness of procurement procedures. Even though the COVID-19 outbreak may have a long-term impact on the amount of government debt, KSA is still in a strong

position to finance future infrastructure projects and carry out its reforms, which are aimed at facilitating business establishments such as vaccine manufacturing organizations (KSA Vision 2023; Global Infrastructure Hub, 2023, pp. 3-6).

Table 2.5

Ease of Doing Business in KSA

Components	Rate
GDP	779.3 USD billion
GDP growth rate	0.2%
GDP per capita growth rate	-2.9%
Gini coefficient	42.2 (0-100 worst)
Gross Government Debt	23.0% of GDP
Inflation rate	-1.1%
Summary credit rating	76.0 (0-100 best)
Unemployment rate	5.9%
Urbanization ratio	84.0% of total population
Road connectivity	100.0 (0-100 best)
Quality of road infrastructure	5.2 (1-7 best)
Efficiency of train services	4.5 (1-7 best)
Efficiency of air transport services	5.4 (1-7 best)
Efficiency of seaport services	4.8 (1-7 best)
Electricity access	99.4% of population
Electricity supply quality	8.1% of output lost
Exposure to unsafe drinking water	9.5% of population
Reliability of water supply	5.8 (1-7 best)
Digital Adoption Index	0.7 (0-1 best)
Mobile-broadband subscriptions	111.1 per 100 population
Fixed-broadband Internet subscriptions	5.6 per 100 population

Note. Adapted from Global Infrastructure Hub, 2023, pp. 3-6.

(d) Technical Knowledge for Vaccine Manufacturing

The vaccine industry is about know-how, both explicit and tacit (Price, Rai, & Minssen, 2020, p. 4). Explicit knowledge can be codified or written down, stored in documents or databases, and is relatively straightforward to transfer from one person to another via training (Ahmad et al., 2021; Johari et al., 2021). Transferring

tacit knowledge, intuitive knowledge, and know-how rooted in context, experience, practice, and values is much more difficult (Abu-Rumman, 2021; Zheng, 2017).

Vaccine manufacturing is not just following a fixed recipe (explicit knowledge) but involves a large amount of experiential-based tacit knowledge, which only comes from doing things repeatedly, preferably in the presence of a more experienced mentor. For example, the average person still cannot replicate a dish from a top restaurant even if they were given the recipe due to their relative lack of tacit knowledge (Price, Rai, & Minssen, 2020, p. 4; Druedahl, Minssen, & Price, 2021).

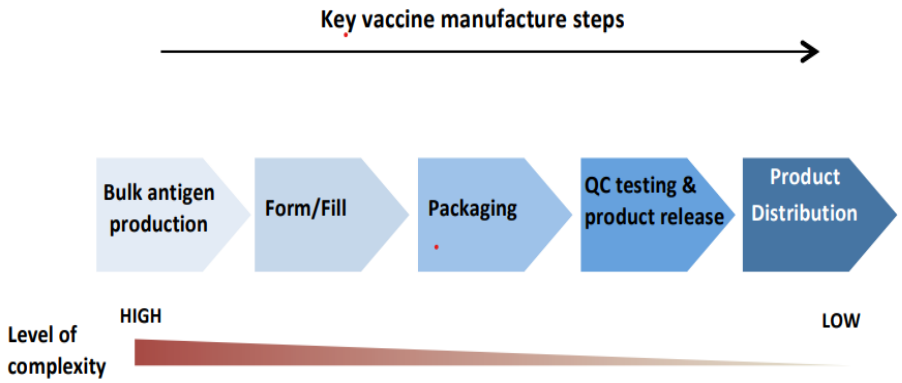
Specific scientific and biotechnical engineering expertise is required to be able to understand the production process and interpret any deviations encountered along the way, and to pass on this understanding to other personnel (Jerving & Ravelo, 2022).

The establishment of bulk antigen marks the start of the vaccine manufacturing process, which concludes with the distribution of the completed, use-ready product. Furthermore, a technology transfer partnership involves assigning a local partner to handle a portion of these manufacturing steps. Backwards integration is a widely employed technique in which the local partner distributes products initially and progressively acquires the knowledge required to carry out higher-value processes. In most cases, the process's early steps considerably increase the whole product's added value compared to its later stages. The earlier a facility begins production, the more technological impediments there are to the successful creation of a vaccine. However, these early processes are also more

technically demanding (Graham, 2020, p. 945; Makenga et al., 2019). See (Figure 2.10).

Figure 2.11

Key Stages in the Manufacture of Vaccines



Note. Adapted from, Makenga et al., 2019, p. 5.

Minssen and Price (2021) argue that, as intricate as the vaccine manufacturing process, technological transfer is essential, and this requires a high level of expertise and knowledge. In the opinion of Alzahrani and Harris (2021), in a country with a sizeable pharmaceutical sector but where local regulatory standards are not up to international standards, recruiting from the pool of local pharmaceutical experts may not be viable; even if suitable people with pharmaceutical experience are recruited, they will need to be trained to relinquish the pharmaceutical way of thinking and indoctrinated into the "treating the process as the product" mindset for them to be fully effective in the vaccine industry (Jerving & Ravelo, 2022; Zheng, 2017).

Antiviral vaccines fall into two main groups. Gene-based vaccinations transfer host cell-produced protein antigens encoded in gene sequences. Live virus vaccines, recombinant vaccine vectors, and nucleic acid vaccines are a few examples of these. In vitro-produced whole-inactivated viruses, single viral proteins or subdomains, or viral proteins packaged into particles are examples of protein-based vaccinations. Because they can be more readily adapted to platform manufacturing technologies, where upstream supply chains and downstream procedures are the same for each product, recombinant vaccine vectors and nucleic acid vaccines are most suited for speed. Understanding the vaccine antigen's atomic structure and the vaccine's preservation of the targeted epitopes are necessary for precision (Graham, 2020, p. 945; Ahmad et al., 2021; Alzahrani & Harris, 2021).

Therefore, the ability to hire, train, and maintain quality personnel to maintain the process and quality systems is a challenge even for highly experienced manufacturers. Technical competence is essential, as is knowledge of the latest technologies and global regulatory requirements (Robinson, 2016; Denault, Coquet, & Dodelet, 2008). Globally, there is a scarcity of personnel with the requisite skills and expertise needed by the vaccine industry (Plotkin et al., 2017; Sharpe et al., 2020).

Vaccine production requires deep scientific knowledge and persistent curiosity to understand and detect the subtle signals a biological process may send that are not detectable in release data. Experienced workers use caution when considering changes in processes or facilities or when responding to process or equipment failure (Vidor & Soubeyrand, 2016). Sustaining vaccine manufacturing

requires developing a strong base of scientific, technical, product-specific manufacturing, and quality control system knowledge (Koff et al., 2021).

Countries such as Switzerland, India, Brazil, and China, with large populations and sound technical and scientific education systems, have succeeded in creating a new and growing cohort of technicians and skilled workers suited for the highly detailed work of vaccine manufacturing (Rauch et al., 2018). New market entrants in other geographies may underestimate the difficulty of developing this type of knowledge base in tandem with a comprehensive training system (Koff et al., 2021).

In KSA, human capital has remained at substantial low rates compared to the developed economies, which has resulted in a scarcity of technicians and scientists, particularly in the manufacturing sector of the economy (Alzahrani & Harris, 2021; Badreldin & Atallah, 2021). Researchers have argued that flexibility in production processes and the ability to absorb new technologies are directly related to the stock of indigenous human capital (Kumraj et al., 2022; Badreldin & Atallah, 2021; Tinworth & Young, 2020). Labor costs vary significantly depending on the capabilities and education of the local workforce. The typical personnel roster for an average facility in low-resource countries will often include local and expatriate employees to secure the relevant technical skills required for vaccine production and release (Badreldin & Atallah, 2021; Tinworth & Young, 2020).

Most expatriate staff will require higher total compensation and benefits than local employees, increasing the overall cost of labor and decreasing local employment opportunities (Sheikh et al., 2021; Makenga et al., 2019). However,

specialists are needed in setting up a new vaccine manufacturing facility; hence, hiring foreign experts to work in key facility positions is often necessary as local skilled workers will require significant training, which may include being sent abroad for months at a time, compounding the challenges towards successful vaccine manufacturing (Sheikh et al., 2021; Patil & Shreffler, 2019).

As Mihigo et al. (2019) argued, appropriate efforts to recruit, train, and retain a skilled local workforce are essential to support the long-term sustainability and viability of developing country vaccine manufacturers promotion and recognition, and innovation opportunities should be included in comprehensive brain drain management strategies.

(e) Government Support for Vaccine Manufacturing

The COVID-19 pandemic situation caused several nations, including KSA, to face the scarcity of vaccines for the protection of their citizens, and therefore, to mitigate future challenges of this nature, business professionals and experts should step in and take actions to improve vaccine manufacturing as well as sales to reduce bottlenecks in production, supply chain, and access to vaccine portfolios (Assiri et al., 2021). Furthermore, this involves the participation of the government agencies tasked with regulation and evaluation of the quality, safety, and effectiveness of all vaccines before usage; hence, the support of the government is crucial in the production and manufacturing processes (Assiri et al., 2021; Alzahrani & Harris, 2021).

In a survey conducted by WHO (2015), findings indicated that vaccine availability has grown, vaccination accessibility has improved, and vaccine costs

have decreased because of technological transfer to poorer nations. The finding also indicated that it is not always economical to start a local vaccine production operation. Instead of seeing vaccine production only as a business, what is important is to consider vaccine manufacturing as public health security. The formulation of a national vaccination policy might help determine if and when to consider local manufacturing. Hence, a sizable local or regional market or a government commitment to assist technology transfer are necessary for vaccine manufacturing businesses to be beneficial (WHO Report, 2015).

According to Kumraj et al. (2022, p. 11), empirical evidence of sustained political backing is essential for a nation to be able to produce vaccines domestically, which should be supported by a strong regulatory infrastructure, policy coherence, incentives, government facility investment alongside commercial capital, other support projects, such as the provision of affordable land, human resource capacity building for making available skill development, and a supportive business atmosphere. These are ways the government can support an effective vaccine manufacturing business.

Milstien, Gaulé, and Kaddar (2007) posit that the long-term viability of vaccine manufacturing depends on government assistance; proper rules to access capital given to vaccine manufacturers are considered major factors that facilitate the growth of any national vaccine manufacturing business. Ho et al. (2011) emphasized that although private access to capital has increased because of overall economic development, vaccine manufacturers have identified the need for capital investment to ensure successful cGMP compliance and adoption of new production technology as a particular challenge that governments should take into consideration and

support. Aldossari et al. (2021) noted that the Kingdom of Saudi Arabia is the only G20 nation without a national infrastructure for the manufacture of vaccines. Therefore, the government had to take the lead in encouraging local pharmaceutical firms to manufacture vaccines by providing funding through the Saudi Industrial Development Fund (SIDF).

Furthermore, Raja and Alshamsan (2020) stressed that the SFDA must play a significant role in supporting public and private alignment of pharmaceutical businesses since the primary cause of the low performance associated with vaccine manufacturing is a lack of information regarding bioprocessing.

(f) Partnership Opportunity for Vaccine Manufacturing

As stated by Beasley (2015, p. 7), it is a common understanding that vaccines are not the best products for revenue generation because vaccines are intricate biological products with challenges in their design, testing, long duration of production, and huge cost, which in most cases are not attractive to investors. In this case, forming alliances and partnerships is a vital strategy by which the private and public organizations can circumvent these challenges and achieve effective vaccine manufacturing business (Hayman, Suri, & Downham, 2022, p. 2).

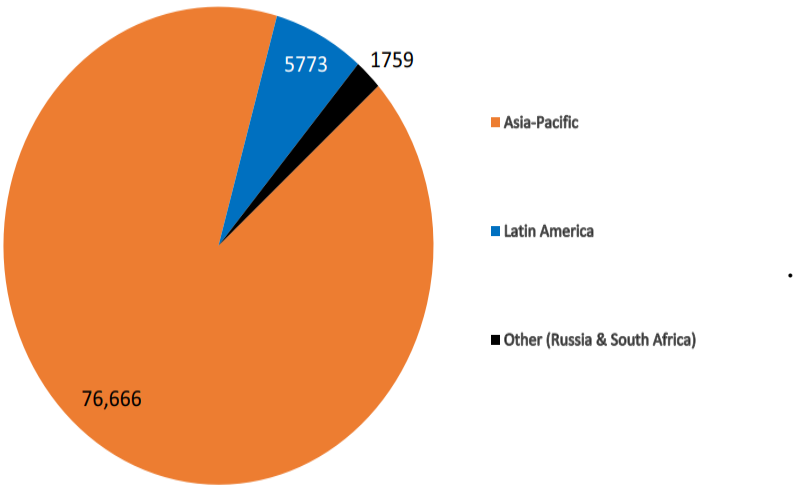
According to the World Economic Situation and Prospect—United Nations (WESP-UN) Report (2019), one notable alliance is the developing nations Vaccine Makers Network (DCVMN), which is an association of corporate vaccine manufacturers in developing nations around the world working with international agencies such as WHO, UNICEF, PAHO, and GAVI to expedite access to necessary vaccine manufacturing.

As further emphasized by WESP-UN (2019), the mission of association is to safeguard all people from infectious illnesses, both known and unknown, through increasing access to high-quality vaccines on a worldwide scale and acknowledging the necessity of international collaboration in science, technology, and the economy.

In a study conducted by the Global Burden of Disease Collaborative Network (GBD) (2017), findings describe the proactive measures taken by DCVMN members to lessen the worldwide burden of infectious disease and their dedication to vaccine manufacturing as well as the alliance ability to generate employment. See Figure (2. 11). Furthermore, findings highlighted the contributions made by the corporate members specifically focused on vaccine research and development, considering new innovations in vaccines and their impact on the battle against infectious diseases.

Figure 2.12

Regional Distribution of Employment Provided by DCVMN



Note. Adapted from Hayman and Pagliusi, 2020, p. 3.

Dellepiane and Wood (2015, p. 2) point out that there has been a considerable increase in the quantity of vaccines from DCVMN members attaining WHO pre-qualification and certification during the last five years, indicating a reliable system for the world's supply of vaccines as well as showing how manufacturers and developing nations have advanced to fulfill strict regulations, quality control, and production standards.

Pagliusi et al. (2020, p. 15) study revealed that members of DCVMN can now offer more than 3.5 billion vaccine doses yearly due to partnership and corporation demonstrated an even greater ability to produce specific antigens, which included multivalent vaccines. Hayman and Pagliusi (2020, p. 4) point out that DCVMN members have also been able to supply up to 170 nations with vaccines against 50 different diseases spread across nearly 200 products. Considering that DCVMN members have started vaccine manufacturing capacity of over 3.5 billion doses yearly, this indicates the reliability of the associated in facilitating vaccine manufacturing to maintain the domestic need of its member organization as well as for the global demand of vaccine products (Hayman & Pagliusi, 2020, p. 4; Pagliusi et al., 2020, p. 15; van Riel & de Wit, 2020). However, Alzahrani and Harris (2021) argue that in KSA, local pharmaceutical businesses have not been benefiting from partnering with international organizations to develop their local competence through knowledge and expertise exchange to mitigate challenges that arise frequently while creating infrastructure for vaccine manufacturing and financing biotechnology research. Plotkin (2017, p. 2) asserts that global access to safe, efficacious, and reasonably priced vaccines is a prerequisite for sustainable vaccine manufacture. In this case, companies need to have strong business plans and

incentives to produce vaccines. Owing to the difficulties and expenses involved in developing, producing, and distributing vaccines, it is difficult for businesses to stay in business, and as a result, facilities close and organizations leave the field of vaccine manufacturing for other lucrative business ventures (Ibid., p. 2).

Researchers have emphasized the benefits of partnership, which include increased vaccine manufacturing capabilities of members, the creation of innovative, higher-quality vaccines, universal vaccine accessibility, simplifying licensing procedures, access to capital, a decrease in the labor-intensive portion of vaccine development, and increased expertise and efficiency (Rappuoli, Black, & Bloom, 2019; Cohen, 2020). Similarly, Bulc and Ramchandani (2021) add that public-private partnerships (PPPs), known as "product development partnerships" (PDPs), work to create innovations and goods for underserved markets, which is crucial for developing vaccines that lack strong commercial challenges. However, researchers (Barlow, Roehrich, & Wright, 2013; Roehrich, Lewis, & George, 2014) argued that PPPs have some disadvantages that are worthy of consideration, such as stifling of innovation, private sector rent-seeking, high transaction and establishment costs, higher capital costs, challenges with relationship management, poor risk distribution, lower value-for-money (VfM), and restricted competitive behaviors.

In the opinion of researchers (Rappuoli, Black, & Bloom, 2019; Cohen, 2020; Roehrich, Lewis, & George, 2014), these concerns justifies requests from different sectors for ways to fill the gaps and address the fundamental issues of how to successfully forge alliances between public and private actors, how to develop and assess the effectiveness of suitable incentive systems, enhancement of learning between members across projects, as well as how to set up governance frameworks

that combine the best aspects of relational and contractual frameworks for the efficiency of PPPs.

(g) Government Regulations and Policy

Regulatory law and policies are the fundamental tenet that guides the vaccine manufacturing business to ensure that every vaccine manufactured is safe, effective, and consistent throughout a vaccine's life cycle (Robinson, 2016, p. 5). Government agencies are the final authority on whether a new vaccine manufacturing organization will obtain approval to manufacture a product as well as the decision to be a partner in steering and guiding the manufacturer to comprehend the regulatory obstacles necessary to achieve necessary permits to start a manufacturing activity. Specifically, products for export must attain WHO prequalification (PQ) status, and one of the criteria for this process is for the local regulatory body to be highly functional to meet WHO qualification requirements (Ibid., p. 6).

Generally, regulations for vaccine manufacturing are specific; hence, manufacturers must adhere to all national regulatory authority (NRA) standards, as well as those of the nations in which they plan to distribute or sell their vaccine and adapt to any changes in laws (Gruber & Marshall, 2018, p. 12). These specifications include the yearly reporting of production information (such as data trends, change management, stability reviews, and critical investigations of any process failures or unexpected patterns) and the regular monitoring of adverse event data (Ibid., p. 12).

According to WHO Pre-Qualification (2020), a manufacturing facility must be subjected to routine and unannounced regulatory inspections to review compliance with Current Good Manufacturing Processes (cGMP), upkeep of the

manufacturing facilities and equipment's processes and quality systems, as well as an overall production. Similarly, to export products, a precise license must be approved by the importing nation and its authorized agency, which may require national clinical trials, including repetitive inspections from those NRAs and international for the evaluation of adverse event monitoring and reporting.

Procurement groups such as the Pan American Health Organization (PAHO) may accept approvals from certain NRAs, such as the FDA and EMA, or the WHO PQ. Pre-Qualification (PQ) is a highly structured and systematic process aimed at ensuring the quality of vaccines. It involves ensuring that the policies and practices of the manufacturing company produce a product that not only satisfies international quality standards but also complies with the programmatic requirements of the national immunization program and WHO use recommendations (WHO Pre-Qualification (2020).

According to Vidor and Soubeyrand (2016), a company that exports goods internationally has to keep track of numerous distinct licenses for every market in which the goods are authorized and are subject to almost constant inspection by various NRAs. According to Kis et al. (2019), producers also need to have procedures in place for handling problems that can develop during regular production as well as any new safety or field use concerns that might surface after the product is being used widely, and manufacturers that want to market their products through channels like the UNICEF Supply Division, which obtains hundreds of millions of doses on behalf of its constituents, must adhere to WHO Pre-Qualification (PQ) regulations in addition to the licensing process.

According to Gomez et al. (2013, p. 3), as a requirement, the approval of new vaccines must go through a precise regulatory process. There are four main components to the approval procedure. See Table (2.6).

Table 2.6

Vaccine Approval Process

Item No	Principal elements
1	Preparation of preclinical materials for proof-of-concept testing in animal models, manufacture of clinical materials according to current GMP (cGMP), and toxicology analysis in an appropriate animal system.
2	Submission of an investigational new drug application (IND) for submission to FDA for review.
3	Testing for safety and effectiveness through clinical and further nonclinical studies (phase 1 to 3 clinical studies).
4	Testing for safety and effectiveness through clinical and further nonclinical studies (phase 1 to 3 clinical studies).
5	Submission of all clinical, nonclinical, and manufacturing data to the FDA and EMA in the form of a Biologics License Application (BLA) for final review and licensure.

Note. Adapted from Gomez et al., 2013, p. 3.

The development and functionality of local regulatory authorities, while completely outside of the influence of any manufacturer, can significantly impact the process of any manufacturing project and hence should be a vital consideration when planning a vaccine manufacturing project (Vidor & Soubeyrand, 2016). In this case, Cid and Bolivar (2021) opined that local regulatory agencies are responsible for granting initial licenses to manufacturers, as such problems or delays can lead to a termination of the whole manufacturing project. Consequently, a well-functional regulatory authority with good scientific knowledge in vaccine technology should be

able to offer support and guidance on the operation of a manufacturing facility as well as the registration of products that are produced for the global market. However, as opined by Mueller, Altenburger, and Mohl (2018), one critical barrier to sustainably manufacturing vaccines relates to rigorous regulatory procedures for vaccine manufacturing. Although low prices of vaccine, production uncertainty, and limited capabilities to expand to new markets are also identified, nonetheless, a rigorous and ever-changing list of laws and regulations is frequently being cited by manufacturers as a factor that impedes vaccine manufacturing (Cid & Bolivar, 2021; Kis et al., 2019; Vidor & Soubeyrand, 2016).

In KSA, laws and regulations relating to medicine and vaccine manufacturing are regulated by the Saudi Food and Drug Authority (SFDA) (Khan et al., 2016, p. 3). SFDA responsibilities include regulating, registering, and approving pharmaceuticals in Saudi Arabia. Thus, monitoring the efficacy, safety, and quality of medications is one of its primary goals. The department is also in charge of creating and carrying out medicine-related policies and procedures. According to Khan et al. (2016), further duties as a regulator include educating the public about all things linked to medicines. See Table (2.7).

Table 2.7

SFDA Regulatory Process

Process	Description
Validation process:	In this process, the SFDA will validate and evaluate the drug file in terms of the completeness and accuracy of all information according to the SFDA generic medicine market authorization requirements and procedure. At this stage, the manufacturer must provide samples of the product for testing in a further step.
Assessment process:	In this process the product file will be assessed by two groups: quality and efficacy groups in the SFDA. The product file can proceed to the next step only after being recommended for approval and successfully passing the quality and efficacy assessment; otherwise, it will be rejected
Pricing process:	The pricing unit according to the SFDA pricing rules will determine the price of the product
Testing process:	The drug samples received from the drug company will be sent to the laboratory for testing.
Inspection process:	In this process, the SFDA will check the product manufacturing line to ensure compliance with current good manufacturing practice (GMP). It must hold a valid certificate from the Saudi MOH or SFDA; otherwise, an inspection team will be sent to check the line before granting the approval.
Product licensing:	This is the final stage in which the product will be granted marketing authorization (MA) based on reviewing all the reports (quality and efficacy assessment reports, pricing report, testing report, GMP inspection report and company registration) by the SFDA registration committee.
Appeal process:	The company has the right to appeal within 30 days of the final decision by the SFDA.

Note. Adapted from SFDA, 2020, p. 12.

Alrasheedy et al. (2017, p. 4) point out that the SFDA implements stringent regulations and a rigorous product registration process, which is claimed to be a measure for guaranteeing the effectiveness, safety, and quality of medications. It has been noted that the KSA laws and regulatory system enforce the strictest regulations throughout the Middle East, which are in most cases a hindrance to manufacturers

(Ibid., p. 4). Table (2.8) shows the SFDA regulatory process and drug review timelines that must be followed for the manufacture and marketing of medicines and vaccines.

Table 2.8

SFDA Drug Review Timelines

Drug Type	SFDA Timelines (working Days)
Human Generic	155
Human New Drugs registered in SRA	280
Human New Drugs not registered in SRA	405
Human Biologics registered in SRA	280
Human Biologics not registered in SRA	405
Radiopharmaceuticals	280
Veterinary Generics	165
Veterinary New Drugs registered in SRA	260
Veterinary New Drugs not registered in SRA	385
Veterinary Biologics registered in SRA	260
Veterinary Biologics not registered in SRA	385
Herbal & health products	155

Note. Adapted from SFDA, 2020, p. 13.

Research indicates that the KSA encounters several obstacles in obtaining dependable and economical vaccines since there are insufficient production facilities in the domestic market. As a result, the country depends mostly on foreign markets to get efficacious vaccines. Raja and Alshamsan (2020, p. 2) draw attention to the fact that the "Saudi Food and Drug Authority" (SFDA), which oversees assessing the nation's pharmaceutical operations, is attempting to give priority to the manufacture of vaccines by carefully examining current regulation and policies to streamline procedures. In addition, Assiri et al. (2021, p. 11) commented that the government of KSA has expanded regulations and policies aimed at supporting pharmaceutical and biotechnology industries in the development of local vaccine manufacturing as

well as to facilitate partnerships with multinational corporations and bolster vaccine manufacturing.

(h) Vaccine Manufacturing Business

The incident of the COVID-19 pandemic ushered in a universal vaccination campaign in countries around the world, which has also resulted in vaccine manufacturing being seen as an attractive and sustainable business for several reasons, such as the high rate of vaccine demand that has grown rapidly over the past decade and looks certain to grow further; the significant unmet medical needs and a range of important disease targets for which vaccines do not currently exist to tackle them; and innovative financing methods that have significantly expanded vaccine markets, particularly in the developing world (Shuman et al., 2020; Badreldin & Atallah, 2021). In addition, there are also emerging advances in immunology and microbiology that have given a better understanding of pathogenesis as well as a sharp revenue increase in the pharmaceuticals industry (Portnoy et al., 2023; Arif et al., 2023; Surya et al., 2019).

The determination for countries to be autonomous in the manufacture of essential vaccines has led to the expansion and technological development of various local manufacturers in the process of attaining the necessary WHO pre-qualification requirements and engaging in the vaccine market through organizations such as UNICEF and GAVI (Del Poeta et al., 2023; Alruthia et al., 2018; Ni et al., 2017).

Several pharmaceutical organizations (Pfizer/BioNTech, Moderna, Janssen, Sinopharm, Sinovac, and AstraZeneca-Oxford) reported an increase in revenue due

to the surge in vaccine demand because of the of the COVID-19 pandemic, as shown in Table (2.9).

Table 2.9

Funding, Revenues, Profit Generation of EUL COVID-19 Vaccines

	Pfizer/BioNTech	AstraZeneca–Oxford	Janssen	Moderna	Sinopharm	Sinovac
Funding [1] (APA included) (million USD)	18,549	4967	5928	8337	145	515
Funding [2] (APA excluded) (million USD)	800	115	1028	955	145	515
Revenues from vaccine sales in 2021 (Q1–Q2 this year, billion USD)	11.3	1.2	0.3	5.9	- [3]	-
Announcements	"Marginal profit"	no profit	no profit	"will not charge too high a price"	-	-

Note. Adapted from Sung et al., 2021, p. 21.

Growth and development in the manufacturing sector, specifically in the pharmaceutical industry, has been reported (Narayana et al., 2019; Atkins et al., 2018). Generally, the relationship between industrial production and economic growth has attracted economic researchers. Moreover, the intellectual contributions of Kaldor (1957, 1966) are the theoretical basis for many modern economic studies that examine the leading role of the industrial sector in economic growth.

Economic experts have generally been interested in the connection between industrial production and economic growth. Furthermore, many contemporary economic studies that look at the leading role of the industrial sector in economic growth are theoretically based on the intellectual contributions of Kaldor (1957, 1966).

Several studies have been conducted to examine the effects of the manufacturing sector and economic growth in different areas. For instance, using

panel vector autoregression (PVAR) for the fixed effects approach for 115 countries over the 1990–2011 period, along with estimated impulse-response functions (IRF) and forecast error variance decomposition (FEVD), Gabriel and De Santana (2019) examined the relationship between manufacturing and economic growth over time. Their findings suggested that in emerging nations, the manufacturing sector could serve as an "engine for growth." Moreover, for many developing nations, the manufacturing sector was the sole strategically important one for economic growth.

Olanrewaju (2018) investigated the long- and short-term relationships between manufacturing output and economic growth in Nigeria from 1980 to 2017 using a cointegration approach and a Granger causality test. The study's findings showed that the factors included in the estimation have a long-term association, and the results of the causality test point to a one-way relationship between manufacturing production and economic growth. Tunali and Boru (2019) investigated the causal effects of the manufacturing sector on macroeconomic variables such as gross fixed capital formation, the services sector, savings, and economic growth in Turkey. Their findings suggested that there is a one-way causal relationship between manufacturing and gross fixed capital formation and the manufacturing sector. Furthermore, there was a causal relationship between manufacturing and services as well as manufacturing and economic growth. According to their findings, developing nations might use the industrial sector as an "engine for growth."

The findings also revealed that for many emerging nations, the manufacturing sector remained the only strategically important area for economic growth.

In a sample of 134 developing nations, Haraguchi et al. (2019) looked at the variables that contributed to higher manufacturing growth rates between 1970 and 2014. Their results demonstrated that, given macroeconomic policies pertaining to openness to foreign investment, money, and trade, human capital and institutions constitute factors that assist the development of manufacturing industries. The authors also discovered that a variety of factors contribute to the development of the sector in the ongoing industrialization process that defined the economic development of a few prosperous nations between 1970 and 2014. Furthermore, the results of the causality test point to a one-way relationship between manufacturing production and economic growth.

In a similar study, using a combination of statistical analysis of secondary data and literature, Szirmai et al. (2013) investigated an overview of the key points advancing the engine of growth concept. Their conclusion was that manufacturing still plays a significant role in spurring economic growth in underdeveloped nations. In South Africa, Mongale and Tafadzwa (2018) examined the connection between economic growth and the manufacturing sector and tested Kaldor's first law. The study's conclusions demonstrated that the manufacturing sector, as measured by manufacturing production, has a significant positive coefficient, indicating that the industry has a beneficial impact on economic growth.

By putting Kaldor-Verdoorn and Thirlwall's laws to the test, Almosabbeh and Almoree (2018) investigated the long-term relationship between the performance of the manufacturing sector and economic growth in KSA. The results demonstrate that, with decreasing returns to scale, Kaldor's law holds true for data on KSA.

Furthermore, given diminishing returns to scale, Verdoorn's law is relevant at both the macro and sectoral levels.

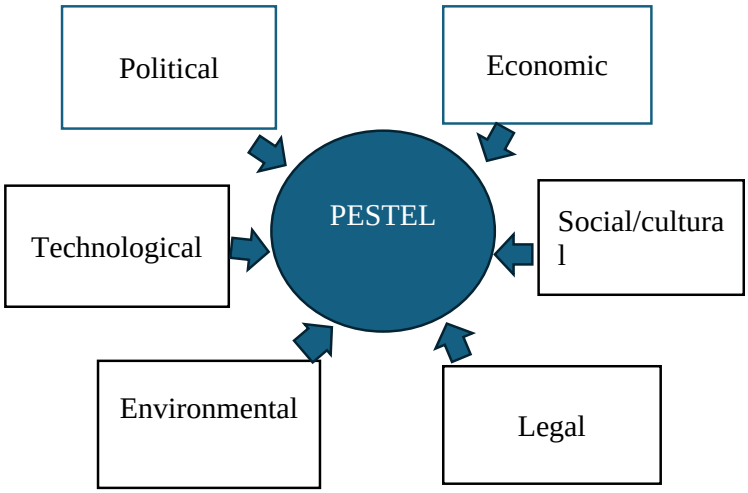
PESTEL Analysis of Biopharmaceutical Manufacturing Industry in KSA

Organizations often utilize the PESTEL analysis technique to assess a country's stability. Specifically, the political, economic, social, technological, and legal aspects are the focus of this national macro-environment measuring tool, which helps to identify opportunities and risk in the context of PESTEL analysis (Fadil, Davis, & Geraghty, 2023; Tasios, 2018).

According to Briguglio et al. (2014), PESTEL factors are essential components for comprehending the regional market and guaranteeing its longevity. Therefore, PESTEL analysis in this section is utilized to uncover the possibility of vaccine manufacturing in KSA.

Figure 2.13

Pestel Analysis



Note. PESTEL Analysis developed by the Researcher.

According to Kolios and Read (2013), analyzing PESTEL factors can help predict positive and negative impacts of doing business in a particular market. The pharmaceutical industry is a globalized industry, with many of the big companies operating on a multinational level. PESTEL Analysis in this regard facilitates specifying the factors that decision makers can take into consideration (Kolios & Read, 2013).

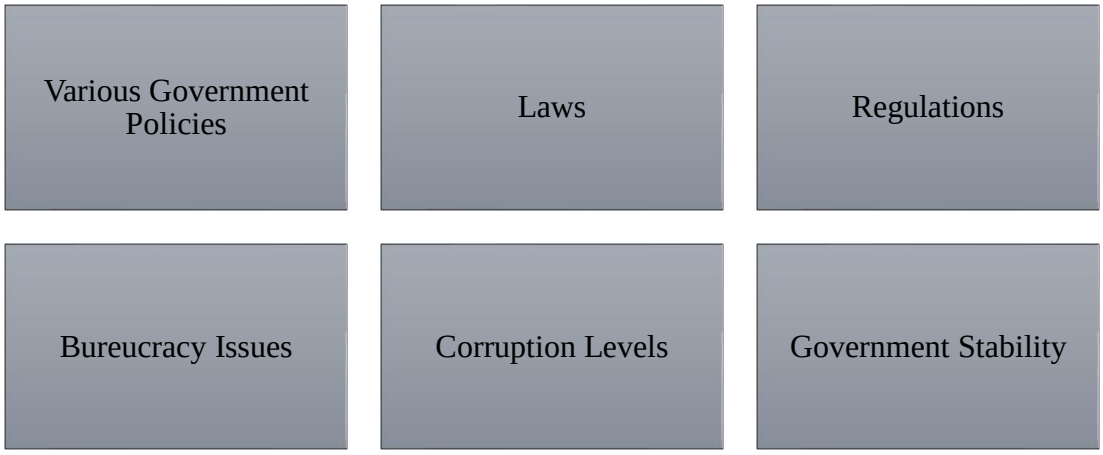
Political Factors. Political factors consist of matters driven by the government that influence economies and industries.

These matters include:

a. various government policies
b. laws
c. regulations
d. bureaucracy issues
e. corruption levels

Figure 2.14

PESTEL Factors – Political



Note. PESTEL – Political Analysis developed by the Researcher.

As stated in KSA Vision 2030 (2023, p. 10), political considerations play a crucial part in many corporate decisions, including how businesses formulate their business plans and how they handle their operations. Tax laws, political stability, international relations, consumer laws, trade barriers, entry mode controls, and other fiscal policies and government interventions are examples of political influences (KSA Vision 2030, p. 10).

The political environment in KSA is stable with an absolute monarchy system. The stability of the government is indicated by the following factors:

- Good ranking by the global country risk index (GCRI).
- KSA is currently ranked 31st out of 153 nations in the Global Country Risk Index (GCRI) Q3 2023 (KSA Vision 2030, p. 10).
- Unified national visa application system.
- KSA has launched a visa platform, known as a unified national visa application system connecting over 30 ministries and organizations to facilitate visa applications for Hajj, Umrah, tourism, business, and employment.
- Promotion and development of pharmaceutical products.
- The government currently offers a secure and supportive environment for businesses through a policy of encouraging and promoting the development of pharmaceutical products (KSA Vision 2030, p. 10).

Risk and Challenges – Political. These are the risk and challenges involved under political factors:

High Level of Corruption. As stated by Alruthia et al. (2018), high levels of corruption and bribery in government ministries are a concern for smooth processing and approval of applications. Generally, biopharmaceutical products in the KSA market are subject to a marketing authorization assessment (Alzahrani & Harris, 2021). Approval is contingent upon the product meeting the necessary requirements. These applications are classified according to their intended use when it comes to biological products. The three categories are: renewal, variation, and new registration. Validation starts the process, which ends with acceptance or rejection (Alzahrani & Harris, 2021).

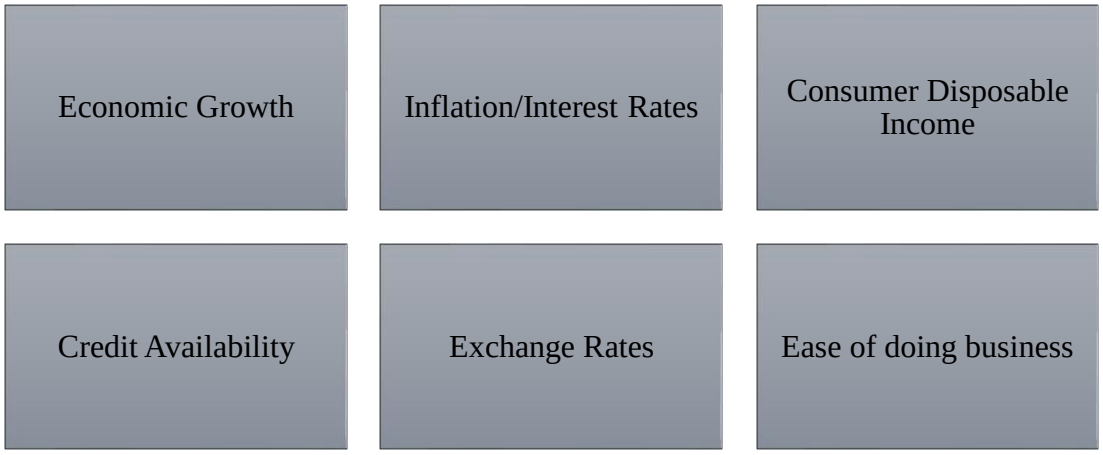
Lack of Efficient Government Agencies. While KSA is unlikely to have significant budgetary restrictions in the near future, one area of concern is the absence of effective government agencies to carry out the Visions 2030 initiative. Despite the establishment of these institutions, there is still a risk that bureaucracy will continue to be opaque, overcentralized, and unaccountable, making it difficult to solve the scarcity of energetic and vibrant administration officials capable of implementing changes. In general, KSA has a fairly efficient political environment in comparison to many other oil-producing nations (Alzahrani & Harris, 2021).

Economic Factors. Economic factors are those aspects of the economy that have a direct effect on the operations and profitability of enterprises and industries. Economic considerations have a direct impact on every aspect of a business's operations, as they have an impact on investments, products, services, demand, and

overall profit. These factors are dynamic and affect businesses over the long term. Therefore, having a strong and adaptable business strategy is essential to a company's capacity to manage these conditions. Economic factors include economic growth, inflation/interest rates, consumer disposable income, credit availability, exchange rates, and global trade are examples of economic factors (El-Chaarani, 2019).

Figure 2.15

PESTEL Factors – Economic



Note. PESTEL – Economic Analysis developed by the Researcher.

The economic business environment in KSA has improved over the years due to various government reforms, which have resulted in growth and development of the economic growth in the kingdom.

As of 2023, the KSA economy ranks 17th globally in terms of purchasing power parity and is a member of the G-20. In 2021 and 2022, KSA GDP share

adjusted for purchasing power parity stands at 1.19% and 1.25 percent, respectively, of the world's gross domestic output.

KSA is among the most significant pharmaceutical markets in the Middle East Region and has a swiftly increasing population. The gross domestic product (GDP) was $1.1 trillion in 2023 and is included in the top 30 worldwide (Alrasheedy, 2020; El-Chaarani, 2019). This makes KSA an encouraging market for biopharmaceutical organizations. Studies by El-Chaarani (2019) showed that KSA is the largest economy in the Gulf Cooperation Council (GCC). By population and gross domestic product (GDP), KSA has the region's largest pharmaceuticals market, despite having a low local production of branded drugs compared to generic products.

With its sizeable population and readiness to pay for such products, KSA is an exceptionally attractive market for pharmaceutical companies (Alzahrani & Harris, 2021; Nabil, Al-Ammar, & Mostafa, 2009). According to Alzahrani and Harris (2021, p. 4), KSA accounts for approximately 65 percent of all pharmaceutical purchases in the GCC, while 82 percent of the kingdom's requirement is satisfied via imports, thereby signifying a major growth opportunity for domestic pharmaceutical organizations.

Risk and Challenges – Economic. These are the risk and challenges involved under economic factors:

Low UNDP Ranking. KSA still belongs to group five (5), which is the worst category in the ranking, notwithstanding the reforms and developments indicating the lack of local expertise for the manufacturing industry. As indicated by

Alrasheedy (2020), the KSA pharmaceutical sector depends heavily on imported drugs from the US, Europe, China, and India. About 30 percent of the total drugs in the Saudi market are manufactured locally (Alrasheedy, 2020; El-Chaarani, 2019).

Limited Investments. Poor investments in research and development due to a lack of sufficiently skilled personnel, a dearth of technical knowledge, and insufficient infrastructure are a major concern for investors in the pharmaceutical industry. Tawfik et al. (2022, p. 23) point out that a major concern is the poor or inadequate quality of pharmaceutical base materials in the country, which has led to the dependence of local drug manufacturers on imported materials from France, Germany, Switzerland, Belgium, and the UK. Alshehri et al. (2023, p. 8) also echoed similar concern that the reliance on imported-based material for pharmaceutical production has increased the expense activities and decreased profit margins.

Lack of Government Support in Funding. The lack of government funding and qualified workers limits R&D operations and is a major concern for the industry. Generally, there are no foreseeable and imminent risks in the pharmaceutical industry, although the lack of local research and development (R&D) limits the ability to manufacture new drugs locally (Mirza et al., 2023; Alrasheedy, 2020).

Socio-Cultural Factors. Social-cultural factors examine the social environment and measure the societal aspects that impact businesses and markets. Businesses must comprehend social factors, as these are at the core of client behavior and purchasing patterns. Businesses can better understand consumer behavior and

market demands, as well as cultural differences and societal standards, by analyzing social aspects (Mirza et al., 2023). Socio-cultural factors include:

- educational attainment
- availability of skills
- wealth distribution
- cultural norms and distinctions
- population demographics

Figure 2.16

PESTEL Factors – Socio-Cultural

Note. PESTEL – Socio-Cultural Analysis developed by the Researcher.

KSA has moved up three spots from the previous edition to 35th place out of 191 nations in the United Nations Development Program (UNDP) 2022 Human

Development Index, with a score of 0.875. In 2020, the Gender Development Index (GDI) has a value of 0.918; in 2021, it is still almost unchanged at 0.917 (UNDP, 2022). With a score of 0.64 in the 2022 Global Gender Gap Index and 0.247 in the 2021 Gender Inequality Index, KSA demonstrated notable progress over the previous ten years. This improvement reflects women's greater access to healthcare and education, as well as their increased involvement in the workforce and public life (UNDP, 2022). According to Alsheddi (2020), socio-cultural dynamics in KSA are conditioned by factors that are challenging for the pharmaceutical industry. In general, KSA societal-cultural values lend toward re-adhering to tribalism, acknowledging hierarchy or a higher authority, seeking prestige, and maintaining conservative practices.

Risk and Challenges – Socio-Cultural. These are the risk and challenges involved under socio-cultural factors:

High Level of Cultural and Religious Belief. In the opinion of Alsheddi (2020), social-cultural factors greatly influence choice of medication acceptance and involvement in pharmaceutical business. It has also been noted that the Islamic faith has a major influence on KSA society due to its definition of social customs, obligations, and economic practices (Algahtani, 2022).

Lacks Capacities Necessary to Maintain the Reform Program. Algahtani (2022) also noted that KSA lacks the capacities necessary to maintain reform programs, requiring the kingdom to currently import a significant number of foreign experts to handle administrative and industrial projects.

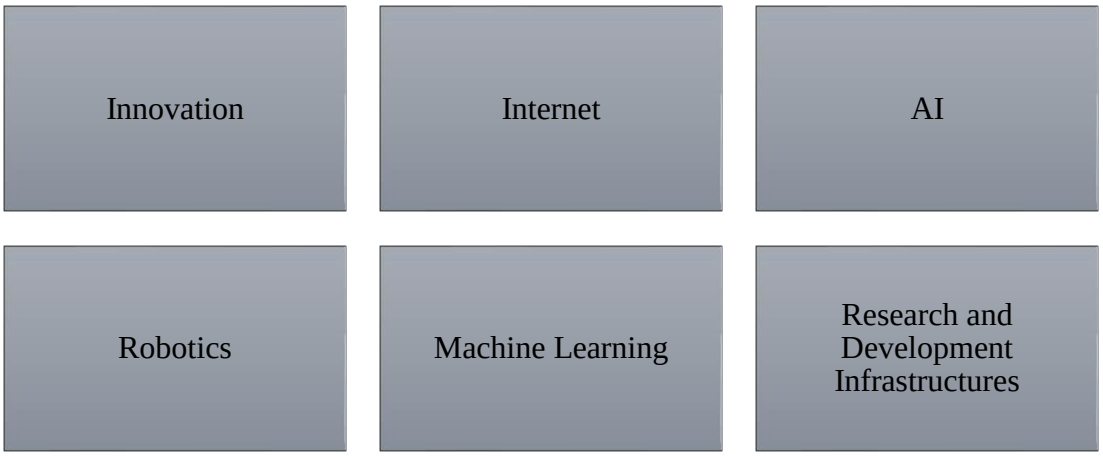
Unemployment Rate. According to Alanzy (2021), the KSA unemployment rate stands at about 5.1 percent, which seems to be tolerable; however, a closer examination indicates a concerning mismatch between the workforce's abilities and the demands of the job market. Presently, over 60 percent of KSA's higher education students are enrolled in courses that do not prepare them for jobs that are in great demand. Furthermore, it has been emphasized that the industries that are most important to Vision 2030's long-term success are those that are likely to provide the most employment possibilities, including manufacturing, information and communication, wholesale and retail, transportation and storage, and finance and insurance. In this regard, Alanezi, Darwish, Singh, and Miroux (2020) stated that to meet and realize the objectives of KSA Vision 2030, the government has initiated "The Human Capability Investment Initiative (HCI)," a strategic program aimed at enhancing the skills and capabilities of KSA's workforce to align with the demands of a knowledge-based economy in meeting the primary goal of HCI, which is to foster the development of a highly skilled and adaptable workforce capable of driving innovation, productivity, and sustainable economic growth.

Technological Factors. Improvements in biotechnology and research have made it possible to produce high-quality drugs at lower production costs, making it possible for more people to access medications that were previously not possible (Yousif 2022). Impact of innovation infrastructure on business and industry in general is the main emphasis of technological factors (Galea & Sammut-Bonnici, 2015). Technology is a major consideration when assessing the possibility of establishing a vaccine manufacturing organization in an emerging economy such as KSA. In terms of the KSA pharmaceutical industry, technological factors include

the internet, artificial intelligence, machine learning, robotics, infrastructures for research and development (R&D), and the presence or absence of these impact businesses (Galea & Sammut-Bonnici, 2015).

Figure 2.17

PESTEL Factors – Technological



Note. PESTEL – Technological Analysis developed by the Researcher.

According to KSA Vision (2030), the country is taking concrete steps to achieve its goals to become a leading regional hub of AI in the coming years. These concrete steps in terms of technological infrastructure include the following:

- Establishment of Smart Cities with intelligent solutions to improve urban services, enhance sustainability, and create an innovative urban environment.
- Setting up Regional AI Center in Riyadh to attract global companies and provide a supportive environment for startups and innovation.

- Launching financing and support programs for AI startups such as grants, loans, incubation, and acceleration programs.
- Development of a regulatory environment that is supportive of AI and encourages investment in the field and protects users' rights.
- Investment fund worth US$40 Billion dedicated to investing in AI technology and related technologies necessary to power the Artificial Intelligence revolution such as semiconductor chips and data centers (KSAVision 2030, p.3).

According to Alkofahjobs and the KSA strategy is aimed at attracting foreign investments worth US$ 21.33 billion in the field of AI, establishing 400 AI startups, creating 25,000 new jobs, and transforming the Kingdom into a regional center for artificial intelligence by 2030 with a critical focus on healthcare, energy, transportation, and manufacturing sectors.

In the pharmaceutical industry, KSA has made significant advancements, leveraging technology, partnerships, and investment to drive growth and enhance its presence in the global market. Alghaith et al. (2020) point out that the pharmaceutical sector is the largest in the Middle East in terms of investment size. It encompasses around 30 percent of the region's total value. Furthermore, KSA has 40 local factories in the pharmaceutical sector, covering 29 percent of the country's needs with revenue exceeding SR1.5 billion ($399 million). According to Alshehri et al. (2023), the pharmaceutical market in KSA is projected to reach SR56.6 billion in 2027, with a compound annual growth rate of 5.2 percent, stated Fitch Solutions, the research arm of US-based Fitch Ratings. To boost the local biopharmaceutical

industry, concrete plans have been laid for manufacturing essential pharmaceutical products such as insulins, vaccines, plasma therapeutics, monoclonal antibodies, cell and gene therapies, and innovative small molecules.

Additionally, the Kingdom is investing in infrastructure and facilities to strengthen the pharmaceutical industry. Another important improvement is the move by "The Saudi Authority for Industrial Cities and Technology Zones (MODON), which has signed investment agreements to establish joint venture factories for vaccine manufacturing and research. Vaccine Industrial Company will establish a factory in Sadeer City to localize vaccine manufacturing and strengthen the pharmaceutical security system. Furthermore, the Public Investment Fund (PIF), Saudi Arabia's global investment organization, announced on June 18, 2023, that it has launched LIFERA, a commercial-scale contract development and manufacturing organization (CDMO). The CDMO will enable growth of the local bio/pharmaceutical industry, strengthen national resilience, and support Saudi Arabia's position as a global pharmaceutical manufacturing destination (Othman & Albuainain, 2022). In the digital transformation of the pharmaceutical sector, Google Cloud has partnered with Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO) for a significant SAP ERP workload migration project. This project will enable SPIMACO to accelerate its digital transformation, support regulatory requirements, and position itself for future growth.

Risk and Challenges – Technological. These are the risk and challenges involved under technological factors:

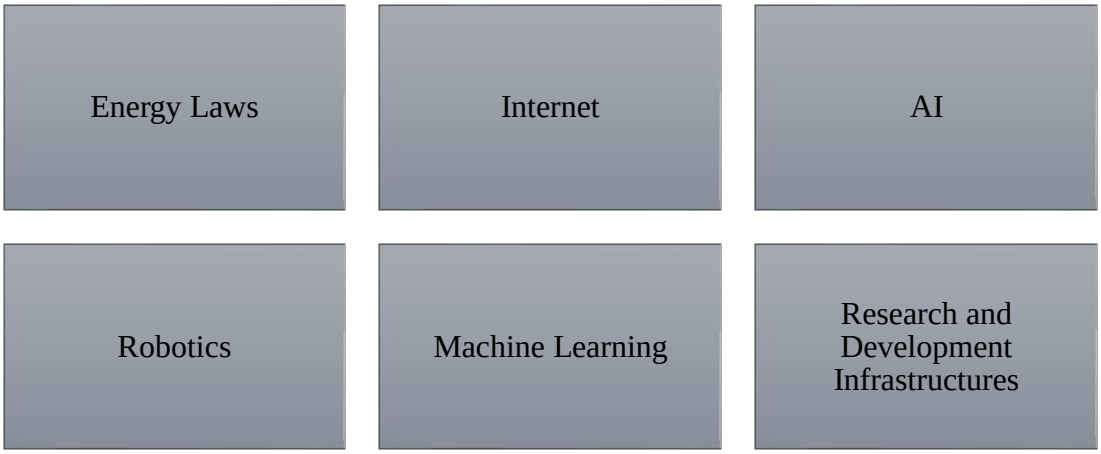
Weak R&D Regulations. Yasuda and Kotabe (2021) point out that some notable business risks include weakness in regulations related to R&D that reduce potential investments and instability in implementing R&D initiatives.

Lack of adequate skills and expertise. Alrasheedy (2020) emphasized the lack of adequate skills and expertise within the population as the KSA is heavily dependent on foreign expats. In general, the KSA government has implemented a number of initiatives that aim to significantly advance the pharmaceutical industry, including digital transformation, localization of manufacturing, infrastructure investment, and technological collaborations. These initiatives are aimed at supporting the manufacturing industry's expansion and advancement on a national and worldwide scale (Alshehri et al., 2023).

Environmental Factors. As the business community realizes that changes to the physical environment might create material threats as well as possibilities for business, environmental considerations have become a logical addition to the original PEST framework. Examples of environmental factors include laws governing energy use, waste disposal, environmental protection, carbon footprint, public perceptions of the environment, and the effects of climate change (Alhawassi et al., 2018; Al-Rubaie et al., 2015).

Figure 2.18

PESTEL Factors – Environmental



Note. PESTEL – Environmental Analysis developed by the Researcher.

KSA Vision 2030 identified the pharmaceutical and biotechnology cluster as a priority area for investment and growth, and the National Industrial Development and Logistics Program (NIDLP) lays out an explicit strategy for development of the biopharmaceutical industry in KSA (KSA Vision 2030, p. 4).

As part of the national transformation program, enhancing the RDI is aimed at improving the quality of pharmaceutical production and local competition between different industrial sectors.

KSA has implemented plans for the collaboration of the national research centers, such as King Abdulaziz City for Science and Technology (KACST), King Abdullah University of Science & Technology (KAUST), the R&D enterprises, such as Saudi Basic Industries (SABIC), and the research centers in universities, which

are all involved. In the development stage, the technology transfer facilitators, such as KACST, KAUST, incubators, and accelerators, such as Badir, and Technical Park, such as Wadi Makkah, are playing major roles in developing and improving outcomes of research into a potential product 'prototype' (Mohamed et al., 2022).

KSA has implemented technologies for the good manufacturing practice of protein and cell-based vaccines with level 2 biosafety capabilities, which are in progress.

Risk and Challenges – Environmental. These are the risk and challenges involved under environmental factors:

Increase in Innovation. The pharmaceutical industry needs to increase its innovation capabilities as national industries, including pharmaceutical and biopharmaceutical, still suffer from a lack of effective strategies to achieve the goals of a successful RDI system. There is still a lack of awareness of an RDI system's importance and the absence of a long-term effective plan, as stated by Mohamed et al. (2022).

Delayed Expenditure. Issues of delayed expenditure by the authorities, extended registration and procurement procedures, weak knowledge and experience on drug discovery and development, and lack of R&D for new drugs are major challenges that might face the drug producers in Saudi Arabia (Alruthia et al., 2018, Alrasheedy, 2020).

High Operation and Production Expense. The impact of COVID-19 has led to the rise of other challenges, such as the high operating and production expenses, high labor rate, high import rate, funding, and financial limitation (NIDLP, 2018).

Technical Infrastructure. Lack of infrastructure, efficiently skilled, and technically knowledgeable personnel (Alzahrani & Harris, 2021; Alrasheedy, 2020).

Overall, KSA has made significant progress in the pharmaceutical manufacturing sector, and the plans outlined in Vision 2030 are progressing efficiently (Alzahrani & Harris, 2021).

Legal Factors. Legal factors include product regulations, copyright laws, competitive regulations, antitrust laws, import and export regulations, and health and safety regulations (Pereira 2023).

Figure 2.19

PESTEL Factors – Legal

Note. PESTEL – Legal Analysis developed by the Researcher.

KSA Vision (2030) includes significant focus on the pharmaceutical industry, and this has led to the establishment of various legal and regulatory frameworks for pharmaceutical manufacturing, which includes:

i. The Establishment of a Regulatory Body (SFDA) - Saudi Food and Drug Authority (SFDA) was established in March 2003. The body under the Royal Decree No. M/6 of 25/1/1428 H (13/2/2007 G), is tasked with licensing pharmaceutical products and manufacturing facilities (Issa, Al-Ammar, & Mostafa, 2009).

ii. Regulatory Flexibility - In the event of the COVID-19 pandemic, KSA implemented regulations regarding flexibility in manufacturing and distribution of pharmaceutical products to expedite the production and supply of COVID-19 vaccines and therapeutics. This includes regulatory flexibility in manufacturing site inspections, labeling requirements, and distribution protocols to ensure timely access to medical products while maintaining quality and safety standards (IFPMA, 2021).

iii. Improvement in Transparency International Corruption Index - In the Transparency International Corruption Index, KSA ranks 52 out of 180 countries, which is among the better rankings in the region. The World Bank's Governance Indicators (WBGI) (2023), which include various measurements of institutions and the regulatory environment, place the country above the average for the region in terms of regulations and corruption.

Risk and Challenges – Legal. These are the risk and challenges involved under legal factors:

Weak Regulatory Implementation. There are weaknesses primarily in the enforcement of court judgments and management of insolvency, mainly because a legal process takes a long time, and the outcome is uncertain (WBGI, 2023).

Bureaucracy and a Lack of Transparency. Bureaucracy and a lack of transparency in the legal system pose a risk to foreign companies. According to the WBGI (2023), the quality of the regulatory environment is just above average. In general, legal factors rating are significant and show the potential success of the pharmaceutical sector. Hence, the manufacturing sector does not face any imminent threat, although the lack of native R&D in this area limits the ability to manufacture new drugs locally.

Summary of Literature Review and Gap in Literature

This section presents a summary of the literature review and gaps in literature based on the research problem and objective.

Decision-makers, donors, and investors in KSA lack factual data on the local impediments to vaccine manufacturing (Tawfik et al., 2022, p. 1; Alzahrani & Harris, 2021, p. 12). Thus, it is believed that to make difficult business decisions, further research into the complexities and aspects associated with vaccine manufacturing is necessary (Saudi Industrial Development Fund, 2020, p. 21; Tawfik et al., 2022, p. 1).

By definition, a vaccine is a live pathogen that has been killed or weakened, or it can be a pathogen component (such as protein or nucleic acid) that, when given to a human or animal, causes the immune system's cells to mount a defense (Burdin, Handy, & Plotkin, 2017).

According to Plotkin et al. (2017), it is difficult to overstate the effect that vaccinations have on global health. No other technique has had such a significant impact on population growth and mortality reduction apart from safe water.

Although vaccinations have generally been quite effective in controlling infectious diseases, some still require improvement. For instance, the previous pertussis vaccination was effective in controlling illness; however, it had a major negative impact on children.

Currently, worldwide vaccination campaigns are in place to safeguard most of humanity, and as new forms of diseases that cause illness continue to emerge, vaccine manufacturing has become paramount to healthcare sustainability, which impacts the general economic development of a nation (Mustapha & Harrison 2018). Studies have indicated impediments to vaccine manufacturing around the world, and as summarized in the table below, some of these studies are mentioned in light of research problems.

Table 2.10

Summary of Major Literature Review

Author(s)	Research title	Findings	Gap Identified
Tawfik, E. A., Tawfik, A. F., Alajmi, A. M., Badr, M. Y., Al-Jedai, A., Almozain, N. H., ... & Almalik, A. M. (2021)	Localizing pharmaceuticals manufacturing and its impact on drug security in Saudi Arabia. *Saudi Pharmaceutical Journal*.	The authors here in this journal have aimed to show the importance of localizing pharmaceuticals manufacturing that also includes the vaccine manufacturing and its importance. In addition to this, it has discussed the national health system of Saudi Arabia, the R&D department for pharmaceutical manufacturing companies, international supply chains, lack of government initiatives, lack of manpower or professional human resource and many others. This paper has critically drawn reviews of various other literature that is based on current pharmaceutical production systems that are maintained or operated in Saudi Arabia. Apart from this, it has also discussed both major challenges and possible solutions for Saudi Arabia in	Here, from this research paper there is no significant literature gap that has not been found. However, this research has not been able to discuss the overall context that is outlined in this research paper. Therefore, it can be stated that due to shortage of time and the limitations of words have been considered as the major barriers while reviewing or resourcing the important information and data from this journal (Durdyev, 2021). Apart from that, the journal has highlighted the local pharmaceutical manufacturing companies and has addressed less about the vaccine manufacturing in Saudi Arabia. It has neither discussed the previous or current situation of vaccination implication strategy of Saudi Arabia and about the future possibilities of opportunities that can impact localization.

		term of producing vaccine manufacturing companies in local areas.	
Hollis (2019)	Research and development initiates for vaccine manufacturing	The author emphasized on pharmaceutical organization spending on research and development (R&D) is influenced by multiple factors, which are controlled by the expected revenues, expenses, and policies that are required to produce and market vaccines and other drugs	Concentrated only on R&D, and revenue generation
Patil and Shreffler (2019, p. 20)	Novel vaccines: Technology and Development	The development and widespread use of vaccines, defined by the World Health Organization (WHO) as, “biological preparations that improve immunity to a particular disease,” represents one of the most significant strides in medicine. Vaccination was first applied to reduce mortality and morbidity from infectious diseases. The WHO estimates that vaccines prevent 2–3 million human deaths annually, and these numbers would rise	Lack of factors that impede vaccine manufacturing

		by at least 6 million if all children received the recommended vaccination schedule. vaccine technology has been applied beyond the prevention of infection, including in the treatment of cancer and allergic diseases. Elaborated more rational approaches to vaccine development utilize novel biotechnology, target new mechanisms, and shape the immune system response with an emphasis on discoveries that have direct translational relevance to the treatment of allergic diseases.	
Alaamri, O., Okmi, E. A., & Suliman, Y. (2022).	Vaccine hesitancy in Saudi Arabia: A cross-sectional study. *Tropical Medicine and Infectious Disease*, *7*(4), 60.	The authors in this particular literature paper have stated about the vaccination hesitancy seen in Saudi Arabia. Furthermore, the authors have also aimed to state about the major causes and problem's magnitude that can lead to the public's health risk from the vaccine preventable diseases. Furthermore, it is found that this research has more descriptive	The major gap identified in this paper has critically focused on whether the vaccination hesitancy is higher or lower. The author has not discussed the other factors that create issues or any other problems during establishment of vaccine manufacturing in local areas of Saudi Arabia. According to Jaakkola (2020), literature gap in research defines the area that researchers or authors may not have

		observational study rather than being rational and logical. Both qualitative and quantitative methods have been chosen in this study that has brought a conclusion that vaccine hesitancy is comparatively low in Saudi Arabia. Additionally, it is also found that the vaccine decision making in Saudi Arabia is complex that has included such as emotional, cultural, spiritual, social, and political aspects.	discussed although it is essential to highlight. Furthermore, one of the major gaps is that it is assumed in this paper that it has used both mixed method primary quantitative and secondary qualitative. Therefore, it creates confusion to rely on quantitative results or qualitative results.
Boschiero, N. (2021).	COVID-19 vaccines as global common goods: An integrated approach of ethical, economic policy and intellectual property management. *Global Jurist*, *22*(2), 177-230.	The authors of this particular literature review have confronted the recent debate over the COVID-19 vaccines as a global public good. The paper has introduced a brief information about both global epidemiological and economic implications of the pandemic. In addition to this, this paper has various relatable and relevant theories that include economic theories. It has discussed various aspects of vaccines when seen as global common goods such as academics, policy makers, access to health products including medications, vaccines, health &	One of the major literature gaps that has been identified is that this particular article has critically discussed about COVID-19 vaccines as global common goods. It has not mentioned about the vaccination's requirements or the challenges vaccine manufacturing faces by Saudi Arabia. It has been stated that discussing random things instead of being specific or limited within the current study may distract the researcher from acquiring the actual outcome or results (Al Doghan et al. 2019). Furthermore, the factors that have been discussed in this article such as

biomedical technologies, availability of medical services and many others. In short, the paper has discussed the covid -19 vaccines policies, process and initial stages that are followed by countries in global context.

academics, policy makers, access to health products including medications, vaccines, health & biomedical technologies, availability of medical services are also based on the global point of view.

Evans, W. D., & French, J. (2021)	Demand creation for COVID-19 vaccination: overcoming vaccine hesitancy through social marketing. *Vaccines*, *9*(4), 319.	In this particular research paper, authors have put their critical focus on the demand creation during COVID-19 vaccines has produced. Furthermore, the research paper has discussed overcoming vaccine hesitancy through social marketing. It has shared information about the process of demand creation of approved vaccines after two years the virus has burst throughout the country. In addition to this, the study has further reviewed various theories, evidence, and practice recommendations that have been actively resistant to COVID-19 vaccination. Furthermore, the authors have discussed other key elements that have impacted on the demand creation for COVID-19 vaccinations, such as supply chain, supply side confidence, health communication, social marketing, and others.	Here, for this particular research paper, the major literature gap that has been found is that this has focused on the demand for COVID-19 vaccination in a global context. Furthermore, both of the authors have discussed the different country's policies, processes and other strategies adopted for overcoming the obstacles such as vaccine hesitancy. As per the view of Hernandez et al. (2021), it has been stated that vaccination hesitancy has been overcome using social media or social media marketing. This study has highlighted the major factors only that are associated with the social media impact to overcome the vaccine hesitancy.

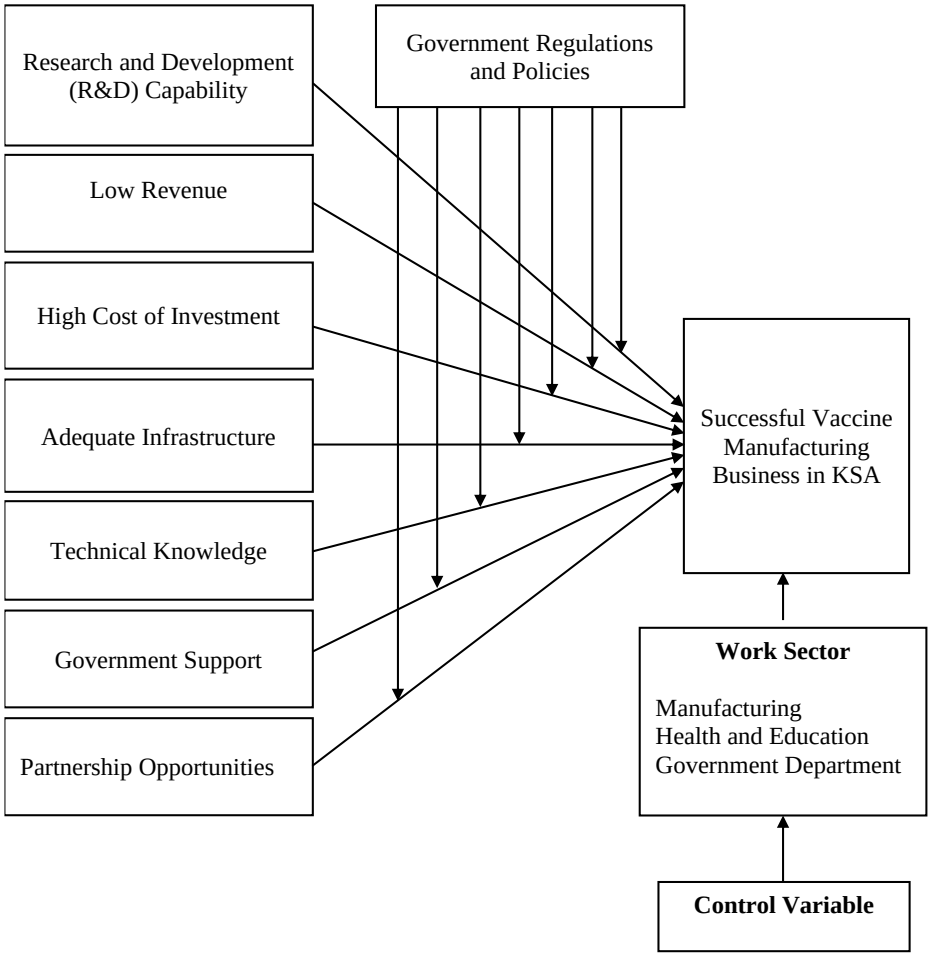
Ahmed et al. (2020)		The author emphasized that to meet the future demand of the upcoming generation, it is essential for KSA to develop local vaccine manufacturing factories which can do done through the Contract Development and Manufacturing Organization model (CDMO). Authors recommended CDMO model as a means for both government and private sector local manufacturer to develop and manufacture most needed vaccines.	Focused only means through which local manufacturer can acquire technology transfer skill and materials
Sharma et al. (2020); Pronker et al. (2013)	A Review of the Progress and Challenges of Developing a Vaccine for COVID-19	Vaccine manufacturing constitutes an elaborate process that takes 10 to 15 years to complete, thus adequate funding must be provided by reputable government, donors, and investors to offset vaccine manufacturing expenditure.	Focused only on vaccine investment

Conceptual Framework

Based on the factors identified in the literature review, the following conceptual framework is proposed. The framework indicates that the independent variables have the potential to impede local vaccine manufacturing in KSA.

Figure 2.20

Conceptual Framework



Note. Developed by the Researcher (2023).

The independent variables and the dependent variables are as follows:

Independent Variables:

- Research and development (R&D) capability (Makenga et al., 2019; Plotkin et al., 2017; Kumraj et al., 2022; Black et al., 2020; Altman et al., 2023; Walkinshaw et al., 2023; Chandra et al., 2023).
- Low revenue (Sharma et al., 2020; Pronker et al., 2013; Gouglas et al., 2018; Emami & Klein, 2020; Alruthia et al., 2018).
- High cost of investment in process development technology (Ramli et al., 2022; Popoola et al., 2022; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).

  Adequate infrastructure (research labs/supply chain) (Tirole, 2018; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).
- Technical knowledge (Minssen & Price, 2021; Alzahrani & Harris, 2021; Ahmad et al., 2021; Johari et al., 2021; Jerving & Ravelo, 2022; Plotkin et al., 2017; Sharpe et al., 2020; Alzahrani & Harris, 2021; Badreldin & Atallah, 2021; Badreldin & Atallah, 2021; Tinworth & Young, 2020; Mihigo et al., 2019).
- Government support (Assiri et al., 2021; Alzahrani & Harris, 2021; Gaulé & Kaddar, 2007; Aldossari et al., 2021; Raja & Alshamsan, 2020).
- Limited Partnership opportunities (Hayman, Suri, & Downham, 2022; Alzahrani & Harris, 2021; Rappuoli, Black, & Bloom, 2019; Cohen, 2020).

Dependent Variable:

- Successful vaccine manufacturing business in KSA (Shuman et al., 2020; Badreldin & Atallah, 2021; Portnoy et al., 2023; Arif et al., 2023; Surya et al., 2019).

Moderating Variable:

- Government Regulations and Policies (Mueller, Altenburger, & Mohl, 2018; Gomez et al., 2013; Kis et al., 2019; Cid & Bolivar, 2021; Vidor & Soubeyrand, 2016; Alrasheedy et al., 2017; Raja & Alshamsan, 2020; Assiri et al., 2021).

Control Variable:

- Work Sector (Nguyen & Schwalbe, 2019, Pagliusi, 2013; Tawfik et al., 2022; Alzahrani & Harris, 2021; Tawfik et al., 2022).

Hypothesis Statements

Based on the above Conceptual Framework, figure (2.12), the following Hypothesis Statements are stated:

Hypothesis one:

Null Hypothesis ($H1_o$): Lack of research and development capability does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H1_A$): Lack of research and development capability significantly impede vaccine manufacturing business in KSA.

Hypothesis two:

Null Hypothesis ($H2_o$): Low revenue does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H2_A$): Low revenue significantly impede vaccine manufacturing business in KSA.

Hypothesis three:

Null Hypothesis ($H3_o$): High cost of investment does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H3_A$): High cost of investment significantly impede vaccine manufacturing business in KSA.

Hypothesis four:

Null Hypothesis ($H4_o$): Lack of adequate infrastructure does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H4_A$): Lack of adequate infrastructure significantly impede vaccine manufacturing business in KSA.

Hypothesis five:

Null Hypothesis ($H5_o$): Lack of technical knowledge does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H5_A$): Lack of technical knowledge significantly impede vaccine manufacturing business in KSA.

Hypothesis six:

Null Hypothesis ($H6_o$): Lack of government support does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H6_A$): Lack of government support significantly impede vaccine manufacturing business in KSA.

Hypothesis seven:

Null Hypothesis ($H7_o$): Lack of partnership opportunities does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H7_A$): Lack of partnership opportunities significantly impede vaccine manufacturing business in KSA.

Hypothesis eight

Null Hypothesis ($H8_o$): Government regulation and policies does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H8_A$): Government regulation and policies significantly impede vaccine manufacturing business in KSA.

Hypothesis nine:

Null Hypothesis ($H9_o$): Government regulation and policies does not moderate the relationship between lack research and development capability and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H9_A$): Government regulation and policies moderates the relationship between lack research and development capability and vaccine manufacturing business in KSA.

Hypothesis ten:

Null Hypothesis ($H10_o$): Government regulation and policies does not moderate the relationship between low revenue and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H10_A$): Government regulation and policies moderates the relationship between low revenue and vaccine manufacturing business in KSA.

Hypothesis eleven

Null Hypothesis ($H11_o$): Government regulation and policies does not moderate the relationship between high cost of investment and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H11_A$): Government regulation and policies moderates the relationship between high cost of investment and vaccine manufacturing business in KSA.

Hypothesis twelve:

Null Hypothesis ($H12_o$): Government regulation and policies does not moderate the relationship between lack of adequate infrastructure and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H12_A$): Government regulation and policies moderates the relationship between lack of adequate infrastructure and vaccine manufacturing business in KSA.

Hypothesis thirteen:

Null Hypothesis ($H13_o$): Government regulation and policies does not moderate the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H13_A$): Government regulation and policies moderates the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.

Hypothesis fourteen:

Null Hypothesis ($H14_o$): Government regulation and policies does not moderate the relationship between lack of government support and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H14_A$): Government regulation and policies moderates the relationship between lack of government support and vaccine manufacturing business in KSA.

Hypothesis fifteen:

Null Hypothesis ($H15_o$): Government regulation and policies does not moderate the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H15_A$): Government regulation and policies moderates the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA.

Hypothesis sixteen:

Null Hypothesis ($H16_o$): There are no significant difference in perception of respondents across work sector regarding vaccines manufacturing business in KSA.

Alternative Hypothesis ($H16_A$): There are significant difference in perception of respondents across work sector regarding vaccines manufacturing business in KSA.

Summary of the Chapter

The chapter presented extant literature relating to vaccine manufacturing as well as challenges faced by vaccine manufacturing.

The main objective of this research is to investigate the factors that impede a successful vaccine manufacturing business in KSA. Furthermore, theories such as Resource-Based View Theory (RBV) and Knowledge-Based View Theory (KBV) have been used to underpin the importance of identifying strategic resources that an organization needs to sustain growth and productivity. Similarly, knowledge assets are also important in gaining a competitive advantage that addresses better performance and efficiency in productivity in terms of long-term competitive advantage on vaccine manufacturing.

Various studies elaborated on factors such as research and development (R&D) capability, low revenue, high cost of investment in process development technology, adequate infrastructure (research labs/supply chain), technical knowledge, government support, limited partnership opportunities, government laws, regulations, and policies as factors that impede local vaccine manufacturing. These factors have been used to propose and formulate the conceptual framework and subsequently used to state the hypothesis statements.

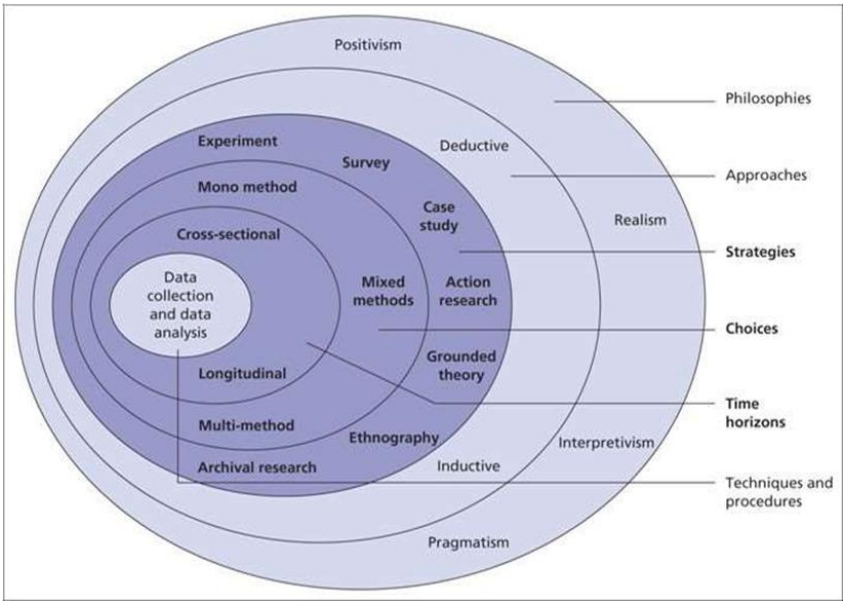
Chapter Three: Methods and Procedures

Introduction to the Chapter

This chapter presents methods and procedures employed to facilitate data collection and analysis. The research onion process by Saunders, Lewis, and Thornhill (2016, p. 121) (Figure 3.1) was utilized to guide the various procedures to gather data and achieve the research objectives. Methods and procedures discussed in this chapter include the philosophical stance, research design, research methods, research strategy, research target population and sample size, development of the research instrument utilized in gathering appropriate data, methods of statistical analysis of the data gathered, and ethical research statement.

Figure 3.1

Research Onion



Note. Adapted from Saunders, Lewis & Thornhill, 2016, p. 121.

Research Philosophy

Research philosophy as a researcher thinking about the development of knowledge. However, there are four types of research philosophy based on researchers' views about the research process: positivism, interpretivism, realism, and pragmatism. Whereas Collis and Hussey (2013, p. 46) classified the research paradigms into two types: the positivistic paradigm and the phenomenological (or interpretivist) paradigm. More specifically, paradigm refers to "the progress of scientific practice based on people's philosophies and assumptions about the world and the nature of knowledge." In other words, people's beliefs about the world will impact research design and the procedures of research (Saunders, Lewis, Thornhill, & Bristow, 2019, p. 121).

Interpretivism Research Philosophy

The interpretivism research philosophy involves understanding the facts as they are from the subjective experiences of individuals. In this philosophy, the inductive research approach is adopted. The inductive approach leads to the emergence of generalizations and new theories (Creswell, 2015).

Positivism Research Philosophy

Positivism research philosophy reflects that quantitative methods are the most suitable way of research. Thus, this involves a conviction that legitimate learning must be delivered based on direct perception by the faculties, and this would incorporate the capacity to quantify and record what might be viewed as information. Positivism research philosophy follows the deductive approach, which

is mainly used to assess an assumption's validity of a theory or hypothesis (Creswell, 2015).

Realism Research Philosophy

Realism is another research philosophy that relates to scientific inquiry. The realist philosophy is based on the belief that reality exists in the world, and this reality is independent of human thoughts and beliefs and is opposed to idealism due to the existence of reality being independent (Saunders, Lewis, Thornhill, & Bristow, 2019). Realism is a type of epistemology, and therefore it is similar to positivism that assumes a scientific approach to develop knowledge. However, there are two types of realism, namely direct realism, what we see is what we get', and the researchers see the real world accurately; and critical realism, what we see is not what we got' researchers see the world as sensations, not the real things directly, that requires more criticism in the reality (Saunders, Lewis, Thornhill, & Bristow, 2019, pp. 114-115).

Pragmatism Research Philosophy

Pragmatism declares that reality exists in the world, and it supports the objective nature of science. This philosophy assumes that individuality may impact how people perceive the world, and therefore research is subjective. This view of this philosophy brings multiple explanations and interpretations for science. This philosophy uses both objective and subjective criteria (Saunders, Lewis, Thornhill, & Bristow, 2019). Hence, the pragmatist philosophy is between positivist and interpretivist research philosophy; it refers to there is no one appropriate philosophy and therefore researchers can adopt more than one research philosophy. Pragmatism

argues that it is possible to work with variations in epistemology (Saunders, Lewis, Thornhill, & Bristow, 2019). According to Creswell's (2057) classification, he refers to that positivistic paradigm as a quantitative paradigm and the phenomenological paradigm as a qualitative paradigm. Whereas Collis and Hussey (2013) summarized the main features of the positivistic paradigm, and the phenomenological paradigm related to research methodology and method.

Selection of Research Philosophy

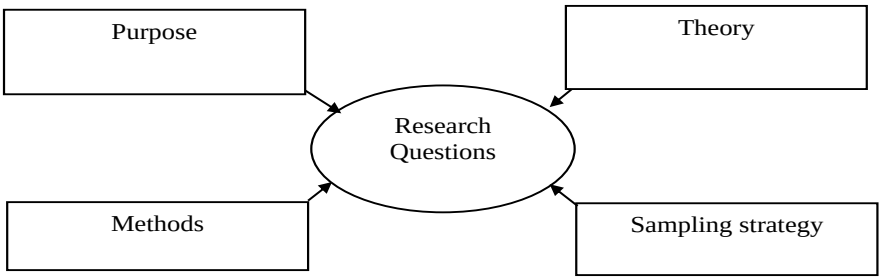
The main objective of this research is to investigate factors that impede successful vaccine manufacturing businesses in KSA for the enhancement and sustainability of the healthcare sector. Therefore, objectivity was highly considered in the process of data gathering. Hence, data was gathered quantitatively through a survey questionnaire.

Research Design

Research design is a crucial part of any research as it is concerned with turning research questions into projects. Research design is important in deciding the research processes and elements such as research methods, research strategy, and sampling (Creswell, 2015). Figure (3.2) displays the components of research design.

Figure 3.2

Components of Research Design



Note. Adapted from Robson, 2002, p. 82.

The choice of research design depends on the purpose(s) of research, and hence there are three types of research design that are normally considered: exploratory study, descriptive study, and explanatory study (Saunders, Lewis, Thornhill, & Bristow, 2019).

Exploratory Design

This type of study focuses on investigating what is happening, asking questions, seeking new insights, assessing phenomena in a new light, as well as generating ideas and hypotheses for future research. An exploratory study is characterized as flexible design (Saunders, Lewis, Thornhill, & Bristow, 2019). An exploratory study is conducted when there is no information available or little information is known about how similar research has been conducted in the past. Therefore, exploratory study provides a better understanding of the nature of the

problem being researched since very few studies have been conducted in the same area (Sekaran & Bougie, 2019). This study is useful for clarifying and understanding an imprecise problem; it can be conducted based on three main ways: a search of the literature, interviewing experts, and conducting focus group interviews (Saunders, Lewis, Thornhill, & Bristow, 2019).

Descriptive Design

This study displays an accurate profile of persons, situations, or events. This type requires collecting a lot of information about the situation that will be studied. The descriptive study may be flexible and/or fixed design (Robson, 2002). A descriptive study is conducted in order to determine and describe the characteristics of the variables in the situation. Therefore, the descriptive study aims to provide researchers with a profile or describe aspects of the phenomena being researched at different levels, such as individual, organizational, industry-oriented, and other perspectives (Sekaran & Bougie, 2019). This study is considered a piece of, or a forerunner to, exploratory research, and therefore it is necessary to have a clear picture of phenomena before conducting exploratory study (Saunders, Lewis, Thornhill, & Bristow, 2019).

Explanatory Design

This study seeks an explanation of a situation or problem being studied that is not necessary to be in a causal relationship and an explanation of patterns relating to the studied phenomenon. This study may be flexible and/or fixed design (Robson, 2002). An explanatory study investigates the relationship between variables of a phenomenon in order to establish a causal relationship between variables (Saunders,

Lewis, Thornhill, & Bristow, 2019). Other authors called this type of study hypothesis testing. Hypotheses testing is usually conducted to explain the nature of the specific relationships or indicate the difference among groups of independent variables, as well as explain the variance in the dependent variables or to predict outcomes (Sekaran & Bougie, 2019).

Selection of Research Design

Based on the main objective of this research, which is to investigate factors that impede successful vaccine manufacturing business in KSA for the enhancement and sustainability of the healthcare sector. Therefore, a descriptive/explanatory research design is appropriate for obtaining an accurate description of persons, situations, or events in pharmaceutical manufacturing related particularly to vaccine manufacturing. Generally, explanatory research design is appropriate as it facilitates designing a research process suitable for quantitative data gathering in order to establish a causal relationship between variables.

Research Methods

Various research methods are employed during the conduct of research. Methods include qualitative method, quantitative method, mixed method, and case study method. Qualitative research methods focus on the way through which data is gathered to answer the research questions. Hence, the qualitative method is based on methods such as interviews, focus groups, observation, etc. In this method, the researcher interprets the analysis and interprets the results based on a subjective approach (Berger, 2018).

Qualitative Research Method

The qualitative method of data gathering follows the inductive approach, wherein the researcher constructs concepts and gathers data to develop explanations and theories. Quantitative and qualitative research methods will be utilized in gathering relevant data to answer the research questions and realize the objectives of this research (Berger, 2018).

As emphasized by Briggs and Coleman (2019), the qualitative research method facilitates gaining insight into a research problem by providing a rich and detailed nature through subjective interpretation. However, it is limited by a lack of clear differentiation between the research viewpoints and beliefs from the respondent's standpoint as their exit biases. The results of qualitative methods are more descriptive, and the inferences can be drawn quite easily from the data that is obtained.

According to Creswell (2015), commonly used qualitative research methods include: (1) one-on-one interviews: Conducting in-depth interviews is one of the most common qualitative research methods. It is a personal interview that is carried out with one respondent at a time. This is purely a conversational method and invites opportunities to get details in depth from the respondent. One of the advantages of this method is that it provides a great opportunity to gather precise data about what people believe and what their motivations are. If the researcher is well experienced in asking the right questions, the researcher can collect meaningful data. If more information is needed, the researchers should ask such follow-up questions that will help them collect more information. These interviews can be

performed face-to-face or on the phone. When an in-depth interview is conducted face-to-face it gives a better opportunity to read the body language of the respondents and match the responses. (2) Focus group: A focus group is also one of the commonly used qualitative research methods used in data collection. A focus group usually includes a limited number of respondents within your target population. The main aim of the focus group is to find answers to the why, what, and how questions. One advantage of focus groups is that the researcher does not necessarily need to interact with the group in person. Focus groups are an expensive method as compared to the other qualitative research methods. Typically, it is used to explain complex processes.

Quantitative Research Method

The quantitative research method follows the deductive research approach for data collection. Statistical findings are interpreted to develop general inferences about the data gathered. In quantitative design, the researcher's beliefs and perceptions are not incorporated. Quantitative study designs are specific, well structured, and can be explicitly defined and recognized (Creswell & Clark, 2007, p. 5).

Common types of data under quantitative research design include surveys, questionnaires, and observations (Green & Thorogood, 2018). The quantitative method facilitates gathering numerical data, which can be analyzed using appropriate statistical tools. It is also suitable when a large population is considered for broader application and generalization of findings (Creswell, 2015; Berger, 2018). Furthermore, quantitative methodology has advantages over qualitative methods as

participant answers do not impact or determine how and which questions researchers should ask. Similarly, the use of highly structured methods such as questionnaires and surveys facilitate objectivity in data gathering (Crewell, 2015).

Generally, in business management studies, utilizing quantitative design through the use of surveys is normally employed. However, Green and Thorogood (2018) pointed out that the main disadvantage of the quantitative method is that it is time-consuming with regards to data collection and requires a substantial budget.

Mixed Research Method

According to Sekaran and Bougie (2019), mixed research methods utilized the advantages of qualitative research methods and quantitative research methods to solve research problems by using various methods in gathering data for the study. The combination of qualitative research method and quantitative research method gives a mixed research method added advantages. Mixed methods focus on bridging the gap between both qualitative and quantitative research methods to address a research problem in a comprehensive manner. In mixed research methods, the research utilizes multi-stages of data gathering, hence overcoming the weaknesses of the qualitative research method and the quantitative research method (Creswell & Clark, 2007; Robson, 2002).

Advantages of using the mixed method include (1) that the method provides strengths that offset the weaknesses of both quantitative and qualitative research. Quantitative research is weak in understanding the context or setting in which people behave, something that qualitative research makes up for. On the other hand, qualitative research is seen as deficient because of the potential for biased

interpretations made by the researcher and the difficulty in generalizing findings to a large group. Quantitative research does not have these weaknesses. Thus, by using both types of research, the strengths of each approach can make up for the weaknesses of the other. (2) The method is a more complete and comprehensive understanding of the research problem than either quantitative or qualitative approaches alone. (3) It provides an approach for developing better, more context-specific instruments. By using qualitative research, it is possible to gather information about a certain topic or construct to develop an instrument with greater construct validity that measures the construct that it intends to measure. (4) It facilitates explaining findings or how causal processes work (Creswell, 2015).

Disadvantages of mixed research methods include: (1) it may be unclear how to resolve discrepancies that arise in the interpretation of the findings. (2) It takes much more time and resources to plan and implement this type of research. (3) It may be difficult to plan and implement one method by drawing on the findings of another; (4) the research design can be overly complex (Creswell, 2015). Table (3.1) compares the components of quantitative, qualitative, and mixed research methods as shown below:

Table 3.1

Comparaison between Quantitative/Qualitative Méthodologies

	Quantitative	Qualitative	Mixed Research Method
Characteristics	Involves numerical data, and objectivity is applied in data analysis	Involves non-numerical data. Data is analyzed using thematic or other methods to explore participants' perceptions subjectively in order to develop new theories.	Numerical and non-numerical data are collected and emerged to make inferences.
Contribution of Theory	Established theories are validated using specific context (deduction).	Specific context is used to propose new theories and already established theories are not referred to (induction).	Theories are validated as well as developed.
Research Philosophy	Positivism	Interpretivism	Positivism and interpretivism research philosophy are integrated.
Hypothesis	Hypothesis formulated by referring to existing theories.	Hypothesis may or may not be formulated.	Involves hypothesis development and confirmation.
Research Strategy	Surveys, experiments, observation, and grounded theory	Case study, ethnography, grounded theory	Integration of case study, surveys, and others
Data Analysis	Inferential statistical tools (regression and correlation analysis).	Non-statistical analysis like thematic analysis and hermeneutical analysis.	Involves combinations of inferential, thematic, and hermeneutical analysis.

Note. Developed by the Researcher.

Selection of Research Method

This study is based on quantitative data gathered through a structured survey questionnaire to answer the research questions and hypothesis statements. Quantitative methodology is selected for the present study for the following reasons:

According to Creswell and Creswell (2017), the quantitative method is suitable when dealing with large sample sizes. Since the present research aims at investigating factors that impede successful vaccine manufacturing business in KSA for the enhancement and sustainability of the healthcare sector. Hence, there is a need to explore the phenomenon through large data and, thus, the selection of quantitative methodology (Saunders, Lewis, Thornhill, & Bristow, 2019).

Another crucial advantage of the quantitative method is the inherent objectivity that is embedded in the quantitative process of collecting numerical data. Objectivity denotes the detachment of the researcher from influencing the respondent's opinion in responding to the research questions. As the present research investigates factors that impede successful vaccine manufacturing business in KSA for the enhancement and sustainability of the healthcare sector, it is desirable that the researcher's personal opinions are not incorporated into the interpretation of data, which is unavoidable when adopting qualitative methods like interviews.

Bell, Bryman, and Harley (2018) posit that quantitative research methods of data gathering improve reliability and validity of data as well as enhance the quality and replicability of the findings. In business research, utilizing survey strategy emphasizes higher management, usefulness, and easy explanation of the data gathered.

Research Approach

Research approaches can be classified into two approaches: deductive approaches and inductive approaches. The deductive approach should be used when research focuses on developing theory and hypothesis and designs a research strategy to test hypotheses. The inductive approach should be used when collecting data and developing a theory as a finding of the data analysis (Saunders, Lewis, Thornhill, & Bristow, 2019). It is necessary to match research philosophies and research approaches; the deductive approach relates more to the positivist philosophy and the inductive approach to the interpretivist philosophy (Saunders, Lewis, Thornhill, & Bristow, 2019).

A deductive approach was chosen in this study by using theoretical arguments based on existing phenomena and testing hypotheses (Creswell & Clark, 2007; Robson, 2002). This approach is used to describe the causal relationship between variables, test hypotheses, and generalize the regularities in human social behavior (Saunders, Lewis, Thornhill, & Bristow, 2019). On the other hand, Creswell (2015) identified that there are two types of research paradigms based on the assumptions of the paradigms. Firstly, the quantitative paradigm is termed the traditional, positivist, experimental, or empiricist paradigm. Secondly, the qualitative paradigm is termed constructivist approach, naturalistic, interpretative approach, or post-positivist or postmodern perspective.

To explain the relationship between the study's variables, a deductive approach can be used to describe causal relationships between variables and measure the facts of variables quantitatively (Saunders, Lewis, Thornhill, & Bristow, 2019).

To analyze the association of variables, a quantitative methodology can be used to test hypotheses in a cause-and-effect relationship by using a deductive approach (Creswell, 2015). Indeed, the qualitative paradigm can be used as a part of the quantitative paradigm.

Case Study and Implications

This research also involved a qualitative case study as a validation of the quantitative survey results. The case study was conducted face-to-face (online interview) through the Zoom platform (Zoom.com) with 22 respondents (key opinion leaders) selected from (entrepreneurs, healthcare practitioners, academicians, and government workers in KSA) who were not part of the respondents that participated in the quantitative study through a survey questionnaire. Details of data collection and analysis are presented in chapter five (case study and implications).

Development of Data Collection Instrument

This section presents the development of the data collection instrument used in the gathering of data. The data collection instrument was developed based on literature review.

The sources of the research variables from literature review as indicated in the survey questionnaire are as follows:

Independent Variables:

- Research and development (R&D) capability (Makenga et al., 2019; Plotkin et al., 2017; Kumraj et al., 2022; Black et al., 2020; Altman et al., 2023; Walkinshaw et al., 2023; Chandra et al., 2023).
- Low revenue (Sharma et al., 2020; Pronker et al., 2013; Gouglas et al., 2018; Emami & Klein, 2020; Alruthia et al., 2018).
- High cost of investment in process development technology (Ramli et al., 2022; Popoola et al., 2022; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).
- Adequate infrastructure (research labs/supply chain) (Tirole, 2018; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).
- Technical knowledge (Minssen & Price, 2021; Alzahrani & Harris, 2021; Ahmad et al., 2021; Johari et al., 2021; Jerving & Ravelo, 2022; Plotkin et al., 2017; Sharpe et al., 2020; Alzahrani & Harris, 2021; Badreldin & Atallah, 2021; Badreldin & Atallah, 2021; Tinworth & Young, 2020; Mihigo et al., 2019).
- Government support (Assiri et al., 2021; Alzahrani & Harris, 2021; Gaulé & Kaddar, 2007; Aldossari et al., 2021; Raja & Alshamsan, 2020).
- Limited Partnership opportunities (Hayman, Suri, & Downham, 2022; Alzahrani & Harris, 2021; Rappuoli, Black, & Bloom, 2019; Cohen, 2020).

Dependent Variable:

- Successful vaccine manufacturing business in KSA (Shuman et al., 2020; Badreldin & Atallah, 2021; Portnoy et al., 2023; Arif et al., 2023; Surya et al., 2019).

Moderating Variable:

- Government Regulations and Policies (Mueller, Altenburger, & Mohl, 2018; Gomez et al., 2013; Kis et al., 2019; Cid & Bolivar, 2021; Vidor & Soubeyrand, 2016; Alrasheedy et al., 2017; Raja & Alshamsan, 2020; Assiri et al., 2021).

Control Variable:

- Work Sector (Nguyen & Schwalbe, 2019, Pagliusi, 2013; Tawfik et al., 2022; Alzahrani & Harris, 2021; Tawfik et al., 2022).

Survey Questionnaire Measurement Scale

A structured survey questionnaire was utilized for data collection. The survey questionnaire was divided into two (2) sections. The survey questionnaire was developed based on literature review.

The first section contains the general information of the respondents, such as gender, age, nationality, educational background, job title, years of working experience, and work sector.

The second section contains factors that impede vaccine manufacturing business (research and development (R&D) capability, low revenue, high cost of investment in process development technology, adequate infrastructure (research labs/supply chain), technical knowledge, government support, limited partnerships, opportunities, government regulations and policies, and successful vaccine manufacturing business in KSA).

The survey questionnaire followed questions rated on a seven-point (7) Likert scale (1- Strongly Disagree, 2- Disagree, 3- Somewhat Disagree, 4- Neither agree nor disagree, 5- Somewhat Agree, 6- Agree, 7- Strongly Agree). To increase the respondents' objectivity and to ensure that the data gathered is comparable, the researcher opted to utilize closed-ended questions in the questionnaire design. A seven-point Likert scale was used as it provides respondents with a wider range of options, enabling them to express subtle differences in their thoughts and experiences. This detailed input is valuable for evaluating and enhancing the research questions.

Content Validity of the Survey Questionnaire

Establishing instrument validity includes the researcher following a generated procedure set to ensure the instrument is accurately measuring the desired outcomes of the research. In research, there are different approaches used as a method to ensure the validity of an instrument (Creswell, 2015). To establish the validity of the questionnaire, the researcher obtained feedback from two experts in the pharmaceutical industry to ensure the content validity of the questionnaire. The

two experts' judgments helped the researcher in ensuring that the questions were aligned and suitable for data collection.

Pilot Study of Survey Questionnaire

Bhattacherjee (2012) emphasized that pilot studies are conducted to establish the understandability, appropriateness, and reduction in measurement error of the survey instrument. Similarly, Bolarinwa (2015) posits that in studies, reliability occurs simultaneously, where researchers ethically and technically try to attain quality measurements in line with the research scope and objective.

Reliability denotes the repeatability, stability, or internal consistency of a survey research questionnaire for measuring internal consistency of the questionnaire (Creswell, 2015). Normally, reliability is measured by applying the universal measure of internal consistency statistics known as Cronbach's alpha (Omar & Baharum, 2018). Cronbach's alpha presents a coefficient of correlations between the items, which is the correlation of each item with the sum of all the other items. Cronbach's alpha quantifies reliability by suggesting a coefficient, which in theory ranges from 0 to 1. If alpha (<0x07>) is close to 0, then the quantified responses are not reliable, and if alpha (<0x07>) is near 1, the answers are very reliable. The function of the test is mentioned as the average inter-correlation between the items and the number of test items (Bell, Bryman, & Harley (2018)).

Cronbach's alpha test formula are as follows:

$$\alpha = \frac{N \cdot \bar{c}}{\bar{v} + (N-1) \cdot \bar{c}}$$

Where:

N = the number of items.

$\bar{c}$ = average covariance between item-pairs.

$\bar{v}$ = average variance.

The internal consistency is acceptable when the alpha coefficient is (.70) are more.

Development of the Research Variables

Based on the literature review, various variables that impede the vaccine manufacturing business were identified, which include:

- Research and development (R&D) capability (Makenga et al., 2019; Plotkin et al., 2017; Kumraj et al., 2022; Black et al., 2020; Altman et al., 2023; Walkinshaw et al., 2023; Chandra et al., 2023).
- Low revenue (Sharma et al., 2020; Pronker et al., 2013; Gouglas et al., 2018; Emami & Klein, 2020; Alruthia et al., 2018).

- High cost of investment in process development technology (Ramli et al., 2022; Popoola et al., 2022; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).
- Adequate infrastructure (research labs/supply chain) (Tirole, 2018; Ibahimov et al., 2023; Bekhti et al., 2022; Felber & Titchier, 2021).
- Technical knowledge (Minssen & Price, 2021; Alzahrani & Harris, 2021; Ahmad et al., 2021; Johari et al., 2021; Jerving & Ravelo, 2022; Plotkin et al., 2017; Sharpe et al., 2020; Alzahrani & Harris, 2021; Badreldin & Atallah, 2021; Badreldin & Atallah, 2021; Tinworth & Young, 2020; Mihigo et al., 2019).
- Government support (Assiri et al., 2021; Alzahrani & Harris, 2021; Gaulé & Kaddar, 2007; Aldossari et al., 2021; Raja & Alshamsan, 2020).
- Limited Partnership opportunities (Hayman, Suri, & Downham, 2022; Alzahrani & Harris, 2021; Rappuoli, Black, & Bloom, 2019; Cohen, 2020).

Dependent Variable:

- Successful vaccine manufacturing business in KSA (Shuman et al., 2020; Badreldin & Atallah, 2021; Portnoy et al., 2023; Arif et al., 2023; Surya et al., 2019).

Moderating Variable:

- Government Regulations and Policies (Mueller, Altenburger, & Mohl, 2018; Gomez et al., 2013; Kis et al., 2019; Cid & Bolivar, 2021; Vidor & Soubeyrand, 2016; Alrasheedy et al., 2017; Raja & Alshamsan, 2020; Assiri et al., 2021).

Control Variable:

- Work Sector (Nguyen & Schwalbe, 2019, Pagliusi, 2013; Tawfik et al., 2022; Alzahrani & Harris, 2021; Tawfik et al., 2022).

Reliability Test of the Survey Questionnaire

A sample of the survey questionnaire was sent to selected respondents (n = 20) from the university and research institutions for the pilot study. These professionals were selected based on years of experience and job position by the researcher. According to Pallant (2010), pilot tests can be conducted within the range of five (5) to thirty (30) respondents. Completed survey questionnaires received by the research were encoded into SPSS version 28 for Cronbach Alpha analysis. Summary Cronbach Alpha values for the study construct are presented in Table (3.2):

Table 3.2

Cronbach's Alpha Analysis for Reliability Test

No	Factor	No of Item	Cronbach Alpha
1	Lack of research and development (R&D) capability	4	0.85
2	Low revenue	4	0.83
3	High cost of investment in process development technology	4	0.79
4	Lack of adequate infrastructure	4	0.80
5	Lack of technical knowledge	4	0.80
6	Lack of government support	3	0.93
7	Lack of partnership opportunities	4	0.85
8	Government regulations and policies	4	0.91
9	Successful vaccine manufacturing business in KSA	4	0.80

Table (3.2) above shows the Cronbach's Alpha Values for the reliability analysis of the study factors. The result of the Cronbach Alpha (α) for all constructs ranged from (0.7 to 0.93), respectively.

Furthermore, as indicated in table (3.2) Cronbach's Alpha values are all above (0.7) which is considered acceptable (Hair et al., 2010; Hair, Ringle & Sartedt, 2014).

Target Population

The target population of this study includes key opinion leaders (KOL) working in health ministry departments, research and university institutions, and entrepreneurs in the Kingdom of Saudi Arabia. Hence, the target population is unknown.

Sample Size

According to Creswell (2017), sample size refers to the number of units that are selected from the population that the researcher desires to use as a representative of the population for data collection. The desired size will vary according to the

variability in the population being sampled (Yin, 2003). The sample size should neither be too large nor too small. It should be optimal in order to represent the population.

The best sample is one that achieves the requirements of efficiency, representativeness, reliability, and flexibility. While deciding the sample size, the researcher must determine the desired precision as well as an acceptable confidence level for the estimate (Creswell, 2017).

Cochran's formula (Cochran, 1963), which allows the researcher to calculate an ideal sample size given a desired level of precision and desired confidence level within an estimated proportion of the attributes present in the population, was used to determine the sample size for this research. Cochran's formula is considered especially appropriate in situations with large populations, as in the case of this research (Burns, Veeck, & Bush, 2017).

The Cochran formula is: $n_0 = \frac{z^2 pq}{e^2}$

Where:

e = is the desired level of precision or margin of error (i.e., 5%)?

p = is the estimated proportion of the population that has the attribute in question (i.e., 0.5).

q = is 1- p (i.e., 0.5)

The z value is sourced from the Z table (95% confidence level gives us a Z value of 1.96).

Based on these values, we get n as $(1.96)^2$ (0.5) (0.5)) / $(0.05)^2$ = 385.

Sampling Frame

A sampling frame is the subset of the population that provides full and detailed scope for the chosen sample units. According to Singh and Kultar (2007), sampling frames consist of entities from which the sampling units are selected for a particular survey. Similarly, Creswell (2017) stated that a sampling frame is a list or other specification of the units in the population from which a sample may be selected. Furthermore, Creswell (2017) defined sampling frame as a framework that serves as the basis for the selection of a survey sample and affects many other important aspects of a survey as well. For this research, the sampling frame consists of key opinion leaders (KOL) working in health ministry departments, research and university institutions, and pharmaceutical businesses in the Kingdom of Saudi Arabia.

Sampling Technique

According to Pallant (2010), sampling can be used to make inferences about a population. This depends on the choice of sampling technique. Sampling techniques can be divided into two categories: Probability sampling and non-probability sampling techniques as shown in Figure (3.1). Probability sampling means that every item in the population has an equal chance of being included in the

sample, and non-probability sampling is a method wherein the chances of each element being chosen are not known (Creswell, 2017).

Types of probability sampling technique include simple random technique, stratified random technique, cluster sampling technique, systematic sampling technique, and non-probability sampling technique includes quota sampling technique, snowball sampling technique, judgment sampling technique, and convenience sampling technique.

This study utilized the convenience sample technique to reach the key opinion leaders (KOL) working in the health ministry department, research and university institutions, and pharmaceutical business in the Kingdom of Saudi Arabia. This is done to overcome the limitations of other sampling techniques, such as cost and availability of respondents.

Distribution of the Survey Questionnaire

The survey questionnaire was distributed to participants who are working in the following sectors: (1) government; (2) healthcare; (3) academia; (4) manufacturing; and (5) entrepreneurs through Google Form, an online platform, from July 13th to August 17th, 2023. Completed survey questionnaires were downloaded to Microsoft Excel and further exported to SPSS Software (Version 28.1) for analysis.

Data Analysis

The main objective of this research is to investigate factors that impede successful vaccine manufacturing business in KSA for the enhancement and sustainability of the healthcare sector. As stated in the research methods section, quantitative data

was gathered through a survey questionnaire, and the following statistical analysis was conducted.

Quantitative Data Analysis

Descriptive Statistics: Analysis of the demographic variables of the respondents was conducted using descriptive statistics for mean and standard deviation. The demographic variable includes gender, age, nationality, educational background, job title, years of working experience, and work sector.

One-way ANOVA. One-way analysis of variance (ANOVA) was utilized to determine the difference (means) in the perception of respondents regarding the vaccine manufacturing business in KSA.

Regression analysis: Regression analysis was used to test the moderating effect of government regulation and policies between the independent variables (lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations) and vaccine manufacturing business in KSA.

Statistical Significance: Statistical significance performed in this study will be determined utilizing the p-value principle and contrasting with a pre-characterized significance level of 0.05% ($\alpha = 0.05$), which is the normal dimension utilized in research. Statistical significance will be based on 0.05% level of significance.

Ethical Statements

Standard ethical procedures were adequately undertaken in dealing with the respondents that provided the needed information for the study. All respondents willingly accepted to participate in the study by giving detailed acknowledgment with respect to their consent to participate. All respondents were requested to sign a debriefing and withdrawal letter. The point of the two letters was to promise respondents that their support in the study is intentional and that they were allowed to pull back from it anytime and for any reason.

Respondents were fully informed with respect to the goals, purpose, and objectives of the study while they were consoled that their answers were treated as secret and utilized just for scholastic purposes. With the exception of the above mentioned, respondents were not hurt or manhandled, both physically and mentally, amid the conduction of the exploration. The researcher endeavored to make and keep up an atmosphere of solace with all the respondents in the study.

Summary of the Chapter

This chapter presented the procedures and methodology employed in this research. The positivist research philosophy was used as the guiding philosophy in the gathering and analysis of data. The study utilized a quantitative research method following a deductive research approach. The target population consisted of key opinion leaders from entrepreneurs from the manufacturing sector, government offices, and healthcare practitioners in KSA.

Data collected was encoded into Statistical Package for Social Sciences (SPSS Version 28.1). Statistical analysis of the data gathered was conducted for descriptive statistics and inferential statistics to test the hypothesis statements. A summary of the methods and procedures is shown in Table (3.3):

Table 3.3

Overall Summary of Procedures and Methods

Research Objectives	Research Questions	Hypothesis	Methods
1. To assess if there is a relationship between lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack partnership opportunities,	1. To what extent does lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, and government regulations and policies impede vaccine manufacturing business in KSA?	Hypothesis one: Null Hypothesis ($H1_o$): Lack of research and development capability does not significantly impede vaccine manufacturing business in KSA, Alternative Hypothesis ($H1_A$):	Regression analysis

government regulations and policies on vaccine manufacturing business in KSA.	Lack of research and development capability significantly impede vaccine manufacturing business in KSA.	
	Hypothesis two: Null Hypothesis ($H2_o$): Low revenue does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H2_A$): Low revenue significantly impede vaccine manufacturing business in KSA.	
	Null Hypothesis ($H3_o$): Hypothesis three: High cost of investment does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H3_A$): High cost of investment significantly impede vaccine	Regression analysis

		manufacturing business in KSA.	
		Hypothesis four: Null Hypothesis ($H4_o$): Lack of adequate infrastructure does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H4_A$): Lack of adequate infrastructure significantly impede vaccine manufacturing business in KSA.	Regression analysis
		Hypothesis five: Null Hypothesis ($H5_o$): Lack of technical knowledge does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H5_A$): Lack of technical knowledge significantly impede vaccine	Regression analysis

		manufacturing business in KSA.	
		Hypothesis six: Null Hypothesis ($H6_o$): Lack of government support does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H6_A$): Lack of government support significantly impede vaccine manufacturing business in KSA.	Regression analysis
		Hypothesis seven: Null Hypothesis ($H7_o$): Lack of partnership opportunities does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H7_A$): Lack of partnership opportunities significantly impede vaccine	

		manufacturing business in KSA.	
		Hypothesis eight: Null Hypothesis ($H8_o$): Government regulation and policies does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H8_A$): Government regulation and policies significantly impede vaccine manufacturing business in KSA.	
2. To analyze the moderating effect of government regulations and policies in the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government	2. To what extent does government regulations and policies moderate the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and	Hypothesis nine: Null Hypothesis ($H9_o$): Government regulation and policies does not moderate the relationship between lack of research and development capability and vaccine manufacturing business in KSA. Alternative Hypothesis ($H9_A$):	Regression analysis

support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA	vaccine manufacturing business in KSA?	Government regulation and policies moderates the relationship between lack of research and development capability and vaccine manufacturing business in KSA.	
		Hypothesis ten: Null Hypothesis ($H10_o$): Government regulation and policies does not moderate the relationship between low revenue and vaccine manufacturing business in KSA. Alternative Hypothesis ($H10_A$): Government regulation and policies moderates the relationship between low revenue and vaccine manufacturing business in KSA.	Regression analysis
		Hypothesis eleven: Null Hypothesis ($H11_o$): Government regulation and policies does not	Regression analysis

		moderate the relationship between high cost of investment and vaccine manufacturing business in KSA. Alternative Hypothesis ($H11_A$): Government regulation and policies moderates the relationship between high cost of investment and vaccine manufacturing business in KSA.	
		Hypothesis twelve: Null Hypothesis ($H12_o$): Government regulation and policies does not moderate the relationship between lack adequate infrastructure and vaccine manufacturing business in KSA. Alternative Hypothesis ($H12_A$): Government regulation and policies moderates the relationship between adequate infrastructure and	Regression analysis

		vaccine manufacturing business in KSA.	
		Hypothesis thirteen: Null Hypothesis ($H13_o$): Government regulation and policies does not moderate the relationship between lack of technical knowledge and vaccine manufacturing business in KSA. Alternative Hypothesis ($H13_A$): Government regulation and policies moderates the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.	Regression analysis
		Hypothesis fourteen: Null Hypothesis ($H14_o$): Government regulation and policies does not moderate the relationship between lack of government support	Regression analysis

		and vaccine manufacturing business in KSA. Alternative Hypothesis ($H14_A$): Government regulation and policies moderates the relationship between lack of government support and vaccine manufacturing business in KSA.	
		Hypothesis fifteen: Null Hypothesis ($H15_o$): Government regulation and policies does not moderate the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA. Alternative Hypothesis ($H15_A$): Government regulation and policies moderates the relationship between lack of partnership opportunities and vaccine	Regression analysis

		manufacturing business in KSA.	
3. To evaluate if there is any difference in the perception of respondents according to work sector regarding vaccine manufacturing business in KSA	3. Is there any significant difference in perception of respondent according to work sector regarding vaccine manufacturing business in KSA?	Hypothesis sixteen: Null Hypothesis ($H16_o$): There are no significant differences in perception of respondents across work sector regarding vaccines manufacturing business in KSA. Alternative Hypothesis (H156): There are significant differences in perception of respondents across work sector regarding vaccine manufacturing business in KSA.	One-way ANOVA

Note. Developed by the Researcher.

Chapter Four: Findings and Discussion

Introduction

This chapter presents the findings and discussion as per the analysis of data gathered from the participants in this research (n = 265). Data was collected through a quantitative survey questionnaire distributed through an online platform (Google Form) from July 13th to August 17th, 2023. A total of 385 questionnaires were distributed, and 265 questionnaires were completed and returned, resulting in a 68.8% return rate.

This research was conducted to establish factors that impede the vaccine manufacturing business in KSA. The following objectives were stated:

1. To assess if there is a relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA.
2. To analyze the moderating effect of government regulations and policies in the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA.

3. To evaluate if there is any significant difference in the perception of respondents according to work sector regarding vaccine manufacturing business in KSA.

To analyze the data gathered, Statistical Package for Social Science (SPSS Version 28.1) was employed for coding and analysis. The following statistical analysis was conducted. (1) descriptive statistics—for the mean and standard deviation of the variables as well as for the demographic profile of the participants (gender, age groups, nationality, educational background, job title, years of working experience, and work sector). (2) Inferential statistics (multiple regression analysis and one-way ANOVA for the hypothesis statements).

Descriptive Statistics

Descriptive statistics for the mean and standard deviation of the research variables are presented in this section.

A. Normality test

Table (4.1) presents a normality test of the data set conducted to evaluate whether the dataset adheres to the assumptions of a normal distribution as per the Kolmogorov-Smirnov and Shapiro-Wilk tests.

Table 4.1

Tests of Normality

Tests of Normality						
	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
RDEV	.131	265	<.001	.934	265	<.001
LOWR	.101	265	<.001	.953	265	<.001
IVESTec	.216	265	<.001	.797	265	<.001
Infras	.198	265	<.001	.836	265	<.001
TECH	.187	265	<.001	.857	265	<.001
GOVSP	.192	265	<.001	.909	265	<.001
PARTOP	.176	265	<.001	.890	265	<.001
GOVPOL	.234	265	<.001	.808	265	<.001
VACCINEM	.198	265	<.001	.853	265	<.001
a. Lilliefors Significance Correction						

Table (4.1) shows the normality test indicating Shapiro-Wilk test result with a statistical value within the acceptable range, however, the p-value is below 0.05 significance level indicating that the data deviated from a normal distribution.

Table 4.2A
Descriptive Statistics - Research and Development Capacity

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
RD1	265	6	1	7	4.52	.103	1.672	2.796	-.386	.150	-.958	.298
RD2	265	6	1	7	4.18	.109	1.777	3.156	-.387	.150	-1.206	.298
RD3	265	6	1	7	5.09	.094	1.528	2.336	-.891	.150	-.025	.298
RD4	265	6	1	7	4.99	.097	1.584	2.508	-1.147	.150	.272	.298
RDEV	265	6.00	1.00	7.00	4.6981	.07840	1.27620	1.629	-.817	.150	.030	.298
Valid N (listwise)	265											

Table (4.2A) shows the descriptive statistics relating to research and development capacity variable. The descriptive statistics reveal an overall mean score of 4.70 (SD = 1.276) a kurtosis of (.030). This shows a positive perception of the respondents regarding research development capacity variable on vaccine manufacturing business in KSA. Question three (RD3) had the highest mean values indicating that

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
LR1	265	6	1	7	3.55	.108	1.753	3.074	.335	.150	-1.248	.298
LR2	265	5	2	7	4.12	.089	1.445	2.087	.115	.150	-1.366	.298
LR3	265	5	2	7	4.74	.088	1.426	2.032	-.488	.150	-.932	.298
LR4	265	6	1	7	4.81	.103	1.677	2.813	-.762	.150	-.512	.298
LOWR	265	5.33	1.67	7.00	4.1409	.07873	1.28161	1.643	.042	.150	-1.146	.298
Valid N (listwise)	265											

the respondents are in favor that lack of research and development capacity impedes vaccine manufacturing business in KSA.

Table 4.2B

Descriptive Statistics - Low Revenue

Table (4.2B) shows the descriptive statistics relating to low revenue variable. The descriptive statistics reveal an overall mean score of 4.14 (SD = 1.281) and a kurtosis of (-1.146). This shows a positive perception of the respondents regarding low revenue variable on vaccine manufacturing business in KSA.

Table 4.2C

Descriptive Statistics - High Cost of Investment

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
INV1	265	6	1	7	4.91	.095	1.543	2.381	-.682	.150	-.606	.298
INV2	265	5	2	7	5.73	.069	1.129	1.274	-1.694	.150	3.445	.298
INV3	265	6	1	7	5.26	.086	1.399	1.958	-1.208	.150	1.115	.298
INV4	265	6	1	7	5.69	.074	1.208	1.458	-1.563	.150	2.953	.298
INVESTEC	265	5.25	1.75	7.00	5.3953	.05742	.93472	.874	-2.009	.150	5.109	.298
Valid N (listwise)	265											

Table (4.2C) shows the descriptive statistics relating to the high cost of investment variable. The descriptive statistics reveal an overall mean score of 5.40 (SD = .934) and a kurtosis of (5.109). This shows a positive perception of the respondents regarding high cost of investment *variable on vaccine manufacturing business in KSA.*

Table 4.2D
Descriptive Statistics

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
AF1	265	6	1	7	6.19	.082	1.327	1.762	-2.257	.150	4.868	.298
AF2	265	6	1	7	5.84	.075	1.228	1.508	-1.815	.150	3.530	.298
AF3	265	6	1	7	5.57	.086	1.394	1.942	-1.684	.150	2.642	.298
AF4	265	6	1	7	5.72	.075	1.226	1.503	-1.635	.150	3.139	.298
INFRAS	265	6.00	1.00	7.00	5.8321	.06591	1.07291	1.151	-1.779	.150	4.072	.298
Valid N (listwise)	265											

Table (4.2D) shows the descriptive statistics relating to adequate infrastructure variables. The descriptive statistics reveal an overall mean score of 5.83(SD = 1.072) and kurtosis of (4.072). This shows a positive perception of the respondents regarding adequate infrastructure variable on vaccine manufacturing business in KSA.

Table 4.2E

Descriptive Statistics - Technical Knowledge

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
TK1	265	6	1	7	5.39	.088	1.429	2.042	-1.077	.150	.387	.298
TK2	265	6	1	7	5.68	.074	1.211	1.467	-1.433	.150	2.242	.298
TK3	265	6	1	7	5.60	.074	1.205	1.453	-1.453	.150	2.567	.298
TK4	265	6	1	7	5.43	.091	1.488	2.215	-1.509	.150	1.743	.298
TECH	265	6.00	1.00	7.00	5.5245	.07092	1.15444	1.333	-1.519	.150	2.852	.298
Valid N (listwise)	265											

Table (4.2E) shows the descriptive statistics relating to technical knowledge variable. The descriptive statistics reveal an overall mean score of 5.52 (SD = 1.154) and kurtosis of (2.852). This shows a positive perception of the respondents regarding adequate technical knowledge on vaccine manufacturing business in KSA.

Table 4.2F

Descriptive Statistics - Government Support

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
GS1	265	6	1	7	4.58	.090	1.473	2.169	-.640	.150	-.314	.298
GS2	265	6	1	7	4.66	.091	1.482	2.196	-.625	.150	-.581	.298
GS3	265	6	1	7	4.75	.094	1.529	2.339	-.649	.150	-.646	.298
GS4	265	6	1	7	4.75	.096	1.564	2.445	-.730	.150	-.590	.298
GOVSP	265	6.00	1.00	7.00	4.6840	.08668	1.41099	1.991	-.756	.150	-.401	.298
Valid N (listwise)	265											

Table (4.2F) shows the descriptive statistics relating to government support variable. The descriptive statistics reveal an overall mean score of 4.68 (SD = 1.41) and kurtosis of (-.401). This shows a positive perception of the respondents regarding government support on vaccine manufacturing business in KSA.

Table 4.2G

Descriptive Statistics - Partnership Opportunities

Table (4.2G) shows the descriptive statistics relating to partnership opportunities variable. The descriptive statistics reveal an overall mean score of 5.22 (SD = 1.07) and a kurtosis of (2.143). This shows a positive perception of the respondents regarding partnership opportunities on vaccine manufacturing business in KSA.

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
PO1	265	6	1	7	4.94	.080	1.307	1.708	-.698	.150	-.237	.298
PO2	265	6	1	7	5.20	.082	1.329	1.767	-1.152	.150	.983	.298
PO3	265	6	1	7	5.37	.074	1.212	1.470	-1.482	.150	2.111	.298
PO4	265	6	1	7	5.36	.076	1.229	1.511	-1.476	.150	2.095	.298
PARTOP	265	6.00	1.00	7.00	5.2179	.06598	1.07415	1.154	-1.341	.150	2.143	.298
Valid N (listwise)	265											

Table 4.2H

Descriptive Statistics - Government Regulations and Policies

Table (4.2H) shows the descriptive statistics relating to government regulations and policies variable. The descriptive statistics reveal an overall mean score of 5.76 (SD = 1.28) and kurtosis of (2.449). This shows a positive perception of the respondents regarding government regulations and policies on vaccine manufacturing business in KSA.

Table 4.2I

Descriptive Statistics - Vaccine Manufacturing Business

	N	Range	Min	Max	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
VM1	265	6	1	7	5.76	.075	1.225	1.500	-1.494	.150	2.400	.298
VM2	265	6	1	7	5.69	.074	1.204	1.449	-1.669	.150	3.225	.298
VM3	265	6	1	7	5.62	.074	1.213	1.471	-1.516	.150	2.584	.298
VM4	265	6	1	7	5.99	.061	1.000	1.000	-1.565	.150	3.660	.298
VACCINEM	265	5.25	1.75	7.00	5.7670	.05870	.95554	.913	-1.582	.150	3.252	.298
Valid N (listwise)	265											

Table 4.2I shows the descriptive statistics relating to vaccine manufacturing business variable. The descriptive statistics reveal an overall mean score of 5.77 (SD = .955) a kurtosis of (3.252). This shows a positive perception of the respondents regarding vaccine manufacturing business on vaccine manufacturing business in KSA.

Table 4.3

KMO and Bartlett's Test

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.856
Bartlett's Test of Sphericity	Approx. Chi-Square	732.763
	df	36
	Sig.	<.001

Table (4.3) presents KMO and Bartlett's Test conducted to examine the strength of the partial correlation between the variables. As a rule, KMO values closer to 1.0 are considered ideal while values less than 0.5 are unacceptable (Kaiser 1974).

As shown in Table (4.3) KMO and Bartletts test showed a value of .856. This indicates the presence of a strong partial correlation. Hence, it is plausible to conduct factor analysis.

Table 4.4

Total Variance Explained – Common method bias

Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	3.898	43.310	43.310	3.898	43.310	43.310
2	1.000	11.108	54.418	1.000	11.108	54.418
3	.943	10.476	64.894	.943	10.476	64.894
4	.816	9.071	73.965	.816	9.071	73.965
5	.609	6.763	80.729	.609	6.763	80.729
6	.560	6.218	86.947	.560	6.218	86.947
7	.440	4.884	91.831	.440	4.884	91.831
8	.412	4.577	96.408	.412	4.577	96.408
9	.323	3.592	100.000	.323	3.592	100.000

Extraction Method: Principal Component Analysis.

Principal component analysis was conducted using Harman's single factor test to establish the presence of common method bias (CMB) also known as common method variance (CMV) in the data set.

As a rule, Harman's single factor test states that "If the total variance extracted by one factor exceeds 50%, common method bias is present in the data set.

As indicated in the Table (4.4), Total Variance Explained, there is no problem with common method bias in the data since the total variance extracted by one factor is 43.310 percent and it is less than the recommended threshold of 50 percent, indicating that the data set is satisfied.

Descriptive Statistics of the Demographic Variables

This section presents frequency and percentage of the demographic variables which include gender, age groups (years), nationality, educational level, job title, tears of working experience, and work sector.

Table 4.5

Demographic Variables

Characteristics	Description	Frequency	Percent
Gender	Male	169	63.8
	Female	96	36.2
	Total	265	100.0
Age groups (Years)	21 – 30	57	21.5
	31 – 40	107	40.4
	41 – 50	63	23.8
	51 – above	38	14.3
	Total	265	100.0
Nationality	Saudi Arabia National	228	86.0
	Non-Saudi Arabia National	37	14.0
	Total	265	100.0

Educational level	Bachelor's degree	127	47.9
	Master's degree	78	29.4
	Doctorate degree	60	22.6
	Total	265	100.0
Job Title	Government worker	17	6.4
	Entrepreneur	127	47.9
	Academician	39	14.7
	Health practitioner	82	30.9
	Total	265	100.0
Years of working Experience	Less than 5 years	46	17.4
	6 -10 years	71	26.8
	11- 15 years	58	21.9
	16 – 20 years	47	17.7
	21 - and above	43	16.2
	Total	265	100.0
Work sector	Government	16	6.0
	Healthcare	86	32.5
	Academia	35	13.2
	Manufacturing	127	47.9
	Total	265	100.0

As presented in Table (4.5), regarding gender of the respondents, 169 (63.8%) are male and 96 (36.2%) are female (N = 265). For the age groups, 57 respondents (21.5%) are within 21-30 years old, 107 respondents (40.4%) are within 31-40 years old, and 63 respondents (23.8%) are within 41- 50 years old, and 38 respondents are 51 and above years old.

Furthermore, out of the 265 respondents, 228 (86.0%) are Saudi Arabia nationals and 37 respondents (14.0%) are none-Saudi Arabia nationals. The table also indicated that 127 respondents (47.9%) have bachelor's degree, 78 (29.4%) have master's degree, and 60 (22.6%) have doctorate degree.

Similarly, for the job tile, 17 respondents (6.4%) are government workers, 127 respondents (47.9%) are entrepreneurs, 39 respondents (14.7%) are academicians, and 82 respondents (30.9%) are healthcare practitioners.

For the years of work experience, the table also indicated that 71 respondents (26.8%) have worked for less than 5 years, 58 respondents (21.9%) for 11-15 years, 47 respondents (17.7%) for 16-20 years, and 43 respondents (16.2%) for 21 and above years.

Lastly, for the work sector, 16 respondents (6.0%) are from the government sector, 86 respondents (32.5%) are from the healthcare sector, 35 respondents (13.2%) are from the academic sector, and 127 respondents (47.9%) are from the manufacturing sector.

Hypothesis Testing

This section presents analysis of hypothesis statements based on the data gathered from 265 participants in the research. Multiple linear regression analysis was conducted to estimate the liner relationship between the independent variables and the dependent variable.

Multiple Linear Regression Analysis

Multiple linear regression is a statistical technique that estimates the associations between one or more independent variables and a dependent variable (Creswell and Creswell, 2019, p.20). The following hypothesis statements were tested.

Hypothesis one:

Null Hypothesis ($H1_o$): Lack of research and development capability does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H1_A$): Lack of research and development capability significantly impede vaccine manufacturing business in KSA.

Hypothesis two:

Null Hypothesis ($H2_o$): Low revenue does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H2_A$): Low revenue significantly impede vaccine manufacturing business in KSA.

Hypothesis three:

Null Hypothesis ($H3_o$): High cost of investment does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H3_A$): High cost of investment significantly impede vaccine manufacturing business in KSA.

Hypothesis four:

Null Hypothesis ($H4_o$): Lack of adequate infrastructure does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H4_A$): Lack of adequate infrastructure significantly impede vaccine manufacturing business in KSA.

Hypothesis five:

Null Hypothesis ($H5_o$): Lack of technical knowledge does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H5_A$): Lack of technical knowledge significantly impede vaccine manufacturing business in KSA.

Hypothesis six:

Null Hypothesis ($H6_o$): Lack of government support does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H6_A$): Lack of government support significantly impede vaccine manufacturing business in KSA.

Hypothesis seven:

Null Hypothesis ($H7_o$): Lack of partnership opportunities does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H7_A$): Lack of partnership opportunities significantly impede vaccine manufacturing business in KSA.

Hypothesis eight

Null Hypothesis ($H8_o$): Government regulation and policies does not significantly impede vaccine manufacturing business in KSA.

Alternative Hypothesis ($H8_A$): Government regulation and policies significantly impede vaccine manufacturing business in KSA.

Findings from the above stated hypothesis are presented in table 4.11 to 4.13.

Table 4.5A

Coefficient

Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
		B	Std. Error	Beta			Tolerance	VIF
1	(Constant)	2.969	.351		8.452	<.001		
	RDEV	-.057	.047	-.076	-1.211	.227	.702	1.425
	LOWR	.048	.041	.064	1.176	.241	.912	1.096
	IVESTEC	.313	.070	.306	4.483	<.001	.587	1.704
	INFRAS	-.131	.067	-.147	-1.956	.052	.484	2.065
	TECH	-.011	.059	-.013	-.180	.857	.537	1.863
	GOVSP	.026	.041	.038	.626	.532	.738	1.355
	PARTOP	.011	.061	.013	.185	.854	.577	1.735
	GOVPOL	.316	.050	.424	6.302	<.001	.603	1.658

a. Dependent Variable: VACCINEM

Table (4.5A) presents the coefficient correlation of the variables in the data set.

Table 4.5B

Collinearity Diagnostics

Collinearity Diagnostics

Model	Dimension	Eigenvalue	Condition Index	Variance Proportions								
				(Constant)	RDEV	LOWR	IVESTEC	INFRAS	TECH	GOVSP	PARTOP	GOVPOL
1	1	8.727	1.000	.00	.00	.00	.00	.00	.00	.00	.00	.00
	2	.079	10.522	.00	.01	.80	.00	.00	.00	.12	.00	.01
	3	.056	12.446	.01	.04	.12	.03	.02	.01	.64	.02	.01
	4	.044	14.121	.01	.88	.00	.01	.00	.00	.18	.00	.01
	5	.026	18.349	.12	.01	.00	.08	.04	.02	.03	.05	.61
	6	.022	19.768	.07	.02	.00	.03	.00	.35	.01	.25	.35
	7	.019	21.432	.09	.02	.01	.01	.04	.38	.01	.63	.01
	8	.015	24.032	.64	.00	.06	.14	.22	.21	.00	.04	.00
	9	.011	27.797	.05	.02	.00	.70	.68	.03	.01	.00	.00

a. Dependent Variable: VACCINEM

Table (4.5B) presents a collinearity diagnostics test to test the extent to which two independent variables are correlated with each other. As shown in table, the eigenvalues are within the acceptable range where it is said that values above 30 are an indication of a very strong sign with multicollinearity. The eigen values in this data set are below 30 (Hair et al., 2013).

Table 4.5C

Pearson Correlation Matrix

Correlations										
		RDEV	LOWR	IVESTEC	INFRAS	TECH	GOVSP	PARTOP	GOVPOL	VACCINEM
RDEV	Pearson Correlation	1	.208**	.272**	.398**	.387**	.391**	.435**	.379**	.139*
	Sig. (2-tailed)		<.001	<.001	<.001	<.001	<.001	<.001	<.001	.024
	N	265	265	265	265	265	265	265	265	265
LOWR	Pearson Correlation	.208**	1	.147*	.127*	.247**	.138*	.223**	.183**	.158*
	Sig. (2-tailed)	<.001		.017	.038	<.001	.025	<.001	.003	.010
	N	265	265	265	265	265	265	265	265	265
IVESTEC	Pearson Correlation	.272**	.147*	1	.608**	.468**	.260**	.426**	.431**	.397**
	Sig. (2-tailed)	<.001	.017		<.001	<.001	<.001	<.001	<.001	<.001
	N	265	265	265	265	265	265	265	265	265
INFRAS	Pearson Correlation	.398**	.127*	.608**	1	.560**	.364**	.496**	.482**	.234**
	Sig. (2-tailed)	<.001	.038	<.001		<.001	<.001	<.001	<.001	<.001
	N	265	265	265	265	265	265	265	265	265

TECH	Pearson Correlation	.387**	.247**	.468**	.560**	1	.376**	.545**	.498**	.267**
	Sig. (2-tailed)	<.001	<.001	<.001	<.001		<.001	<.001	<.001	<.001
	N	265	265	265	265	265	265	265	265	265
GOVSP	Pearson Correlation	.391**	.138*	.260**	.364**	.376**	1	.329**	.416**	.219**
	Sig. (2-tailed)	<.001	.025	<.001	<.001	<.001		<.001	<.001	<.001
	N	265	265	265	265	265	265	265	265	265
PARTOP	Pearson Correlation	.435**	.223**	.426**	.496**	.545**	.329**	1	.492**	.266**
	Sig. (2-tailed)	<.001	<.001	<.001	<.001	<.001	<.001		<.001	<.001
	N	265	265	265	265	265	265	265	265	265
GOVPOL	Pearson Correlation	.379**	.183**	.431**	.482**	.498**	.416**	.492**	1	.484**
	Sig. (2-tailed)	<.001	.003	<.001	<.001	<.001	<.001	<.001		<.001
	N	265	265	265	265	265	265	265	265	265
VACCINEM	Pearson Correlation	.139*	.158*	.397**	.234**	.267**	.219**	.266**	.484**	1
	Sig. (2-tailed)	.024	.010	<.001	<.001	<.001	<.001	<.001	<.001	
	N	265	265	265	265	265	265	265	265	265

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table (4.5C) presents correlation matrix of the research variables. As the table indicates, the variable is significantly correlated. Correlation and regression analysis are related in the sense that both deal with relationships among variables. The correlation coefficient is a measure of linear association between two variables. The values of the correlation coefficient are always between −1 and +1. A correlation coefficient of +1 indicates that two variables are perfectly related in a positive linear sense, a correlation coefficient of −1 indicates that two variables are perfectly related in a negative linear sense, and a correlation coefficient of 0 indicates that there is no linear relationship between the two variables.

Table 4.5D

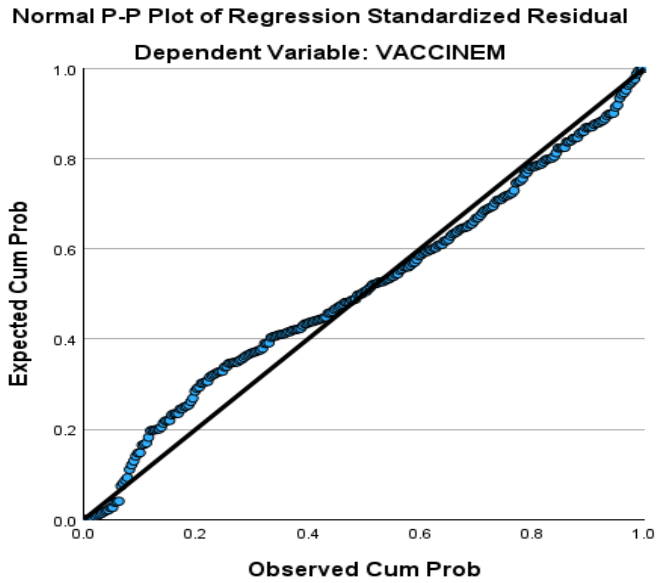
Residuals Statistics

Residuals Statistics					
	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	3.4207	6.7148	5.7670	.52372	265
Residual	-3.22582	2.63183	.00000	.79923	265
Std. Predicted Value	-4.480	1.810	.000	1.000	265
Std. Residual	-3.975	3.243	.000	.985	265
a. Dependent Variable: VACCINEM					

Table (4.5D) presents the residuals statistics. As a rule, if the value in the Minimum column of the Std. Residual row is less than -3, the data set should be investigated. Similarly, if the value in the Maximum column of the Std. Residual row is greater than 3, it should also be investigated. As indicated in the table, the r minimum value of (-3.975) and the maximum value of (3.243) indicate that the data set is within the range, hence no outliers.

Figure 4.1

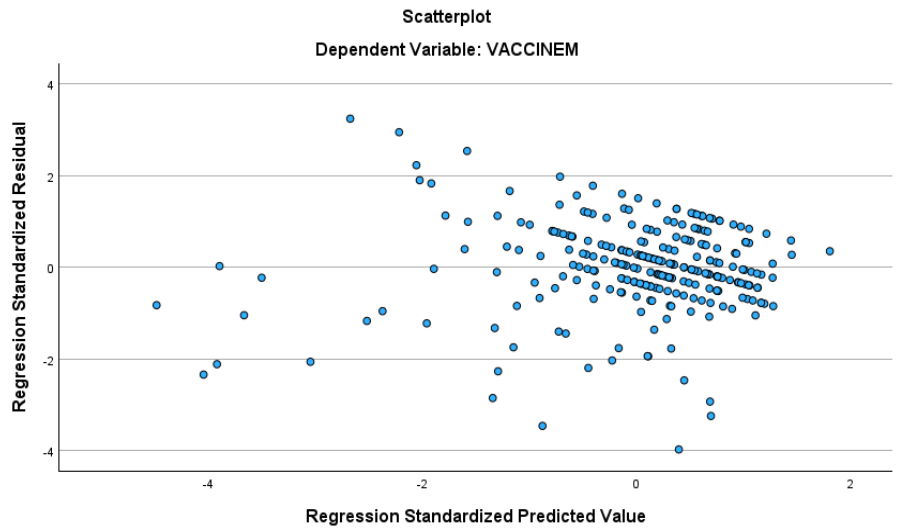
P-P Regression plot



Note. Figure (4.1) shows the normality assumption of the data set. As a rule, normality assumption is met if the dots on your P-P Plot are on, or close to the diagonal line. As indicated in the figure the P-P Plot is within the acceptable diagonal line which meets the normality assumption.

Figure 4.2

Scatter Plot- Homoscedasticity



Note. Figure (4.2) presents the scatter plot of the regression standardized residual to check for the assumption of homoscedasticity.

We can check the assumption of homoscedasticity using the scatterplot of standardized residuals versus standardized predicted values. As the figure indicate, there is an absence of pattern in scatter plot which the homoscedasticity of the data set.

Table 4.6

Linear Multiple Regression Model Summary

Model Summary				
Model	R	R Square	Adjusted R Square	Std. Error of the Est
1	.548[a]	.300	.279	.81163

a. Predictors: (Constant), GOVPOL, LOWR, RDEV, INVESTEC, GOVSP, PARTOP, TECH, INFRAS

b. Dependent Variable: VACCINEM

Legend

RDEV	Research and Development (R&D) Capabilities
LOWR	Low Revenue
INVESTEC	Cost of Investment
INFRAS	Adequate Infrastructure
TECH	Technical Knowledge
GOVSP	Government Support
PARTOP	Partnership Opportunities
GOVPOL	Government Regulations and Policies
VACCINEM	Vaccine Manufacturing Business

Table (4.6) shows a multiple linear regression coefficient (R) of .548 indicating a good measure of the quality of the prediction of the dependent variable based on the independent variables. The table also indicated R^2 value of (.300), which explains that the independent variables account for 30.0% of the variability in the dependent variable (vaccine manufacturing business).

Table 4.7

Linear Multiple Regression ANOVA Output

ANOVA						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	72.412	8	9.051	13.741	<.001[b]
	Residual	168.637	256	.659		
	Total	241.049	264			

a. Dependent Variable: VACCINEM

b. Predictors: (Constant), GOVPOL, LOWR, RDEV, INVESTEC, GOVSP, PARTOP, TECH, INFRAS

Table (4.7) shows regression ANOVA output indicating that the overall regression model is a good fit for the data set. The table also indicated that independent variables statistically significantly predicted the dependent variable (F (8, 256) = 13.741, p = .001).

Table 4.8

Linear Unstandardized Multiple Regression Coefficients

Coefficients						
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	2.969	.351		8.452	<.001
	RDEV	-.057	.047	-.076	-1.211	.227
	LOWR	.048	.041	.064	1.176	.241
	INVESTEC	.313	.070	.306	4.483	<.001
	INFRAS	-.131	.067	-.147	-1.956	.052
	TECH	-.011	.059	-.013	-.180	.857
	GOVSP	.026	.041	.038	.626	.532
	PARTOP	.011	.061	.013	.185	.854
	GOVPOL	.316	.050	.424	6.302	<.001

a. Dependent Variable: VACCINEM

Legend

RDEV	Research and Development (R&D) Capabilities
LOWR	Low Revenue
INVESTEC	Cost of Investment
INFRAS	Adequate Infrastructure
TECH	Technical Knowledge
GOVSP	Government Support
PARTOP	Partnership Opportunities
GOVPOL	Government Regulations and Policies
VACCINEM	Vaccine Manufacturing Business

As shown in Table (4.8), the unstandardized coefficients indicated the extent the dependent variable (vaccine manufacturing business) varies with an independent variable when all the independent variables in the data set are held at constant. Therefore, the following findings are indicated in the multiple regression analysis.

The model fit is significant for all the variables $R^2 = .300$, $F (8, 256) = 13.741$, $p = .001$). Therefore, the independent variables (research and development (R&D) capability, low revenue, cost of investment, adequate infrastructure, technical knowledge, government support, partnership opportunities, government regulations and policies), as predictors were further examined for their individual predictions.

Findings showed that the independent variables: cost of investment ($\beta = .313$, $t = 4.483$, $p < .001$), lack of adequate infrastructure ($\beta = -.131$, $t = -1.956$, $p < .052$), and government regulations and policies ($\beta = .316$, $t = 6.302$, $p < .001$), are significant predictors of vaccine manufacturing business. Therefore, the stated Null hypothesis statements were rejected.

However, the independent variables lack research and development (R&D) capability ($\beta = -.057$, $t = -1.211$, $p = .227$), low revenue ($\beta = .048$, $t = 1.176$, $p = .241$), lack of technical knowledge ($\beta = -.011$, $t = -.180$, $p = .857$), lack of government support ($\beta = .026$, $t = .626$, $p = .532$), lack of partnership opportunities ($\beta = .011$, $t = .185$, $p = .854$), were not significant. Therefore, not a predictors of vaccine manufacturing business. Hence, the Null hypothesis statement is accepted.

Moderation Interaction Analysis

Moderation Interaction Analysis was conducted to establish the moderation effect of government regulations and polices on the factors that impede vaccine manufacturing business in KSA.

The following hypothesis statements were stated:

Hypothesis nine

Null Hypothesis ($H9_o$): Government regulation and policies does not moderate the relationship between lack research and development capability and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H9_A$): Government regulation and policies moderates the relationship between lack research and development capability and vaccine manufacturing business in KSA.

Hypothesis ten

Null Hypothesis ($H10_o$): Government regulation and policies does not moderate the relationship between low revenue and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H10_A$): Government regulation and policies moderates the relationship between low revenue and vaccine manufacturing business in KSA.

Hypothesis eleven

Null Hypothesis ($H11_o$): Government regulation and policies does not moderate the relationship between high cost of investment and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H11_A$): Government regulation and policies moderates the relationship between high cost of investment and vaccine manufacturing business in KSA.

Hypothesis twelve

Null Hypothesis ($H12_o$): Government regulation and policies does not moderate the relationship between lack of adequate infrastructure and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H12_A$): Government regulation and policies moderates the relationship between lack of adequate infrastructure and vaccine manufacturing business in KSA.

Hypothesis thirteen

Null Hypothesis ($H13_o$): Government regulation and policies does not moderate the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H13_A$): Government regulation and policies moderates the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.

Hypothesis fourteen:

Null Hypothesis ($H14_o$): Government regulation and policies does not moderate the relationship between lack of government support and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H14_A$): Government regulation and policies moderates the relationship between lack of government support and vaccine manufacturing business in KSA.

Hypothesis fifteen:

Null Hypothesis ($H15_o$): Government regulation and policies does not moderate the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA.

Alternative Hypothesis ($H15_A$): Government regulation and policies moderates the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA.

Findings from the above stated hypothesis are presented in Table (4.9 to 4.11).

Table 4.9

Moderation Multiple Regression Model Summary

Model Summary [d]									
Model	R	R Square	Adjusted R Square	Std. Error	Change Statistics				
					R Square Change	F Change	df1	df2	Sig.
1	.438[a]	.192	.170	.87061	.192	8.718	7	257	<.001
2	.548[b]	.300	.279	.81163	.109	39.710	1	256	<.001
3	.623[c]	.388	.351	.76980	.087	5.082	7	249	<.001

a. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC RDEV, TECH, INFRAS
b. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC, RDEV, TECH, INFRAS, GOVPOL
c. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC, RDEV, TECH, INFRAS, GOVPOL, PARTOPGOVPOL, GOVSPGOVPOL, INVESTEC GOVPOL, LOWRGOVPOL, RDEVGOVPOL, TECHGOVPOL, INFRASGOVPOL
d. Dependent Variable: VACCINEM

Table 4.10

Moderation Regression ANOVA Output

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	46.253	7	6.608	8.718	<.001[b]
	Residual	194.795	257	.758		
	Total	241.049	264			
2	Regression	72.412	8	9.051	13.741	<.001[c]
	Residual	168.637	256	.659		
	Total	241.049	264			
3	Regression	93.492	15	6.233	10.518	<.001[d]
	Residual	147.557	249	.593		
	Total	241.049	264			

a. Dependent Variable: VACCINEM
b. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC, RDEV, TECH, INFRAS

c. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC, RDEV, TECH, INFRAS, GOVPOL
d. Predictors: (Constant), PARTOP, LOWR, GOVSP, INVESTEC, RDEV, TECH, INFRAS, GOVPOL, PARTOPGOVPOL, GOVSPGOVPOL, INVESTECGOVPOL, LOWRGOVPOL, RDEVGOVPOL, TECHGOVPOL, INFRASGOVPOL

Table 4.11

Moderation Unstandardized coefficients

	Model	B	Std. Error	Beta	t	Sig.
1	(Constant)	3.143	.376		8.366	<.001
	RDEV	-.033	.050	-.044	-.665	.507
	LOWR	.056	.044	.075	1.281	.201
	INVESTEC	.369	.074	.361	4.973	<.001
	INFRAS	-.087	.071	-.097	-1.216	.225
	TECH	.047	.063	.057	.748	.455
	GOVSP	.078	.043	.116	1.811	.071
	PARTOP	.084	.065	.094	1.297	.196
2	(Constant)	2.969	.351		8.452	<.001
	RDEV	-.057	.047	-.076	-1.211	.227
	LOWR	.048	.041	.064	1.176	.241
	INVESTEC	.313	.070	.306	4.483	<.001
	INFRAS	-.131	.067	-.147	-1.956	.052
	TECH	-.011	.059	-.013	-.180	.857
	GOVSP	.026	.041	.038	.626	.532
	PARTOP	.011	.061	.013	.185	.854
	GOVPOL	.316	.050	.424	6.302	<.001
3	(Constant)	1.307	.795		1.644	.001
	RDEV	.249	.234	.332	1.065	.288
	LOWR	.028	.246	.037	.113	.910
	INVESTEC	1.579	.232	1.544	6.817	<.001
	INFRAS	-.636	.263	-.715	-2.423	.016
	TECH	-.332	.253	-.401	-1.313	.190
	GOVSP	-.226	.217	-.334	-1.040	.299
	PARTOP	-.065	.256	-.073	-.254	.799
	GOVPOL	.609	.166	.818	3.675	<.001
	RDEV x GOVPOL	-.047	.039	-.501	-1.194	.233
	LOWR x GOVPOL	.003	.040	.026	.064	.949
	INVESTEC x GOVPOL	-.239	.041	-2.299	-5.787	<.001
	INFRAS x GOVPOL	.096	.047	1.036	2.057	.041
	TECH x GOVPOL	.052	.045	.563	1.160	.247

GOVSP x GOVPOL	.045	.036	.509	1.246	.214
PARTOP x GOVPOL	.021	.044	.218	.481	.631

Legend

RDEV = Research and Development (R&D) Capabilities

LOWR = Low Revenue

INVESTEC =Cost of Investment

INFRAS = Adequate Infrastructure

TECH =Technical Knowledge

GOVSP =Government Support

PARTOP = Partnership Opportunities

GOVPOL = Government Regulations and Policies

VACCINEM = Vaccine Manufacturing Business

Table (4.9 to 4.11) presents findings from the moderation analysis conducted to assess the moderation effect of government regulations and policies on relationship between the independent variables (lack of research and development (R&D) capability, low revenue, cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, partnership opportunities), and the dependent variable (vaccine manufacturing business.

As shown in Table (4.9) model summary, findings show that the R- Square value is (0.388) suggesting that the independent variables explain 38.8 percent of the variation in the dependent variable ($R^2 = .388$, $F (7, 249) = 5.082$, $p < .001$).

Furthermore, as shown in Table (4.10 and 4.11), considering the moderation effect or (interaction effect) of government regulations and policies on the individual variables, findings indicated the following:

i. Significant interaction effect of (β =-.239, SE=.041, β = -2.299, p < .001) between high cost of Investment and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.
ii. Significant interaction effect of (β =-.096, SE=.047, β = 1.036, p = .041) between lack of adequate infrastructure and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.
iii. Non-significant negative interaction effect (β =-.047, SE=.039, β = -.501, p = .233) between lack of research and development and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.
iv. Non-significant interaction effect (β =-.003, SE=.040, β = .026, p = .949) between low revenue and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.
v. Non-significant interaction effect (β =-.052, SE=.045, β = .563, p = .247) between lack of technical knowledge and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.
vi. Non-significant interaction effect (β =-.045, SE=.036, β = .509, p = .214) between government support and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

vii. Non-significant interaction effect (β =.021, SE=.044, β = .218, p = .631) between lack of partnership opportunities and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

One-way ANOVA

This section presents one-way ANOVA conducted to test if there is a significant statistical difference in the perception of respondents from different works sectors. The hypothesis determined the perception of the participants regarding vaccine manufacturing business in KSA. Hence, one-way ANOVA is appropriate as it will facilitate determining various opinion from the respondents regarding vaccine manufacturing business in KSA.

The following hypothesis statements were stated.

Hypothesis fifteen:

Null Hypothesis ($H15_o$): There are no significant differences in perception of respondents across work sector regarding the vaccines manufacturing business in KSA.

Alternative Hypothesis ($H15_A$): There are significant differences in perception of respondents across work sector regarding the vaccines manufacturing business in KSA.

Findings from the above stated hypothesis are presented in Table (4.12 to 4.13).

Table 4.12

Tests of Homogeneity of Variances

Vaccine Manufacturing	Tests of Homogeneity of Variances				ANOVA	
					95% Confidence	
Work Sector	N	Mean	Std. Dev	Levene Statistic	F	Sig
1 Government	16	5.5469	.64043	2.370	3.157	.025
2 Healthcare	86	5.5640	1.07525			
3 Academia	35	5.7071	1.18738			
4 Manufacturing	127	5.9449	.79677			
Total	264	5.7652	.95689			

The Null hypothesis (H_o) was stated to test if there is a significant difference in perception of respondents regarding vaccine manufacturing business in KSA according to work sector. One-way ANOVA results suggest that the test is significant [F ($_3$ = 3.157, p < .025)], as shown in Table (4.12). Therefore, the Null hypothesis (H_O) is rejected. To determine for individual differences between the work sectors post-hoc comparisons was assessed using Tukey HSD. Findings are presented in Table (4.13).

Table 4.13

Tukey Post Hoc Tests

Tukey HSD Multiple Comparisons

Dependent Variable: VACCINEM

Work Sector	Work Sector	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1. Government	2	-.01708	.25738	1.000	-.6826	.6484
	3	-.16027	.28528	.943	-.8979	.5774
	4	-.39801	.25078	.388	-1.0465	.2504
2. Healthcare	1	.01708	.25738	1.000	-.6484	.6826
	3	-.14319	.18954	.874	-.6333	.3469
	4	-.38093*	.13202	.022	-.7223	-.0396
3. Academia	1	.16027	.28528	.943	-.5774	.8979
	2	.14319	.18954	.874	-.3469	.6333
	4	-.23774	.18047	.553	-.7044	.2289
4.	1	.39801	.25078	.388	-.2504	1.0465
Manufacturing	2	.38093*	.13202	.022	.0396	.7223
	3	.23774	.18047	.553	-.2289	.7044

* The mean difference is significant at the 0.05 level.

To determine for individual differences between the work sectors, post-hoc comparisons was assessed using Tukey HSD. The test showed the mean score for

government sector (M = 5.5469, *SD* = .64043), for healthcare sector (M = 5.5640, *SD* = 1.07525), for academia sector (M = 5.7071, SD = 1.18738), and for manufacturing sector (M = 5.9449, *SD* = .79677), indicating that the mean difference between respondents from healthcare sector (M = 5.5640, SD = 1.07525) was significantly different from manufacturing sector (M = 5.9449, SD = .79677).

Summary of Findings

Table (4.14) presents a summary of the findings based on the statistical analysis conducted on the data gathered. This includes the hypothesis testing.

Table 4.14

Summary of Hypothesis Testing

Research objective	Research hypothesis	Findings	Remarks
1. To assess if there is a relationship between lack research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies on vaccine manufacturing business in KSA.	Null Hypothesis ($H1_o$): Lack of research and development capability does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H1_A$): Lack of research and development capability significantly impede vaccine manufacturing business in KSA.	Not statistically significant: (β = -.057, t = -1.211, p = .227),	Accept (H_o)
	Null Hypothesis ($H2_o$): Low revenue does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H2_A$): Low revenue significantly impede vaccine manufacturing business in KSA.	Not statistically significant: (β = .048, t = 1.176, p =.241)	Accept (H_o)

	Null Hypothesis ($H3_o$): High cost of investment does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H3_A$): High cost of investment significantly impede vaccine manufacturing business in KSA.	Statistically significant: (β = .313, t = 4.483, p < .001)	Reject (H_o)
	Null Hypothesis ($H4_o$): Lack of adequate infrastructure does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H4_A$): Lack of adequate infrastructure significantly impede vaccine manufacturing business in KSA.	Statistically significant: (β = -.131, t = -1.956, p < .052),	Reject (H_o)
	Null Hypothesis ($H5_o$): Lack of technical knowledge does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H5_A$): Lack of technical knowledge significantly impede vaccine manufacturing business in KSA.	Not statistically significant: (β = .048, t = 1.176, p =.241)β = -.011, t = -.180, p =.857)	Accept (H_o)
	Null Hypothesis ($H6_o$): Lack of government support does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H6_A$): Lack of government support significantly impede vaccine manufacturing business in KSA.	Not statistically significant: (β = .026, t = .626, p =.532),	Accept (H_o)

	Null Hypothesis ($H7_o$): Lack of partnership opportunities does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H7_A$): Lack of partnership opportunities significantly impede vaccine manufacturing business in KSA.	Not statistically significant: (β = .011, t = .185, p =.854),	Accept (H_o)
	Null Hypothesis ($H8_o$): Government regulation and policies does not significantly impede vaccine manufacturing business in KSA. Alternative Hypothesis ($H8_A$): Government regulation and policies significantly impede vaccine manufacturing business in KSA.	Statistically significant: (β = .316, t = 6.302, p < .001),	Reject (H_o)
2.To analyze the moderating effect of government regulations and policies in the relationship between research and development (R&D) capability, low revenue, high cost of investment in process development technology, adequate infrastructure, technical knowledge, government support, partnership opportunities, government	Hypothesis eight: Null Hypothesis ($H9_o$): Government regulation and policies does not moderate the relationship between lack of research and development capability and vaccine manufacturing business in KSA. Alternative Hypothesis ($H9_A$): Government regulation and policies moderates the relationship between lack of research and development capability and vaccine manufacturing business in KSA.	Non-significant interaction effect (β =-.047, SE=.039, β = -.501, p = .233)	Reject (H_o)
	Null Hypothesis ($H10_o$): Government regulation and policies does not moderate the relationship between low	Non-significant interaction effect (β =-.003,	Reject (H_o)

regulations and policies, and vaccine manufacturing business in KSA	revenue and vaccine manufacturing business in KSA.	SE=.040, β = .026, p = .949)	
	Alternative Hypothesis ($H10_A$): Government regulation and policies moderates the relationship between low revenue and vaccine manufacturing business in KSA.		
	Null Hypothesis ($H11_o$): Government regulation and policies does not moderate the relationship between high cost of investment and vaccine manufacturing business in KSA.	Significant interaction effect of (β =-.239, SE=.041, β = -2.299, p < .001)	Reject (H_o)
	Alternative Hypothesis ($H11_A$): Government regulation and policies moderates the relationship between high cost of investment and vaccine manufacturing business in KSA.		
	Null Hypothesis ($H12_o$): Government regulation and policies does not moderate the relationship between lack of adequate infrastructure and vaccine manufacturing business in KSA.	Significant interaction effect of (β =-.096, SE=.047, β = 1.036, p = .041)	Reject (H_o)
	Alternative Hypothesis ($H12_A$): Government regulation and policies moderates the relationship between adequate infrastructure and vaccine manufacturing business in KSA.		
	Null Hypothesis ($H13_o$): Government regulation and policies does not moderate the relationship between lack of technical knowledge and	Non-significant interaction effect (β =-.052, SE=.045, β = .563, p = .247)	Accept (H_o)

	vaccine manufacturing business in KSA. Alternative Hypothesis ($H13_A$): Government regulation and policies moderates the relationship between lack of technical knowledge and vaccine manufacturing business in KSA.		
	Null Hypothesis ($H14_o$): Government regulation and policies does not moderate the relationship between lack of government support and vaccine manufacturing business in KSA. Alternative Hypothesis ($H14_A$): Government regulation and policies moderates the relationship between lack of government support and vaccine manufacturing business in KSA.	Non-significant interaction effect (β =-.045, SE=.036, β = .509, p = .214)	Accept (H_o)
	Null Hypothesis ($H15_o$): Government regulation and policies does not moderate the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA. Alternative Hypothesis ($H15_A$): Government regulation and policies moderates the relationship between lack of partnership opportunities and vaccine manufacturing business in KSA.	Non-significant interaction effect (β =.021, SE=.044, β = .218, p = .631)	Accept (H_o)
3.To evaluate if there are any significance differences in the perception of respondents	Null Hypothesis ($H16_o$): There are no significant differences in perception of respondents across work sector regarding the vaccines	Statistically significant [F ($_3$ = 3.157, p < .025)],	Reject (H_o)

according to work sector regarding vaccine manufacturing business in KSA.	manufacturing business in KSA. Alternative Hypothesis ($H16_A$): There are significant differences in perception of respondents across work sector regarding the vaccines manufacturing business in KSA.

Discussion of the Research Findings

This research focused on three main objective which are:

1. To assess if there is a relationship between lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies on vaccine manufacturing business in KSA.
2. To analyze the moderating effect of government regulations and policies in the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA.
3. To evaluate if there are any significance differences in the perception of respondents according to work sector regarding vaccine manufacturing business in KSA.

Findings from Descriptive Statistics Analysis

Based on the data gathered from 265 respondents, descriptive statistics of the demographic profile showed that for the gender of the respondents, 169 (63.8%) are male and 96 (36.2%) are female out of 265 respondents. This showed that more males participated in the research. This is expected as the research is conducted in the KSA, wherein the workforce is constituted by men, as women are still responsible for taking care of the household of the family.

For the age groups, 57 respondents (21.5%) are within 21-30 years old, 107 respondents (40.4%) are within 31-40 years old, 63 respondents (23.8%) are within 41-50 years old, and 38 respondents are 51 and above years old. It is evident that most of the respondents are within the age group of 31–40 years old, showing that young entrepreneurs and young professionals participated in the research.

Demographic findings of the nationality of respondents also indicated that more KSA nationals participated in the research (86 percent). Furthermore, 49.9 percent of the respondents are entrepreneurs, indicating that there are more KSA nationals that are engaged in entrepreneurial business. Similarly, 16.2 percent of the respondents have worked for 21 years and above. Lastly, most of the respondents (47.9%) are from the manufacturing sector.

Findings from Hypothesis Testing

The hypothesis statement was tested using multiple regression analysis and one-way ANOVA utilizing data gathered from 265 respondents. The independent variables tested were:

(1) Lack of Research and Development Capability (R&D)

Findings from multiple regression analysis showed that the Null hypothesis was not statistically significant ($\beta = -.057$, $t = -1.211$, $p = .227$), hence, the Null hypothesis for lack of research and development (R&D) capability was accepted. However, previous studies by various authors (Makenga et al., 2019; Plotkin et al., 2017), indicated that lack of adequate R&D impedes local vaccine manufacturing. The study of Kumraj et al. (2022. p. 5), several factors were identified as challenges to an effective vaccine manufacturing business which include inadequate R&D capacity to support technology transfer. Similar challenges were also identified by Hollis (2019, p. 2) stressing that pharmaceutical organization face the huge challenge of investment in R&D while revenue from vaccine products is not always predicted. The recent outbreak of COVID-19 pandemic necessitated the need to localized vaccine manufacturing facilities for quicker availability of vaccines for prompt immunization of people in cases of an outbreak of infectious diseases.

COVID-19 pandemic has also steered a widespread vaccination operation in countries around the world resulting to vaccines manufacturing being seen as an attractive and sustainable business for a number of reasons, including the high rate of vaccine demand that has increased significantly over the past ten years and is expected to continue to rise, the significant unmet medical needs and a number of

significant disease targets for which vaccines are currently unavailable, and the innovative financing techniques that have greatly expanded vaccine markets, particularly in the developing world, vaccine manufacturing is viewed as an attractive and sustainable business (Shuman et al., 2020; Badreldin & Atallah, 2021). Furthermore, recent developments in the fields of microbiology and immunology have improved our understanding of pathogenesis and sharply increased pharmaceutical sector revenue (Portnoy et al., 2023; Arif et al., 2023; Surya et al., 2019).

(2) Low Revenue

Findings from multiple regression analysis showed that the Null hypothesis was not statistically significant ($\beta = .048$, $t = 1.176$, $p = .241$), hence, the Null hypothesis for low revenue was accepted.

Based on previous studies, low revenue from vaccine products is among the factors that impede local vaccine manufacturing due to many factors, which include high competition from established vaccine manufacturers (Sim et al., 2020).

However, Danzon and Nicholson (2012) posit that vaccines are essential for public health sustainability; as such, governments and investors spend huge amounts of money on vaccine R&D due to the elaborate production process. Furthermore, vaccine manufacturing is identified to have an inconsistent requirement in the manufacturing processes in addition to diverse regulatory requirements and limited local capability and experience. It is arguable that challenges to vaccine manufacturing are many and include factors such as costs of development and

maintenance, construction and operation of manufacturing amenities, and fulfillment with local and international regulations (Sim et al., 2020).

According to Plotkin et al. (2017), there are traditional manufacturing costs such as raw material, facilities, maintenance, and labor. There is also the challenge of the high failure rate of vaccine portfolios during production processes. All these challenges add up to high costs, which affect the overall ROI and expected revenue. Therefore, the challenge has always been the high cost and time required to complete the complex processes and capabilities for vaccine production of a broad portfolio of vaccines.

According to Kumraj et al. (2022), global health stakeholders have actively used investment cases and return on investment (ROI) to connect the costs and implications of certain health investments. In the study of Sim et al. (2020), the authors used value-of-a-statistical-life and cost-of-illness models to determine the ROI economic impact. The authors further estimated the ROI from immunization programs against 10 pathogens for 94 low- and middle-income countries (LMICs) between 2011 and 2030 using program costs. The ROI for each dollar spent on immunization against the ten selected pathogens, calculated using the cost-of-illness technique, was 26.1 USD from 2011 to 2020 and 19.8 USD from 2021 to 2030 (Sim et al., 2020). It is projected that even under the best-case scenario, it takes years for a fully integrated facility to reach commercial production capacity, and until the point of product registration and commercialization, there is typically little to no revenue during this period (Kumraj et al., 2022).

(3) High Cost of Investment

Findings from multiple regression analysis showed that the Null hypothesis for high-cost investment was statistically significant ($\beta = .313$, $t = 4.483$, $p < .001$), hence, the Null hypothesis for low revenue was rejected.

A vaccine production facility requires significant capital of an order of tens or hundreds of millions of dollars for commercial production. Facilities for vaccine manufacturing have relatively high operating costs, especially for raw materials, skilled personnel, and to continuously operate the facilities. Hence, a large proportion of the operating cost is attributed to fixed costs that are a function of the facility design (Mokbel et al., 2022, p. 12).

To maintain an organization and enable business operations generally, an entrepreneurial business's primary goal is to turn a profit (Hong et al., 2023; Hikmah, Ratnawati, & Darmanto, 2023). Consequently, even with the rise of social entrepreneurship, which seeks to improve quality of life and create social value, profit continues to be a key tenet and the goal of modern organizations (Ramoglou, Zyglidopoulos, & Papadopoulou, 2023, p. 17).

In business perspectives, an ongoing puzzle that demands an entrepreneur's attention and thought is the cost of investment vs. revenue-generating. As per Ratnasih (2017), an organization's net profit can increase if the management can decrease expenses; conversely, if the business incurs expenses, net profit will decrease.

(4) Lack of Adequate Infrastructure

Findings from multiple regression analysis showed that the Null hypothesis for lack of adequate infrastructure was statistically significant ($\beta = -.131$, $t = -1.956$, $p < .052$), hence, the Null hypothesis for lack of adequate infrastructure was rejected.

The growth of the industrial sector in any economy depends on its infrastructure.

Nworji and Oluwalaiye (2012) and Nnyamzi et al. (2022) empirical studies demonstrate how infrastructure can significantly affect output, as building adequate infrastructure can encourage industrialization, which is a necessary step toward achieving sustainable growth. Furthermore, research has shown that infrastructure, particularly soft infrastructure, can support economic diversification (Ebi & Eke, 2018) and industrial and economic growth by creating an environment conducive to productive activities (Omimakinde, 2022; Vagliasindi, M., & Gorgulu, 2023). According to an empirical study by Azolibe and Okonkwo (2020), the most significant factor influencing productivity in the industrial sector is the quantity and quality of telecommunication infrastructure.

The distribution of resources, such as production inputs and outputs, to and from industries is a useful lens through which to view the relationship between infrastructure and industrialization in any economy. Both developed and developing nations view industrialization as a significant dynamic for growth and development. To be able to achieve sustainable growth in any economy, industrialization and infrastructure work hand in hand (Umofia et al., 2018; Ansar et al., 2016).

(5) Lack of Technical Knowledge

Findings from multiple regression analysis showed that the Null hypothesis for technical knowledge was not statistically significant (β = -.011, t = -.180, p =.857), hence, the Null hypothesis for technical knowledge was accepted. The production of vaccines requires experience-based tacit knowledge, which can only be acquired by doing things repeatedly, ideally under the guidance of a more seasoned professional. (Price, Rai, & Minssen, 2020, p. 4; Druedahl, Minssen, & Price, 2021).

Jerving and Ravelo (2022) emphasized that to be able to comprehend the production process, interpret any variations found along the way, and impart this understanding to other staff members, one needs specialized scientific and biotechnical engineering knowledge. Even though the production of vaccines is a complex process, technology transfer is crucial, according to Minssen and Price (2021), and it calls for a high degree of skill and knowledge. According to Alzahrani and Harris (2021), hiring from the pool of local pharmaceutical experts may not be feasible in a nation with a sizable pharmaceutical sector where local regulatory standards fall short of international norms. As Jerving and Ravelo (2022) and Zheng (2017) further stressed, even if qualified candidates with pharmaceutical experience are found, they will require training and skill development in various and modern pharmaceutical methods of vaccine manufacturing.

There is a dearth of workers with the necessary training and experience required by the vaccination industry worldwide (Abu-Rumman, 2021; Zheng, 2017). To comprehend and identify any subtle signals that a biological activity may send

but which are not discernible in release data, vaccine manufacture needs to hire a worker with a high level of scientific understanding and an unwavering curiosity (Badreldin & Atallah, 2021; Tinworth & Young, 2020). Therefore, experienced workers use caution when considering changes in processes or facilities or when reacting to process or equipment failure (Koff et al., 2021; Kumraj et al., 2022).

Sustaining vaccine manufacturing requires developing a strong base of scientific, technical, product-specific manufacturing, and quality control system knowledge. Maintaining a solid foundation of scientific, technical, and product-specific manufacturing and quality control systems. expertise is necessary to sustain vaccine manufacturing (Ahmad et al., 2021; Johari et al., 2021).

With vast populations and strong technical and scientific education systems, nations like China, India, and Brazil have been able to produce a new generation of trained workers and technicians who are well-suited for the intricate work involved in manufacturing vaccines (Jerving & Ravelo, 2022).

It is possible that new manufacturers in other markets may misjudge how hard it is to create this sort of knowledge base and a thorough training program at the same time (Graham, 2020, p. 2). The cost of labor varies greatly between nations and depending on the qualifications and experience of the local labor force, an average facility in a low-resource nation may employ both local and foreign workers to obtain the necessary technical know-how for producing and distributing vaccines (Alzahrani & Harris, 2021; Zheng, 2017). According to Plotkin et al. (2017), the majority of foreign workers will want more total pay and benefits than local workers, which will raise labor costs overall and reduce the number of local job prospects.

(6) Lack of Government Support

Findings from multiple regression analysis showed that the Null hypothesis for lack of government Support was not statistically significant (= .026, t = .626, p =.532), hence, the Null hypothesis for lack of government support was accepted.

According to Milstien, Gaulé, and Kaddar (2007), government support and appropriate regulations granting vaccine makers access to finance are key elements that support the expansion of any country's vaccine manufacturing industry. Ho et al. (2011) stressed that vaccine manufacturers have identified the need for capital investment to ensure successful cGMP compliance and adoption of new production technology as a particular challenge that governments should take into consideration and support. This is even though private access to capital has increased due to overall economic development. It has been stressed that KSA is the only G20 country lacking a national infrastructure for vaccine manufacturing, according to Aldossari et al. (2021). As a result, the government had to take the initiative to finance the production of vaccines by regional pharmaceutical companies by utilizing the Saudi Industrial Development Fund (SIDF). Additionally, Raja and Alshamsan (2020) emphasized that the Saudi Food and Drugs Authority (SFDA) needs to be a major player in helping the public and private pharmaceutical industries align, as a lack of knowledge about bioprocessing is the main reason for the poor performance of the vaccine manufacturing industry.

Hayman, Suri, and Downham (2022) reported that the process of developing new vaccines is becoming more expensive, although the current development of vaccines received global funding commitments totaling more than US$39 billion.

Under Operation Warp Speed, the United States of America alone provided more than $9 billion. Furthermore, the USA government and the Coalition for Epidemic Preparedness Innovations (CEPI) have committed financing pledges totaling between $957 million and $21 billion to each of the top five companies (Sim et al., 2020).

The governments of China and Russia have made investments in a number of vaccine candidates that are being developed by either government-run or private businesses. This is to help many impoverished countries that lack the technological and financial means to support the development of vaccines (Hayman, Suri, & Downham, 2022, p. 23).

(7) Lack of Partnership Opportunity

Findings from multiple regression analysis showed that the Null hypothesis for lack of partnership opportunity was not statistically significant ($\beta = .011$, $t = .185$, $p = .854$), hence, the Null hypothesis for lack of partnership opportunity was accepted.

Manufacturing of vaccines is challenging, and many businesses will be hesitant to commit resources to sharing their expertise or providing product to an up-and-coming, unproven business that might end up as a rival (Azimi et al., 2019).

In this case, the technology transfer through collaboration with existing manufacturers or associations with equipped manufacturing facilities and specialized staff and equipment's are the crucial components that must be considered in any vaccine manufacturing business (Zaidi, 2021, p. 11). In order to develop local

competence through knowledge and expertise exchange and to mitigate challenges that may arise while creating infrastructure for vaccine manufacturing and financing biotechnology research, Alzahrani and Harris (2021) contend that local pharmaceutical businesses can benefit from partnering with international organizations. Partnerships with existing institutions at many stages of the value chain are essential for the development, production, and delivery of vaccine products (Zaidi, 2021, p. 11).

It is estimated that over 90 percent of manufacturers today acquire licensing agreements through partnerships with DCVM, with 62 percent of manufacturers reporting actively participating in product development partnerships (PDPs) with DCVM (Sim et al., 2020).

According to Rappuoli and Hanon (2018), DCVMN is a key partner in global influenza preparedness and response activities as well as an advocate for sustainable vaccine production capacity in developing countries.

(8) Government regulations and policies

Findings from multiple regression analysis showed that the Null hypothesis for lack of government regulation and policies statistically significant ($\beta = .316$, $t = 6.302$, $p < .001$), hence, the Null hypothesis for government regulation and policies was rejected.

In low- and middle-income countries (LMICs), national regulatory authorities (NRAs) play a crucial role in ensuring product quality, safety, and efficacy. This is crucial as establishing the production of vaccines without sufficient

regulatory capability might result in low-quality products, unfavorable outcomes, and could jeopardize the overall manufacturing processes.

General Manufacturing Practice (GMP) manufacturers depend on clear and timely information and guidance from their NRA. Given the complexity of many vaccines and manufacturing processes, it can take years, if not decades, to build capacity to effectively regulate the vaccine industry at a local level in accordance with international standards (Patil & Shreffler, 2019).

Summary of the Chapter

This chapter presented research findings from the analysis of data gathered from 265 respondents and utilized to test the stated hypothesis statements.

Findings indicated that: the independent variables:

(i) cost of investment ($\beta = .313$, $t = 4.483$, $p < .001$),

(ii) lack of adequate infrastructure ($\beta = -.131$, $t = -1.956$, $p < .052$),

(iii) and government regulations and policies ($\beta = .316$, $t = 6.302$, $p < .001$), are significant predictors of vaccine manufacturing business. Therefore, the stated Null hypothesis statements were rejected.

However, the independent variables

i. lack of research and development (R&D) capability ($\beta = -.057$, $t = -1.211$, $p = .227$),
ii. low revenue ($\beta = .048$, $t = 1.176$, $p = .241$),
iii. lack of technical knowledge ($\beta = -.011$, $t = -.180$, $p = .857$),
iv. lack of government support ($\beta = .026$, $t = .626$, $p = .532$),
v. lack of partnership opportunities ($\beta = .011$, $t = .185$, $p = .854$), were not significant.

Furthermore, the findings indicate the following.

i. significant interaction effect of (β =-.239, SE=.041, β = -2.299, p < .001) between high cost of Investment and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.

ii. significant interaction effect of (β =-.096, SE=.047, β = 1.036, p = .041) between lack of adequate infrastructure and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.

iii. non-significant negative interaction effect (β =-.047, SE=.039, β = -.501, p = .233) between lack of research and development and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

iv. non-significant interaction effect (β =-.003, SE=.040, β = .026, p = .949) between low revenue and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

v. non-significant interaction effect (β =-.052, SE=.045, β = .563, p = .247) between lack of technical knowledge and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

vi. non-significant interaction effect (β =-.045, SE=.036, β = .509, p = .214) between government support and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

vii. non-significant interaction effect (b =.021, SE=.044, β = .218, p = .631) between lack of partnership opportunities and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

One-way ANOVA results suggest that the test is significant [F ($_3$ = 3.157, p < .025)], as shown in Table (4.18). Therefore, the Null hypothesis (H_O) is rejected indicating that participants are in agreements that the study variables impact or impedes vaccine manufacturing business in KSA.

Chapter Five: Case Study and Implications

Introduction

This chapter presents a case study as an application of the findings presented in chapter four and gathers in-depth information using the interview method.

The main objectives of the case study are stated as follows: “To assess the impact of research and development (R&D) capability, low revenue, high cost of investment in process development technology, adequate infrastructure, technical knowledge, government support, partnership opportunities, government on vaccine manufacturing business in KSA.”

Case Study Design

Saunders, Lewis, Thornhill, and Bristow (2019) state that the qualitative method of data collection is an effective method for obtaining respondents opinions to answer a research question. Furthermore, Yin (2016) emphasized that the qualitative case study method of data collection is a competent method for data collection that shows present events surrounding the research topic. In addition, Hair, Page, and Brunsveld (2019) assert that case studies are appropriate for gathering data that deals with technology, innovation, and human skills.

In this research, the case study method was utilized for data collection to enable ascertaining detailed information on the factors that impede vaccine manufacturing in KSA.

Data Collection Procedure

This section presents the procedure employed in gathering qualitative data. The researcher employed an external professional who conducted the interview with respondents that agreed to participate in the study. This was done to avoid bias.

A face-to-face interview was conducted with twenty-two (22) participants (entrepreneurs, healthcare practitioners, academicians, and government workers) who are actively working in KSA but did not participate in the quantitative study reported in chapter four.

The interviews were conducted from September 20th to September 30th, 2023. Each interview session lasted for about twenty to thirty minutes. The interviews were recorded and transcribed by a professional using the Thematic Analysis Method. Table (5.1) lists the interview questions as follows:

Table 5.1

Case Study Interview Questions

Research Objective	Main Factors	Questions
1.To assess the impact of lack research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support,	Lack of research and development (R&D) capability.	In your opinion do you think that KSA has research and development capability to handle vaccine manufacturing? Please explain.
	Low revenue,	Every business needs to make profit to sustain operations, in your opinion do you think entrepreneurs/investor can make enough revenue from vaccine manufacturing in KSA? Please explain.
	High cost of investment in process development technology.	Vaccine manufacturing takes time with high cost of investment. Do you think this is an impediment for entrepreneurs/investors in KSA? Please explain.

lack of partnership opportunities, government on vaccine manufacturing business in KSA	Lack of adequate infrastructure.	In your opinion do you think that KSA has adequate infrastructure to handle vaccine manufacturing? Please explain.
	Lack of technical knowledge,	Technical knowledge in vaccine manufacturing is an indispensable factor. In your opinion, do you think KSA has the expertise? Please explain
	Lack of government support,	Establishing a strong hold in vaccine manufacturing is one of the ways to meet the Saudi Vision 2030 in healthcare. To what extent is the government supporting it? Please explain
	Lack of partnership opportunities.	Vaccine manufacturing needs collaboration and partnership. Do you think there are such opportunities in KSA? Please explain.
	Government regulations and policies	In your opinion do you think that government regulations and policies are an impediment to vaccine manufacturing? Please explain

Data Analysis

Thematic analysis methods facilitated the transcription of the interview data gathered from the 22 professionals that participated in the face-to-face interview session. Appropriate codes were used to identify patterns and themes from the data. The demographic profiles of the participants were determined and filled out before commencing the interview.

Table (5.2) lists the demographic profile of the participants, which includes gender, age, nationality, educational background, job title, years of working experience, and work sector.

Table 5.2

Case Study - Demographic Profile

	Gender	Age	Nationality	Educational background	Job Title	Years of Working	Work Sector
1	Male	41-50	Non-Saudi	Master's Degree	Health Practitioner	16-20 years	Manufacturing
2	Male	51 – above	Non-Saudi	Bachelor's |Degree	Entrepreneur	21 years and above	Manufacturing
3	Male	21 – 30	Saudi	Bachelor's Degree	Entrepreneur	Less than 5 years	Business/Entrepreneur
4	Female	21 – 30	Saudi	Bachelor's Degree	Entrepreneur	Less than 5 years	Business/Entrepreneur
5	Male	21 – 30	Saudi	Bachelor's Degree	Academician	Less than 5 years	Academia
6	Male	31 – 40	Saudi	Master's Degree	Entrepreneur	16 – 20 years	Manufacturing
7	Male	31 – 40	Non-Saudi	Bachelor's Degree	Entrepreneur	16 – 20 years	Manufacturing
8	Male	21 – 30	Saudi	Bachelor's Degree	Government Worker	Less than 5 years	Government
9	Male	21 – 30	Saudi	Bachelor's |Degree	Entrepreneur	Less than 5 years	Manufacturing
10	Male	21 – 30	Saudi	Bachelor's |Degree	Entrepreneur	Less than 5 years	Manufacturing

11	Male	31 – 40	Saudi	Master's Degree	Government Worker	6 – 10 years	Government
12	Male	51 above	Non-Saudi	Bachelor's Degree	Entrepreneur	21 years and above	Manufacturing
13	Male	21 – 30	Saudi	Bachelor's Degree	Entrepreneur	6 – 10 years	Manufacturing
14	Male	41-50	Saudi	Master's Degree	Academician	16 – 20 years	Academia
15	Male	21 – 30	Non-Saudi	Master's Degree	Academician	Less than 5 years	Academia
16	Female	31 – 40	Saudi	Doctorate Degree	Academician	11 – 15 years	Academia
17	Male	21 – 30	Saudi	Doctorate Degree	Health Practitioner	Less than 5 years	Healthcare
18	Male	21 – 30	Saudi	Bachelor's Degree	Health Practitioner	Less than 5 years	Healthcare
19	Male	21 – 30	Saudi	Bachelor's Degree	Health Practitioner	Less than 5 years	Healthcare
20	Male	21 – 30	Saudi	Bachelor's Degree	Government Worker	6 – 10 years	Government
21	Male	51 above	Saudi	Doctorate Degree	Academician	21 years and above	Government
22	Male	51 above	Saudi	Doctorate Degree	Entrepreneur	21 years and above	Healthcare

5.3.2 Analysis of Interview Questions

The section presents analysis of the qualitative data gathered through interviews with 22 key opinion leaders in KSA from entrepreneurs, healthcare practitioners, academician, and government workers.

(i) Variable: Research and Development (R&D) capability

Question #1. In your opinion, do you think that KSA has research and development capability to handle vaccine manufacturing? Please explain.

Participant 1, 17, 18 and 19, all healthcare practitioners said: *"In KSA, there are dedicated government universities known as King Abdulaziz City for Science and Technology (KACST) as well as King Abdullah University of Science and Technology (KAUST). These institutions provide high level of research, development, and clinical trials, which constitute the main potential research centers for vaccine."*

Participants 2, 4, 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: *"Yes. The Kingdom of Saudi Arabia has a high standard of regulations through the Ministry of Health; therefore, I am very positive that KSA can handle the vaccine manufacturing.*

Participant 3, an entrepreneur, and participant 11, a government worker on the other hand answered *both "Yes and "No." He said, "In the past, Saudi government has worked on R&D as there is no vaccine manufacturing in the region. The kingdom is capable to do this in the future but for now, it is not yet ready, considering the current situation."*

Participant 8, a government worker emphasized further*: "KSA capabilities are big and huge when it comes to healthcare sector. One of the aspects or factors to rely on that is the amount or number of Saudi people who achieved first or top in their class on research overseas, like the US, in multiple competition where the Saudi team gathered 22 prizes for their efforts in multiple sectors and we hear a lot of achievements from Saudi people once in a while, like doing sophisticated surgeries and performing biotechnology achievements."*

Participant 14, an academician said: *"Right now, we are at an early stage of R&D, which should be led by Research Centers and universities but as we grow, there would be R&D with local vaccine manufacturing companies. In vaccine development, we need to first conduct animal studies to see whether the vaccine is safe, effective, and has a good quality. Usually, they do it on naïve animals just to see the adverse effect or the safety of vaccines until they reach the step where they can now do the 'challenge models' where they infect the animal. So, the challenge we face right now is that there is no established infrastructure to handle more serious challenges. In KSA, presently, we do not have a vaccines center for research and development. Usually, we only have small labs here and there, but it is not sustainable approach as there are no established entities that deals with vaccine research from A-Z. This is the situation, both in the academia as well as in the industrial scale. For that, I can say that we do not have R&D capability in KSA. It would be great if we could have an opportunity to explore this as I have been to different countries, including the USA, where they have nicely designed infrastructure and R&D capability.*

Participant 16 and 21, both academicians said: *"Actually, when we talk about research and development capability, I can go for a "Yes," as we have plenty of universities, both private and government, and all of these universities have a medical college and also, are doing research particularly in the health field as they even do a lot of publications and journals on this. So, yes, KSA has the ability to do R&D.*

Participants 18, and 19 – both health practitioners added: *"In my opinion, Saudi Arabia (KSA) has the research and development capability to handle vaccine manufacturing. For example, in my college, which is King Saud bin Abdulaziz for Health Sciences as well as in King Faisal Hospital, they have a clinical research center. KSA has made significant investments in scientific research and development in the recent years, including the healthcare sector and has established various research institutions and universities that focus and medical and pharmaceutical research and this can contribute to vaccine development."*

Participant 22, an entrepreneur, and private consultant said: *"The environment now in Saudi Arabia and the resources deployed for anything medical related is being pushed in KSA as the experience we had during the time of Coronavirus pandemic has taught us that we cannot simply rely on other countries. So, even if KSA has not established a strong R&D capability yet, it will not be a problem once this project is established. I am confident that the government will fully support it."*

(ii) Low revenue

Question #2. Every business needs to make a profit to sustain operations. In your opinion, do you think entrepreneurs/investors can make enough revenue from vaccine manufacturing in KSA? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, as well as participant 11, a government worker commented that*: "Currently, for the vaccine manufacturing, there are no companies in Saudi Arabia that fully manufacture vaccines. In this case, we can say on the basis of revenue that there is no competition… but it is very important to choose high value products to be produced in lesser quantity. This way, the revenue will be very high. In addition, Saudi is blessed with a good geographical location with strong economic ties with other countries, which gives us access large markets such as Asia and Africa which can be considered for a profitable business. With the right marketing and distribution strategies, manufacturers can tap into both domestic and international markets."*
- Participants 2, 6, 7, 9, 10 and 12, all entrepreneurs and participant 5, an academician said: *"If the production of the vaccine is manufactured locally and the supply for the local market will come from the local companies, I think it would be profitable, while also considering how the vaccines can be exported to the nearby markets within the GCC region, which I believe is one of the kingdom's aims."*
- Participant 3, an entrepreneur, and participant 16, an academician explained: "*Yes. Actually, vaccine is an important part of fostering the*

nation's health, especially in times of emergency – just like what happened during the time of Covid20. In fact, if a country like Saudi Arabia can produce its own vaccines and deliver it on time, as it is needed, it can prove to be a great source of revenue for entrepreneurs and investors alike."

- Participant 4, an entrepreneur said: *"I believed that investors can definitely find great returns on their investments. Although there is no vaccine manufacturing in KSA right now, I believe that with the right expertise and team, KSA can succeed in this project/business. In fact, we have Saudi Bio that manufactures insulin, which is also the first in Saudi."*
- Participant 14, an academician said: *"I think, 'Yes,' due to several reasons. First, there is a need for KSA to have vaccine manufacturing capabilities. There is zero vaccine manufacturing in Saudi Arabia right now; although there are different entities in Saudi Arabia who are interested to develop vaccines, it is still not fully matured. If opportunities for vaccines or biotechnology opens up, it would be a great opportunity to gather the best minds to make it happen. I was discussing with the Ministry of Health that we need to bring all these packages/initiatives together so we can give these packages/initiatives to the investors and make their life easy to go through the exercise much easier rather than talking to each entity in a separate way. It is important that we make it easier for the investors to fill the gaps, and the support of the government is greatly needed. To be honest, there are different initiatives now on the government level. These initiatives will make it clear not only what kind of vaccines we want in Saudi Arabia since we cannot localize all the vaccines as we have different*

criteria; but to focus on certain vaccines that are very important to be localized based on the need in KSA."

- Participant 21, an academician said: *"Yes, I can actually give an example. I was actually a member of the Saudi parliament for 12 years and during those years, I was able to explore the difficulties that people in the health business are facing. For example, during the time of COVID-19, I was in different meetings with people working for Saudi F&DA (Food and Drug Authority), and most of them are actually talking about the difficulty of transferring some medical items like ventilators and masks and were very shocked to realize that there were not enough manufacturers inside the country that can provide the hospitals with these things, which meant relying on other countries to supply our country. However, there was shortage everywhere so, now, we can even say, "Thanks to COVID-19, we highlighted the importance of having our own manufacturing industry medical products like these, which is also the same for the case of vaccines. In fact, the time of COVID-19 has also made us realize how important it is to avoid long waiting times just to receive the medical supplies we needed, which could be avoided if KSA had its own manufacturing industry and not only relying on importation. Therefore, I am sure that the investors can make enough revenue for vaccines manufacturing in Saudi Arabia based on these examples I provided."*
- Participant 22, an entrepreneur, and private consultant said: *"I think the revenue for vaccine manufacturing would be really good because of the high demand on the vaccine we want to manufacture. Therefore, as an entrepreneur, I have no worry about the income that we are going to make*

from this, if ever this project becomes a reality, especially that it would be the first vaccine manufacturing in Saudi Arabia."

(iii) High cost of investment in process development technology

Question #3. Vaccine manufacturing takes time with high cost of investment. Do you think this is an impediment for entrepreneurs/investors in KSA? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, and participant 11, a government worker responded: *"Saudi government has made healthcare innovation a priority, considering the business opportunities in KSA, there are investors who are interested to invest in this area (vaccine manufacturing) because of the competition landscape. Moreover, the public investment fund is there to support investors to be financially supported and also, there are tax breaks and low-cost land to help in the cost of investment in the process development technology. Furthermore, participant 11 further emphasized: "I have firsthand experience with these investors that showed great interest on vaccine manufacturing should this become a reality in KSA."*
- Participants 2, 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: *"No. It is not an impediment. I can see that by entering into any established partnerships in this field, this will certainly minimize the payback period irrespective of the size of the investment."*
- Participant 3, an entrepreneur responded: *"Some investors are interested in short term return investments, while some do not mind as it can take longer time to see the ROI on special projects like this. But, if I were to invest in*

myself, I would definitely support it. Although it can take some risks, I will definitely take it because I believe that 'high risk means high revenue.'"

- Participant 4, an entrepreneur, and participant 16, an academician both said: *"I believe that vaccine manufacturing will take time as it is a new biotechnology. But I believe that it will have positive encouragement amongst investors as many are interested in exploring this field. So, even if it will take time, I believe that it will give great returns that the high cost of investment would not be an impediment to entrepreneurs and investors."*
- Participant 8, a government worker emphasized further: *"If an investor is coming from the healthcare sector, he might understand this kind of issue that it will take time to do R&D, but if the investor is not from the healthcare sector, he might stand against the obstacles in his ways. Therefore, it is very important to prepare well for this industry to avoid impediments."*
- Participant 14, an academician said: *"Yes, it is right. It will take time and cost which could be a great disadvantage or challenge for investors. Since we do not have our own active lab with R&D capability to boost vaccine manufacturing, we need to bring this technology from outside through partnership with other entities, which will definitely take time to transfer, aside from the costs involved."*
- Participant 21, an academician said: *"Yes, it works as a barrier in this field. Without the support of the government, it's going to be very difficult to invest in vaccine manufacturing. Anything related to the medical field includes high cost of investment, so, it is very important that the government supports it through Saudi Development Bank or Saudi Commercial Bank to support*

anyone who would invest in vaccine manufacturing. Based on my own knowledge regarding this point, I believe it is an impediment as without the support of the government, it is very difficult to start this kind of business."

- Participant 22, an entrepreneur, and private consultant said: *"I know that we had a history before as the first insulin manufacturer in Riyadh. It was done by us, so I really know that it would cost a lot, but the ROI is really great. SO, I think entrepreneurs and investors would be likely to push this and likely to join.*

(iv) Adequate infrastructure

Question #4. In your opinion, do you think that KSA has adequate infrastructure to handle vaccine manufacturing? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, and participant 11, a government worker, responded that: *"For vaccine manufacturing, facilities are still under development in KSA. However, we have good reliable electricity, water treatment facilities, and waste management systems where all cities can meet the standards for vaccine manufacturing production. This is why the government is investing heavily in this, just like the way we have seen with SAUDIBIO, which is why we are positive that this can be done. Therefore, whoever could construct a vaccine manufacturing facility will bring a good opportunity for the infrastructure that considers vaccine manufacturing. Presently, KSA is only doing the repacking of vaccines as there is no manufacturing facility for this sector in the kingdom yet."*

- Participants 2, 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: *"Yes. It can handle. The investors can construct their facilities easily as Saudi is known for building good infrastructures.*
- Participant 3, an entrepreneur responded: *"Yes, but it depends on the capability or the infrastructure handling. Saudi has a lot of support for manufacturing, healthcare, and R & D but I believe that if I were to put it on a scale, it would be around 70%. Nevertheless, I believe that Saudi has the capability to do this if ever vaccine manufacturing would be pursued in the kingdom."*
- Participant 8, a government worker noted: *"I am not totally aware of the existing infrastructure for vaccine manufacturing in particular, but I believe that there is a huge potential for this industry from the top of the leadership pyramid in the country. They really care about this industry as it addresses the future of humanity's health and not just serving the Saudi people. Therefore, it is very important to have the right infrastructure to support this ideal. However, I believe in the capability of Saudi hospitals like King Faisal Hospital or King Khalid Hospital, for example, and some other hospitals owned by the government which have big R&D laboratories, but of course, it would be better if Saudi can open up more laboratories and its own vaccine manufacturing facilities to support the overall healthcare sector in KSA."*
- Participant 14, an academician said: *"No. We still at an early stage so we are dependent for vaccines on importing all of these vaccines from outside sources. And one very important point is that, usually, the vaccines we receive from outside Saudi Arabia has been developed based on the*

pathogenic organisms, either bacterial or viral" which is circulating in those particular countries where they come from, and this may not reflect the situation in Saudi Arabia. Therefore, we need to make our own vaccines based on our national problems for the vaccine to be effective and safe."

- Participant 16 and 21, both academicians said: *"With these development on different aspects of life in Saudi Arabia, especially related to investment and specifically, foreign investment, I would say "Yes, Saudi Arabia can have adequate infrastructure to handle vaccine manufacturing based on what we have seen based on the plans that come out of Saudi Vision 2030."*
- Participant 22, an entrepreneur, and private consultant said: *"I think they do have the facilities to go ahead and do this kind of project. I believe that they are well-equipped, like King Abdullah University and KACST, and they are really helpful to us regarding the start of this project. They are really helping, especially the government."*

(v) Technical Knowledge

Question #5. Technical Knowledge in vaccine manufacturing is an indispensable factor. In your opinion, do you think KSA has the expertise? Please explain.

- In response to the question concerning technical knowledge, Participant 1, 17, 18 and 19, all healthcare practitioners, and participant 11, a government worker. emphasized that: *"While KSA do not currently have it, but it is definitely in the works, and we are currently developing. There are a lot of experts for consulting vaccine manufacturing in KSA, particularly, in the government sector where technical knowledge and support is encouraged,*

like in KACST. However, it is also very important to promote partnerships on this so that technical difficulties will not be a problem.

- In addition, Participants 2 and 4, both entrepreneurs emphasized as well that: *"…there are a lot of scientists in KSA that can work in the research labs and industrial facilities who are capable to execute the technical knowledge for vaccine manufacturing."*
- Participants 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: *"Yes and No." Since vaccine is new in the region, a lot of outsourcing for technical skilled professionals are needed. However, I believe that it is not impossible for KSA to succeed in this as long as it is fully supported in all ways.*
- Participant 8, a government worker, and participant 26, an academician both said*: "I may not be an expert in this field, but as a Saudi national, I believe in our country, in our people, and its ability to produce things that we all can be proud of today. We have great minds and have people with the know how that can pull this on, but they need the right push to gather all the stakeholders to discuss all the pieces of the puzzle together.*
- Participant 14, an academician said: *"This is very important because, even if you have the money and you bought the machines, but you don't have the technical experts that were trained in the field of vaccine manufacturing, it is hard to sustain this business. I also believe that it is equally important to establish robust programs in Saudi Arabia. For example, even in big universities like King Faisal University, we do not have programs for biotechnology or even vaccine-based programs (either in academic,*

graduate, or fellowship/training program. In King Saud University, we are trying pharmaceutical biotechnology for Executive Master Program that aids graduate students on vaccines, biosimilars, and genomics where we are mixing the academic part with the industrial part; so as not only to give them the theoretical part but also handle the experience in the vaccine development and manufacturing. I am working for King Saud University, so I was very lucky to join a fellowship or training program for vaccine development in 2016, which was a collaboration program with Center for Vaccine Development at Maryland College of Medicine and Texas Children Hospital in Houston, where I worked as a scientist and got trained on vaccine development where we also worked to develop vaccine on MERS (Middle East Respiratory Syndrome) which was first identified in Saudi Arabia in 2012 as a viral respiratory disease caused by Middle East respiratory syndrome coronavirus (MERS-CoV) where we have 80% of cases in Saudi Arabia. I realized after this that, it is very important to train people from different level and background, like Focus Area Training with specific programs training from early stage of research and development to bio-process manufacturing, to quality control, and to quality assurance. I believe that KSA is coming to this but there is still a big gap to address."

- Participant 17, a healthcare practitioner further added: *"We have a few research institutions like King Faisal Research Hospital, which sends young researchers abroad to practice in different areas and be part of research in other hospitals abroad and gain expertise so that they can come back home and served our country better."*

- Participant 21, an academician said: *"Nowadays, there are plenty of people who are working in Saudi Arabia, both foreigners and locals, with very high level of education from established institutions and universities all over the world. So, as far as expertise of workers are concerned, I believe that KSA has the capacity."*
- Participant 22, an entrepreneur, and private consultant said: *"Although this is a new subject for Saudi Arabia, thankfully, we have very intelligent researchers; we've met a lot of them during the insulin manufacturing as well as good group of scientists. They are willing and they only need a push. And we are here to push, especially that this is for the greater welfare of our people."*

(vi) Government Support

Question #6. Establishing a strong hold in vaccine manufacturing is one of the ways to meet the Saudi Vision 2030 in healthcare. To what extent is the government supporting it? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, and participant 11, a government worker responded that: *"…the government of KSA is in full support of the healthcare sector as part of the Saudi Vision 2030, and definitely, vaccine manufacturing would be greatly encouraged as it is the first time for the country to attempt manufacturing its own vaccine. Additionally, they provide funding and financial support by investing on it, in fact, there was a conference last week about biotechnology, so I think the*

government is investing a lot in order to achieve the visions of Saudi Vison 2030, which hopefully includes vaccine manufacturing."

- Participants 2, 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: *"The government is fully supportive of anything that has to do with biotechnology or biotech industries. Anything that would support the health of the nation without relying on other countries, especially in vaccine manufacturing, is always welcomed by the Saudi government to position itself as the leader in the Arab region."*
- Participant 3, an entrepreneur added: *"Somehow the government is fully supportive at this moment. The government has established an R&D Supreme Committee and is trying to help investors who are focused to take their investments to Saudi, to manufacture medicines and vaccines locally instead of relying on importation from western countries."*
- Participant 8, a government worker said: *"I believe we are the only country in the world that gives free healthcare and just imagine if we can also have our own vaccine manufacturing inside our own country, it will definitely boost the economy as well as create more jobs and contribute to the GDP of the nation. It is very huge, and I believe that the government of Saudi gives utmost importance to this kind of endeavors, so it is important for the government to put regulations in place in order to guide the process successfully from the vaccine manufacturer to the consumers."*
- Participant 14 and 16, both academicians said: *"Healthcare is one of the most important items to focus on for Saudi Vision 2030, and vaccine manufacturing is one of them. As I said, vaccine is one of the priorities in our*

national biotech strategy, and therefore a top priority for the government to support programs relating to it through the help of Ministry of Health, Ministry of Industry, and Ministry of Investment as well as Saudi FDA and the Health Council. All these efforts must be united so that it would be clear for the investors and vaccine manufacturers how they can move forward and make sure that they have the right support from the government, in every stage, in order to clear pathways and achieve our strategies and objectives."

- Participant 21, an academician said: *"As I was a member of the Saudi parliament for 12 years, I had the privilege to understand two main regulations for health, where I personally worked on. One of them is 'General Health Regulation' is the 'Manpower Health Professional Regulation.' In 2018, we actually had an article pertaining to these two main health regulations. We worked very hard at the time to change all the articles inside of these two health regulations, to cancel or delete anything that does not allow to invest in manufacturing or building a business in Saudi Arabia. Now, all the regulations allow any person to build or work in the professional fields, especially in health-related projects (like vaccine manufacturing) to come and work freely in KSA without any limit or problem."*
- Participant 22, an entrepreneur, and private consultant said: *"They are really supporting in every possible way they can. As I told you, they are really trying to help from the funds to the government support… everything… and we are pushing them on the same track as we are just to move forward with this vaccine manufacturing."*

(vii) Partnership Opportunities

Question #7. Vaccine manufacturing needs collaboration and partnership. Do you think there are such opportunities in KSA? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, and participant 11, a government worker emphasized that: *"…there are a lot of potential investors looking this opportunity, both from the private as well as the public sector, as they can see the potential to invest in Saudi Arabia. Just like the project of SAUDIBIO with Novartis for insulin, as well as other pharmaceutical companies such as LIFERA. These examples are good points to consider partnership opportunities for vaccine manufacturing."*
- Participants 2, 6, 7, 9, 10 and 12, all entrepreneurs, and participant 5, an academician said: "*Many people in Saudi, both from the public and the private sectors, as well as international investors are showing a great deal of interest on vaccine manufacturing. I believe that there is a big opportunity for this, and maybe they will open more ideas when and if this project is done in the kingdom."*
- Participant 3, an entrepreneur added*: "I think, yes." Especially from the government, Saudi Fund for Manufacturing, which gives loans and monetary support (Public Investment Fund), and a lot of investors would be attracted to this to support the MENA region. And anything that the government supports will be successful so if this happens in Saudi, it is certainly ready to take on this challenge."*

- Participant 8, a government worker said: *"In any type of industry, collaboration is crucial, especially in vaccine manufacturing. Therefore, I believe that KSA has these kinds of opportunities because we have always had major collaborations and did very good partnerships with different countries in the world, like France, US, China, and India which has always been very successful that, our country's this year GDP is 1 trillion dollars. Imagine doing the same for vaccine manufacturing, it's going to be massive success."*
- Participant 14 and 21, both academicians said: *"There is a huge opportunity in vaccine manufacturing, not only for the Saudi population but also the for the region of Middle East and North Africa (MENA) and I believe that KSA can lead on this. Currently, collaboration is also encouraged between the national level and the local level unlike before, especially that the private sectors know the business side of vaccine initiatives and it is unfair for the government sector to neglect them. If we were to achieve success on this, partnerships and collaboration is the only way to go, especially in establishing robust R&D through universities, research (R&D), and training centers. Most of all, the technical knowledge needs the international support and help in order to accelerate the vaccine localization."*
- Participant 22, an entrepreneur, and private consultant said*: "Since this is the first facility in Saudi Arabia for vaccine manufacturing, all the major players will be in contact with us for our facility because during Covid pandemic, we received a lot of interest to do the vaccine in our insulin factory. However, we said that we do insulin, and not vaccine. So, according to the input we had during COVID, we started thinking that this is also an important project*

to do. Therefore, we started to talk about this, starting with the ministries and they completely supported our aim. With their help, we can do this without doubt."

(viii) Government regulations and policies

Question #8. In your opinion, do you think that government regulations and policies are an impediment to vaccine manufacturing? Please explain.

- Participant 1, 17, 18 and 19, all healthcare practitioners, referred to the way KSA handles its government regulations and policies, particularly in things concerning the overall health of its people and further emphasized that *"Food and Drug Authority in Saudi has complete guidelines, i.e., Current Good Manufacturing Practice (CGMP) Guidelines with which other regulations and policies follow suit. In fact, the Saudi government gives incentives to entrepreneurs as well as tax breaks to help in product development and further research to understand deeper the value of vaccine manufacturing in KSA."*
- Participants 2, 6, 7, 9, 10, and 12, all entrepreneurs, and participant 5, an academician said: *"The localizing of new industries and know how in KSA is fully supported by the government. Therefore, I am confident that there will be no discouragements when it comes to pursuing vaccine manufacturing in KSA."*
- Participant 3, an entrepreneur added: *"Yes. Somehow. Because there are a lot of new technologies that no one is familiar with in Saudi. Therefore, a lot of*

research and study should be done but if the government supports it, it can be done.

- Moreover, participant 4 who is also an entrepreneur as well as participant 11, a government worker, further emphasized *"…how strict measures must be observed to ensure the safety of the people. Therefore, the partnership must be done with the support of the government and collaborate with private companies to ensure good regulations and policies."*
- Participant 8, a government worker as well as participant 16, an academician both said: *"I am optimistic about the possibility of having our own vaccine manufacturing in KSA. Moreover, I believe in our government and our vision, especially that the top leadership is giving the private sector a chance to join this industry. The regulation is good in order to make sure that KSA can produce only the best, as all sectors come together and make this vision a reality."*
- Participant 14 and 21, both academicians said: *"As of the moment, the system is not clear especially for the investors as it usually takes long time if we take it from the business perspective which is a challenge in itself. But based on my knowledge and connection with different entities, like Saudi FDA, which is part of the national biotech committees and sub-committees, which facilitates how vaccines should be regulated, which are working on their system to support the regulation on vaccine manufacturing, which is what I heard from them. On the other hand, there are also newly established entities including Saudi NIH (National Institute of Health). This is a kind of regulator for health-related projects, and they are also funding money to support different activities in the health system. One of their mandates is to*

support clinical trials in Saudi Arabia, which are very important to have if ever KSA would decide to proceed in the vaccine manufacturing. Therefore, I can say with confidence that the government of Saudi Arabia is fully supportive to make sure that the regulations and policies are not impeding these kinds of developments, by supporting the local pharma as they engage to collaborate with the big pharma outside of KSA."

- Participant 17, a healthcare practitioner further added: *"With the Saudi Vision 2030, the government is trying to ease these obstacles for the greater good but also, to make sure that the regulation and quality of these projects are maintained, as regulated by Saudi FDA and Ministry of Health to ensure that the quality of the products are good for the consumers."*
- Participant 22, an entrepreneur, and private consultant said: *"Since we are the one trying to make this a reality, we are the ones communicating with everybody. I think that the rules and regulations will be customized to what Saudi Arabia needs, rather than anybody else. I think they are really working hard on doing so, so that it would be safe for our people. Normally, when they make vaccine in other countries, they have to make trials for it, but they don't consider our population. And the genes differ a lot, therefore, our aim is to make this vaccine for our own Arab people. And the beauty of the position of Saudi Arabia is that we are in the middle of everything, and we are surrounded by all Arab states. Therefore, we can really study all Arab people."*

Findings and Summary of Qualitative Data

The findings and summary of the main themes from the thematic analysis of the qualitative are presented in Table (5.3).

Table 5.3

Variable and Main Themes - Findings

Main Variables	Interview Questions	Themes
Research and development (R&D) capability	In your opinion, do you think that KSA has research capability to handle vaccine manufacturing? Please explain.	- No research and development for vaccine in KSA - Universities as potential R&D Centers
Low revenue	Every business needs to make a profit to sustain operations. In your opinion, do you think entrepreneurs/investors can make enough revenue from vaccine manufacturing in KSA? Please explain.	- KSA has potential for high revenue from vaccine manufacturing
High cost of investment in process development technology	Vaccine manufacturing takes time with high cost of investment. Do you think this is an impediment for entrepreneurs/investors in KSA? Please explain.	- Financial Investment is a challenge
Adequate infrastructure	In your opinion, do you think that KSA has adequate infrastructure to handle vaccine manufacturing? Please explain.	- There is possibility for making available vaccine infrastructure in KSA
Technical knowledge	Technical knowledge in vaccine manufacturing is an indispensable factor. In your opinion, do you think KSA has the expertise? Please explain.	- Technical knowledge for vaccine manufacturing is a challenge for KSA
Government support	Establishing a stronghold in vaccine manufacturing is one of the ways to meet the Saudi Vision 2030 in healthcare. To what extent is the government supporting it? Please explain.	- Government support is available for vaccine manufacturing

Partnership opportunities	Vaccine manufacturing needs collaboration and partnership. Do you think there are such opportunities in KSA? Please explain.	- Many partnership opportunities for vaccine manufacturing
Government regulations and policies	In your opinion, do you think that government regulations and policies are an impediment to vaccine manufacturing? Please explain.	- KSA has rigorous rules and regulations for the manufacturing sector

Table 5.4

Comparison of Research Findings: Quantitative and Qualitative Case Study

Main factors	Findings from Quantitative Study	Findings from Qualitative Case Study	Points of Convergence	Points on Divergence	Comments Based on Literature Review
1. Lack of research and development capability (R&D).	Findings from multiple regression analysis showed that the Null hypothesis was not statistically significant (β = -.057, t = -1.211, p = .227), hence, the Null hypothesis for lack of research and development (R&D) capability was accepted.	KSA lacks research and development capacity for vaccine in KSA	Findings in both studies indicate a divergence.	Different opinions based on perspectives	Makenga et al., 2019; Plotkin et al., 2017), Hollis (2019, p. 2)
2. Low revenue	Findings from multiple regression analysis showed that the Null hypothesis was not statistically significant (β = .048, t = 1.176, p =.241), hence, the		Findings in both studies indicate a divergence.	Different opinions based on perspectives	Danzon and Nicholson (2012), (Sim et al., 2020). Plotkin et al. (2017), Kumraj et al. (2022),

	Null hypothesis for low revenue was accepted.			
High cost of investment	Findings from multiple regression analysis showed that the Null hypothesis for high-cost investment was statistically significant ($\beta = .313$, $t = 4.483$, $p < .001$), hence, the Null hypothesis for low revenue was rejected.	Findings in both studies indicate a convergence of opinions.	No point of divergence based on both findings.	(Mokbel et al., 2022, p. 12); (Hong et al., 2023; Hikmah, Ratnawati, & Darmanto, 2023). (Ramoglou, Zyglidopoulos, & Papadopoulou, 2023, p. 17).
Lack of adequate infrastructure	Findings from multiple regression analysis showed that the Null hypothesis for lack of adequate infrastructure was statistically significant ($\beta = -.131$, $t = -1.956$, $p <$	Findings in both studies indicate a convergence of opinions.	No point of divergence based on both findings.	Nworji and Oluwalaiye (2012) and Nnyamzi et al. (2022). (Omimakinde, 2022; Vagliasindi, M., & Gorgulu, 2023).

	.052),), hence, the Null hypothesis for adequate infrastructure was rejected.			
Lack of technical Knowledge	Findings from multiple regression analysis showed that the Null hypothesis for technical knowledge was not statistically significant (β = -.011, t = -.180, p =.857), hence, the Null hypothesis for lack of technical knowledge was accepted.	Findings in both studies indicate a convergence of opinions.		(Price, Rai, & Minssen, 2020, p. 4; Druedahl, Minssen, & Price, 2021).
Lack of government support	Findings from multiple regression analysis showed that the Null hypothesis for lack of government Support was not	Findings in both studies indicate a divergence.	Different opinions and perspectives	Milstien, Gaulé, and Kaddar (2007), Aldossari et al. (2021). Alshamsan (2020).

	statistically significant (β = .026, t = .626, p =.532), hence, the Null hypothesis for technical knowledge was accepted.			Hayman, Suri, and Downham (2022)
Lack of partnership opportunity	Findings from multiple regression analysis showed that the Null hypothesis for lack of partnership opportunity was not statistically significant (β = .011, t = .185, p =.854), hence, the Null hypothesis for technical knowledge was accepted.	Findings in both studies indicate a divergence.	Different opinions and perspectives	(Sim et al., 2020; Rappuoli & Hanon, 2018).
Government regulation and policies	Findings from multiple regression analysis showed that the Null hypothesis	Findings in both studies indicate a divergence. Different opinions and perspectives	Different opinions and perspectives	(Patil & Shreffler, 2019). (Azimi et al., 2019).

			for lack of government regulation and policies statistically significant ($\beta = .316$, $t = 6.302$, $p < .001$), hence, the Null hypothesis for government regulation and policies was rejected.

Discussion and Implications of the Findings

The process of manufacturing vaccines is fraught with challenges such as adequate production facilities, machinery, lead times, product portfolio management, life cycle management, intellectual property (IP), process development, and general maintenance, which results in factors that hinder vaccine manufacturing, especially in developing nations (Tawfik et al., 2022; Plotkin et al., 2017).

Studies have identified many of these factors to include lack of R&D capability, the issue of low revenue, high cost of vaccine investment, lack of infrastructure for vaccine manufacturing, technical knowledge for vaccine manufacturing technology, lack of opportunities for partnership with existing associations, and regulation, laws, and policies guiding vaccine manufacturing (Sim et al., 2020; Makenga et al., 2019; Plotkin et al., 2017; Hollis, 2019, p. 2; Danzon & Nicholson, 2012).

Kumraj et al. (2022, p. 5) emphasized that lack of adequate R&D for vaccine manufacturing has been recognized as a challenge for local manufacturers in the developing countries and suggested that efforts should be intensified both from the public and private sectors to facilitate vaccine manufacturing facilities as the COVID-19 pandemic was a wake-up call for many nations for the need of localizing vaccine manufacturing.

Alzahrani and Harris (2021) posit that despite the government's financial support for R&D in general, most of the research projects that are related to pharmaceutical development are scattered and have no true outcome (Sim et al., 2020; Rappuoli & Hanon, 2018). Another major factor impeding vaccine manufacture relates to technical knowledge, specifically biotechnological knowledge in handling biological materials, which are the main component of vaccine manufacturing. Many developing nations are not yet capable of managing biotechnological processes that can facilitate vaccine manufacturing (Hayman, Suri, & Downham, 2022; Alshamsan, 2020).

Findings from this qualitative case study are varied due to different perspectives and personal opinions regarding the factors that impede vaccine manufacturing in KSA. However, participants agreed for the need for establishing vaccine manufacturing facilities in KSA. Some participants believed KSA still has a long way to go when it comes to vaccine manufacturing, while others believe that the existing facilities in universities, hospitals, and manufacturing laboratories have the potential to start local vaccine manufacturing (Aldossari et al., 2021; Alshamsan, 2020).

Summary of the Chapter

This chapter presented a qualitative case study as a validation of the findings presented in Chapter 4, which aimed at investigating factors that impede vaccine manufacturing in KSA. The data was gathered through a face-to-face interview conducted via Zoom platform with 22 professionals working in the government sector, entrepreneurs, academicians, and healthcare practitioners. Findings indicated that many participants agreed that the factors identified in the literature are impediments to vaccine manufacturing in KSA.

Chapter Six: Summary, Conclusion, Implications, and Recommendations for Further Research

Introduction

This chapter presents a summary, conclusions, implications, and recommendations for further research.

The main objective of this research was as follows:

1. To assess if there is a relationship between lack of research and development (R&D) capability, low revenue, high cost of investment, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities, government regulations and policies on vaccine manufacturing business in KSA.
2. To analyze the moderating effect of government regulations and policies in the relationship between lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, government support, lack of partnership opportunities, government regulations and policies, and vaccine manufacturing business in KSA.
3. To evaluate if there are any significance differences in the perception of respondents according to work sector regarding vaccine manufacturing business in KSA.

Summary of Research Findings

Based on the above-stated objectives and hypothesis statements, data was collected through a survey questionnaire distributed to 265 participants. The data was further analyzed to determine the descriptive statistics of the research variables and the demographic profiles of the participants. Similarly, the stated hypothesis statements were analyzed employing multiple regression analysis.

For the case studies conducted as an application of the quantitative study findings into practice, data was collected through a face-to-face interview conducted with 22 professionals working in KSA, and data was analyzed employing thematic analysis methods.

The following is the summary of the overall research findings based on the hypothesis statements and thematic analysis of the interview data (qualitative case study).

1. Findings showed that the independent variables: High cost of investment ($\beta = .313$, $t = 4.483$, $p < .001$), lack of adequate infrastructure ($\beta = -.131$, $t = -1.956$, $p < .052$), and government regulations and policies ($\beta = .316$, $t = 6.302$, $p < .001$), are significant. Therefore, the stated Null hypothesis statements were rejected. However, the independent variables lack of research and development (R&D) capability ($\beta = -.057$, $t = -1.211$, $p = .227$), low revenue ($\beta = .048$, $t = 1.176$, $p = .241$), lack of technical knowledge ($\beta = -.011$, $t = -.180$, $p = .857$), government support ($\beta = .026$, $t = .626$, $p = .532$), lack of partnership opportunities ($\beta = .011$, $t = .185$, p

=.854), were not significant. Hence, the Null hypothesis statement is accepted.

Moderation effect or interaction effect of government regulations and policies on the individual variables (lack of research and development (R&D) capability, low revenue, high cost of investment in process development technology, lack of adequate infrastructure, lack of technical knowledge, lack of government support, lack of partnership opportunities), findings indicated the following:

(i) significant interaction effect of (β =-.239, SE=.041, β = -2.299, $p <$ .001) between high cost of investment and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.

(ii) significant interaction effect of (β =-.096, SE=.047, β = 1.036, $p =$ .041) between lack of adequate infrastructure and vaccine manufacturing business. Therefore, the Null hypothesis is rejected.

(iii) non-significant negative interaction effect (β =-.047, SE=.039, β = -.501, $p = .233$) between lack of research and development and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

(iv) non-significant interaction effect (β =-.003, SE=.040, β = .026, $p =$ .949) between low revenue and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

(v) non-significant interaction effect (β =-.052, SE=.045, β = .563, $p =$ .247) between lack of technical knowledge and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

(vi) non-significant interaction effect (β =-.045, SE=.036, β = .509, p = .214) between lack of government support and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

(vii) non-significant interaction effect (b =.021, SE=.044, β = .218, p = .631) between lack of partnership opportunities and vaccine manufacturing business. Therefore, the Null hypothesis is accepted.

2. One-way ANOVA conducted to evaluate the perception of the participants according to work sector regarding vaccine manufacturing business in KSA, indicated a statistical significance at (p= 0.05%) confidence level [F ($_3$ = 3.157, p < .025)]. To determine for individual differences between the work sectors, post-hoc comparisons was assessed using Tukey HSD. The test showed the mean score for government sector (M = 5.5469, *SD* = .64043), for healthcare sector (M = 5.5640, *SD* = 1.07525), for academia sector (M = 5.7071, SD = 1.18738), and for manufacturing sector (M = 5.9449, *SD* = .79677), indicating that the mean difference between respondents from healthcare sector (M = 5.5640, SD = 1.07525) was significantly different from manufacturing sector (M = 5.9449, SD = .79677).

Theoretical Implications of the Findings

The Resource-Based View (RBV) theory RBV posits that having unique resources and skills that are valued and unmatched enables a business to gain a sustainable competitive advantage, such as better performance and efficiency in productivity (Bodlaj & Čater, 2022; Dogbe et al., 2020). Furthermore, Gunasekaran et al. (2017) state that firm resources are essential for performance and survival in a competitive environment and must be harnessed and utilized to meet set goals and objectives.

A manufacturing organization has internal assets as well as employee skills and abilities that can be utilized to benefit the organizational economic growth and facilitate manufacturing activities. According to Wernerfelt (1984), as cited by Azeem et al. (2021, p. 5), resources are assets that might be viewed as the organization's strength or weakness, and these include assets, both tangible and intangible, that are linked, such as organization names and services, internal knowledge and technology, skilled labor, machinery, and effective processes that can be used to compete in the market. Therefore, RBV theory emphasizes that the sustainability and competitive advantage of manufacturing organizations depend on the ability to use highly valuable, rare, and indispensable organizational resources in settings where policies and procedures for resource exploitation are in place (Furr et al., 2021; Gerhart & Feng, 2021). Barney (1991) posits that resources that are valuable, scarce, unique, and non-replaceable might provide organizations with a competitive edge. Therefore, physical capital, human capital, and organizational capital, all of which are the controllable resources of an organization, create value and facilitate efficiency and effectiveness.

Findings from this research are in line with the application of RBV theory and concepts in the manufacturing industry, which necessitates focusing on knowledge and skills possessed by individuals, both employers and employees, in technologies related to vaccine production and manufacturing, thus contributing to an overall competitive advantage to facilitate performance and productivity (Safari & Saleh, 2020; Assensoh-Kodua, 2019). Vaccine manufacturing constitutes an elaborate and intricate process of biological material and, as such, demands a high level of technology, availability of facilities, and adequate infrastructure (Assensoh-Kodua, 2019).

Findings from this research are also in line with knowledge-based view (KBV) theory, which integrates knowledge assets that are significant, distinctive, rare, and reliant on the resource-based perspective of organizations (Grant, 1996). In KBV perspective, knowledge is regarded as an organizational strategic resource, a key to value, and a long-term competitive advantage (Grant, 1996; Seleim & Khalil, 2007). In this regard, manufacturing organizations can only achieve superior performance if they effectively manage and use their knowledge and intelligence to better care for their internal establishment of vaccine manufacturing processes, which is only feasible through efficient and successful coordination resources of technical knowledge required for vaccine manufacturing (Yildiz & Kara, 2017).

Generally, researchers assert that using knowledge and skills gives a business a competitive edge since having access to these resources helps in fostering innovation of new services and products as well as processes to enhance productivity (Ipek, 2020, p. 4; Arbelo, Arbelo-Perez, & Pérez-Gomez, 2020; Varadarajan, 2020).

Knowledge, according to KBV, is the company's most important resource and the main factor in determining its competitive advantage (Hock-Doepgen et al., 2021; Bamel et al., 2021). This perspective has a significant impact on the applicability of the absorptive capacity construct since it is crucial to growing and expanding a firm's knowledge base (Bamel et al., 2021; Keat et al., 2018). In the case of vaccine manufacturing, available knowledge and the capacity to receive and utilize such knowledge are fundamental to successful vaccine manufacturing (Azeem et al., 2021; Pereira et al., 2021; Plotkin et al., 2017).

Practical Implications of the Findings

The findings from this research have practical implications in various ways. Firstly, vaccines are one of the most efficient intervention methods that can be used to boast citizens health status to prevent infectious diseases.

It has been estimated that immunization saves millions of lives every year from illness and disabilities that can cause death. Secondly, local production of vaccines facilitates immunization of citizens, which has a significant positive correlation to economic and societal advantages (Gerberding & Haynes, 2021; WHO 'Immunization Report, 2019). Hence, establishing a local vaccine manufacturing facility through which vaccines can be made available for immediate immunization of citizens and combat outbreaks of infectious diseases is of paramount importance to the healthcare sector of KSA. Thirdly, the past COVID-19 pandemic was a wakeup call for the KSA government regarding the need to establish local vaccine manufacturing facilities as the scarcity of available vaccines caused the death of many infected with COVID-19 due to a lack of immunization.

According to the World Health Organization (WHO Primary HealthCare report 2020), the KSA healthcare system is ranked 26th among 190 of the world's healthcare systems and comes before many other international healthcare systems such as Canada (ranked 30), Australia (32), New Zealand (41), and other systems in the region such as the United Arab Emirates (27), Qatar (44) and Kuwait (45).

Despite these achievements, the Saudi healthcare system faces many challenges, such as a lack of sufficient drugs and vaccines, a lack of necessary laws, regulations, and policies by the KSA Ministry of Health (MOH), and a lack of effective cooperation with other sectors of the economy (Al-Shahrani et al., 2020; Al-Kubaisi & Shahbal, 2021).

Gallagher (2002, p. 182) stated that "Although many nations have seen sizable growth in their health care systems, probably no other nation (other than Saudi Arabia) of large geographic expanse and population has, in comparable time, achieved so much on a broad national scale, with a relatively high level of care made available to virtually all segments of the population.

KSA is considered the leading spender on healthcare in the Middle East, with nearly USD 37 billion in spending across the Ministry of Health and the private and semi-government sectors (Aitken et al., 2019; Dash et al., 2019; KSA-MoH, 2010).

The average cost of healthcare worldwide (excluding the US) is USD 677 per person; however, in Saudi Arabia, it is more than USD 1,120 per person, which is 66 percent more than the average cost worldwide. This is an indication that the KSA market is lucrative for vaccine manufacturing businesses as well as to serve other nations in the GCC and the region in general.

Conclusion

Previous studies identified the various factors as among the possible impediments to local vaccine manufacturing business. Based on the findings on the analysis of data gathered. The following conclusion can be drawn.

(i) There is a positive relationship between lack of research and development (R&D) capability and vaccine manufacturing business in KSA.

(ii) There is a positive relationship between the issue of low revenue and vaccine manufacturing business in KSA.

(iii) There is a positive relationship between high cost of investment in process vaccine development technology and vaccine manufacturing business in KSA.

(iv) There is a positive relationship between adequate infrastructure and vaccine manufacturing business in KSA.

(v) There is a positive relationship between technical knowledge and skills needed for vaccine technology and vaccine manufacturing business in KSA.

(vi) There is a positive relationship between government support through making available necessary funding for private and public partnership and vaccine manufacturing business in KSA.

(vii) There is a positive relationship between encouragement of partnership opportunities with exiting vaccine associations and alliances around the world vaccine manufacturing business in KSA.

(viii) There is a positive relationship between rigid government regulations and policies and vaccine manufacturing business in KSA.

(ix) Entrepreneurs, academicians, and government workers have a positive perception that KSA has an enabling environment for vaccine manufacturing business.

Limitations of the Research

The process of conducting this research, the following limitations were encountered.

1. The smaller number of participants due to professional reasons from the government sector that participated in the research limited the data that could have been useful in determining the generalization of the findings.
2. Lack of available professional scientist to share their views on the possibility of local vaccine manufacturing in KSA.
3. The cross-sectional method utilized in data gathering wherein data was gathered once during the period of the research.

Recommendations for Further Research

Based on the limitations of this study and other aspects, the following recommendations for further research.

1. Further research that involves more government professionals in the field of biotechnology should be conducted.
2. Longitudinal research that aims at monitoring the quality of vaccine technological institutions should be conducted.
3. A face-to-face qualitative interview with biotechnology professional and scientist to determine their views on the readiness of KSA for local vaccine manufacturing venture.
4. Further research to determine factors that can facilitate harmonization of laws regulation within the government sectors to streamline local vaccine manufacturing.

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