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Griffith College

Compliance Challenges of Indian Pharmaceutical Companies in Global Markets: Navigating Regulatory Requirements and Adaptation Strategies

By

SWATHIKEDINI SUBRAMANNYAN

Dissertation Supervisor: MARY O'DRISCOLL

A research dissertation submitted to Griffith College, Dublin, in partial fulfilment of the requirement for the degree of MSc in Pharmaceutical business and technology

Innopharma Faculty of Pharmaceutical Sciences

Griffith College Dublin

MAY 2025

CANDIDATE DECLARATION

I hereby declare that the dissertation entitled, "COMPLIANCE CHALLENGES OF INDIAN PHARMACEUTICAL COMPANIES IN GLOBAL MARKETS: NAVIGATING REGULATORY REQUIREMENTS AND ADAPTATION STRATEGIES" submitted in partial fulfilment of a MSc in Pharmaceutical Business and Technology is the result of my own work and due acknowledgment is given. I also assure that I have not plagiarized anyone else's work.

Candidate Name: SWATHIKEDINI SUBRAMANNYAN

Candidate Signature:  DATE: 11/05/2025

Supervisor Name: Mary O'Driscoll

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To my **family and friends**—thank you for your patience, motivation, and constant encouragement. Your belief in me helped me stay focused through every challenge.

Lastly, I dedicate this dissertation to my beloved country, **India**, which lies at the heart of this research. It is my hope that this work will contribute, even in a small way, to advancing safer, more effective pharmaceutical practices and regulatory compliance that support India's role in providing affordable, high-quality medicines to the world.

Swathikedini Subramannyan

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ABBREVIATIONS USED IN THIS DOCUMENT

ANDA: Abbreviated New Drug Application
API: Active Pharmaceutical Ingredient
CDSCO: Central Drugs Standard Control Organization
CFR: Code of Federal Regulations
EBR: Electronic Batch Records
EMA: European Medicines Agency
EU: The European Union
FDA: Food and Drugs Administration
FDI: Foreign Direct Investments
cGMP: Current Good Manufacturing Practices
ICH: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IP: Intellectual Property
LIMS: Laboratory Information Management System
MNC: Multi National Company
QA: Quality Assurance
QC: Quality Control
QMS: Quality Management System
RIMS: Regulatory Information Management System
ROW: Rest of the World
SME: Small and Medium Enterprises
US: The United States of America
WHO: World Health Organization

ABSTRACT

The Indian pharmaceutical sector is well-known for being the world's largest provider of affordable and high-quality generic drugs, meeting the needs of more than 150 nations. However, compliance with strict international regulatory standards has become a major challenge for the Indian exporters, especially in regulated markets like the US and the EU. This dissertation examines the various compliance issues that Indian generic drug producers have while exporting to these regulated countries, as well as how companies are adjusting to changing regulatory requirements.

The primary goal of this research is to investigate the challenges Indian pharmaceutical companies have when trying to adhere to the stringent US FDA and EMA standards. This involves examining how the evolving regulatory requirements like Good Manufacturing Practices (GMP), increased focus on data integrity expectations, and pharmacovigilance are affecting the Indian pharmaceutical industry. The study also evaluates how these companies create and apply different strategies to ensure compliance and keep access to markets.

A qualitative research methodology was used, with the main source of data being semi-structured interviews with professionals in the pharmaceutical industry ranging from QA specialists to regulatory affairs officers. From the interview transcripts, recurrent themes and patterns were found using thematic analysis. The secondary data was also gathered from official regulatory reports, academic papers and case studies.

The results showed Indian pharmaceutical companies experience a variety of compliance challenges, such as data integrity, poor documentation practices and inadequate inspection readiness. Participants pointed out that significant investment in training, digital infrastructure and proactive risk management is necessary to adjust to changing global standards. Companies with efficient regulatory affairs departments and digital QMSs showed increased market stability and resilience.

This study emphasizes how important it is for Indian pharmaceutical companies to strengthen their internal compliance systems and quickly adjust to shifting international regulatory requirements. Maintaining India's competitive advantage in foreign markets requires investment in digitalisation, regulatory training, strengthening the quality systems. In an increasingly complicated global pharmaceutical environment, this study offers Indian pharmaceutical manufacturers important insights to ensure long-term compliance and export success.

Keywords: Indian pharmaceutical industry; regulatory compliance; generic drug exports; US FDA; EMA; data integrity; GMP; pharmacovigilance; audit readiness; adaptation strategies

CHAPTER 1: INTRODUCTION

1.1 Background

As the world's largest provider of generic medications, the Indian pharmaceutical industry has reached significant role in the global pharmaceutical market. Every one in five generic drugs sold in the world is a generic drug manufactured in India(Business Standard, 2025). Over the past few decades, India has established itself as one of the leading manufacturers of affordable and high-quality medicines, making a significant contribution to global public health, earning the title 'Pharmacy of the World'(Ministry of Chemicals and Fertilisers, 2024; IBEF, 2024). The strong presence of India in the global pharmaceutical supply chain is demonstrated by the fact that India has the most US FDA-approved pharmaceutical plants outside of the US. Today, Indian pharmaceutical companies serve the healthcare needs of more than 150 nations globally with more than 10,500 manufacturing sites and more than 2,000 WHO-GMP approved facilities(IBEF, 2025).

Although a leader in the production of generic drugs, India is ranked 11th in terms of pharmaceutical export value, demonstrating a disparity between its manufacturing capabilities and global trade power (Shrinivasan, 2025). Nonetheless, by 2030, Indian pharmaceutical exports are expected to double to USD 65 billion, and by 2047 they will reach USD 350 billion.(The Economic Times, 2025). The Bain & Company report, "Healing the World: Roadmap for Making India a Global Pharma Exports Hub," outlines India's potential to become one of the top five global pharmaceutical exporters by 2047(Shrinivasan, 2025). This expansion is fuelled by the country's strong foundation in cost-efficient manufacturing—30% to 35% lower than in the U.S. and Europe—along with affordable research and development (R&D) costs, skilled labour, and strong foreign direct investment (FDI) inflows (IBEF, 2025).

However, with these opportunities for expansion come vigorous regulatory hurdles that can impact the growth of Indian pharmaceutical companies around the world. Complying with demanding global standards is non-negotiable to achieving entry into markets, particularly when exporting to heavily regulated markets such as the United States and the European Union. The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) impose tight regulations to ensure that drug products meet the highest quality, efficacy, and safety standards. Violations of such regulations will attract import bans, warning letters, product recall, and damage to reputation of the company and bring out various economic burdens.

In addition, the recent geopolitical events have also influenced the global regulatory trade. For instance, the recent announcement of the US president Donald Trump to impose 25% tariffs on imported pharmaceuticals. However, Indian generics were later exempted from these tariffs due to the vital role they play in the American healthcare system. Even though trade policy is not the main concern of this study, these developments demonstrate the global reliance on Indian generics as well as the increasingly unstable state of global trade and regulatory frameworks.

1.2 Aim and Objectives

The aim of this study is to explore the various compliance challenges of the Indian pharmaceutical companies manufacturing generic medicines for the export to global markets, with a focus on the U.S. and EU regulatory environments.

The primary research objective is to identify the key regulatory requirements the companies have to follow in order to export their drugs to these regulated markets, and to examine the impact of regulatory changes— e.g., evolving regulatory requirements, enhanced pharmacovigilance requirements, data integrity expectations, and supply chain transparency—on Indian exporters. The study is also intended to examine the effectiveness of current compliance strategies employed by Indian manufacturers to maintain U.S. FDA and EMA guidelines along with exploring potential improvements to effectively address the regulatory needs and market access for Indian generic pharmaceutical exports.
The objectives of the study are:

1. To identify and analyze the key compliance challenges faced by Indian generic drug manufacturers in global markets, specifically focusing on regulations from the US FDA and EMA.
2. To identify the challenges faced by these companies in adapting to the regulatory changes, such as evolving pharmacovigilance and data integrity standards, and the impact of non-compliance and analyze how generic manufacturers adapt to such changes.
3. To assess the effectiveness of current strategies and practices employed by Indian pharmaceutical generic manufacturers to meet these regulatory expectations and explore potential improvements for enhanced market access and compliance.

1.3 Research questions

The following are the research questions intended to achieve the objectives listed above:

1. What are some of the major compliance challenges faced by Indian pharmaceutical manufacturers in order to meet the regulatory requirements set up by the US FDA and EMA
2. How do the evolving regulatory requirements in the US and EU affect the Indian generic drug manufacturers
3. What are some of the measures these companies have taken to enhance the regulatory adherence, and to what degree have they succeeded?
4. What are some of the recommendations to strengthen the compliance for Indian manufacturers exporting to international markets?

1.4 Scope and limitation of the study

The current study is centered around the compliance challenges of Indian pharmaceutical companies manufacturing generic drug medications for export to global markets and deals specifically with the regulation set forth by the US FDA and EMA. The study offers a comprehensive analysis of the Indian generic pharmaceutical sector. The key compliance areas under scrutiny are Good Manufacturing Practices (GMP), data integrity, pharmacovigilance, and regulatory inspections. The research is based on secondary data collected from regulatory reports, case studies, and publications along with primary data collected from senior industry professionals through interviews. The objective is to assess compliance issues, analyze how Indian manufacturers react to evolving regulations, and determine compliance strategies.

The limitations include the fact that this research is largely based on US FDA and EMA regulations, so its use in other markets is restricted. It is primarily about generic drugs and does not deal with novel drugs, biologics, or biosimilars in depth. Also, the primary data relies on a small sample of industry experts, so the result may not be comprehensive of the entire industry. Furthermore, the regulatory requirements are changing constantly. Hence, the results need periodic updating.

1.5 Outline of the thesis

This dissertation is structured into five chapters. Chapter I is the introduction of the study with the background, research problem, objectives, questions, scope, limitations, and significance. Chapter II presents the literature review on the global pharmaceutical regulations, compliance issues and their impacts on the Indian generic manufactures. Chapter III details the research methodology, which includes the qualitative approach, data collection methods, and data analysis methods. The data from the primary and secondary research are presented in chapter IV along with the discussion. And finally, in chapter V will present the

conclusions and suggestions for optimizing the compliance and outlines directions for further research.

1.6 Significance of the study

This study is very much significant to the Indian pharmaceutical industry especially since its projected that the Indian pharmaceutical companies would achieve a revenue growth of 9-11% in financial year 2025 and the exports would double to USD 65 billion by the end of 2030(IBEF, 2025). With the increasing demand for affordable medicines around the world, Indian generic manufacturers have the key to dominate the international markets if they have an understanding of the compliance issues and solutions to overcome them.

With Indian manufacturers expanding their global presence, this research provides valuable insight on how to navigate the regulatory limitations. Three significant information gaps are filled by the study. The first one being the 'Regulatory Understanding Gap', which provides a thorough examination of FDA and EMA compliance standards, explores the difficulties in adjusting to changing rules, and emphasizes the real-world effects of these changes on Indian generic manufacturers. The second one is the 'Implementation Knowledge Gap' which discusses the current successful compliance strategies being used, evaluating their effectiveness, and recommending improvements for ensuring regulatory compliance. Finally, by concentrating on the difficulties associated with increased pharmacovigilance requirements and changing data integrity standards, the study addresses the 'Future Preparedness Gap' and offers strategic ways to ensure compliance and provide a framework for Indian manufacturers to adjust to upcoming regulatory changes.

This study will be particularly beneficial to generic manufacturers as they pursue aggressive growth goals and maintain regulatory compliance throughout India's anticipated expansion phase. The ultimate goal of this research is to help India maintain its position as a trustworthy provider of affordable high-quality medicines worldwide.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The Indian pharmaceutical industry has established itself has a global leader, but expanding to international markets comes with a lot of regulatory challenges, GMP compliance requirements and quality standards. Several countries have established their own drug regulatory boards to ensure only the drugs of highest quality will reach their citizens. For instance, in the US, the Food and Drug Administration (FDA) has stringent requirements through its Current Good Manufacturing Practices (cGMP) to ensure that pharmaceutical products are of high quality and only the best reach its citizen (FDA, 2025). Similarly, the European Medicines Agency also has its own GMP guidelines where manufacturers must follow stringent quality control and assurance standards (EMA, 2022).

Indian generic pharmaceutical manufacturers need to deal with such complex regulatory landscapes, if they aim for expansion in these regions along with compliance with pharmacovigilance requirements, data integrity guidelines, and evolving regulatory expectations. Over the past decades, India has emerged as a leader in the production and export of generic medicines made possible by cost-effective manufacturing, skilled workforce, and extensive production capabilities (Ilin et al., 2024).

However, as global competition intensifies and the regulatory frameworks evolve, these Indian manufacturers constantly need to adapt and maintain their commitment to ensure only quality products reach the consumers in order to sustain their position in the international markets. Hence, this study essentially explores all the regulatory barriers the manufacturers have to go through and analyze the effectiveness of current strategies.

The research process started with identifying key themes associated with the title to write the literature review. ‘Regulatory compliance’, ‘global pharmaceutical regulations’, ‘Indian generic exports’, ‘pharmaceutical market access’, ‘pharmaceutical export challenges’, ‘generic drug approval process in the US and the EU’ were some of the key themes identified and these themes were used to collect the literature, regulations and case studies. Both the FDA and EMA guidelines are central to the research and both these websites were frequently visited. The sources of this research were gathered from various academic databases like Google Scholar, SAGE articles. EBSCO, PubMed etc. Sci-Hub was also used to retrieve several articles.

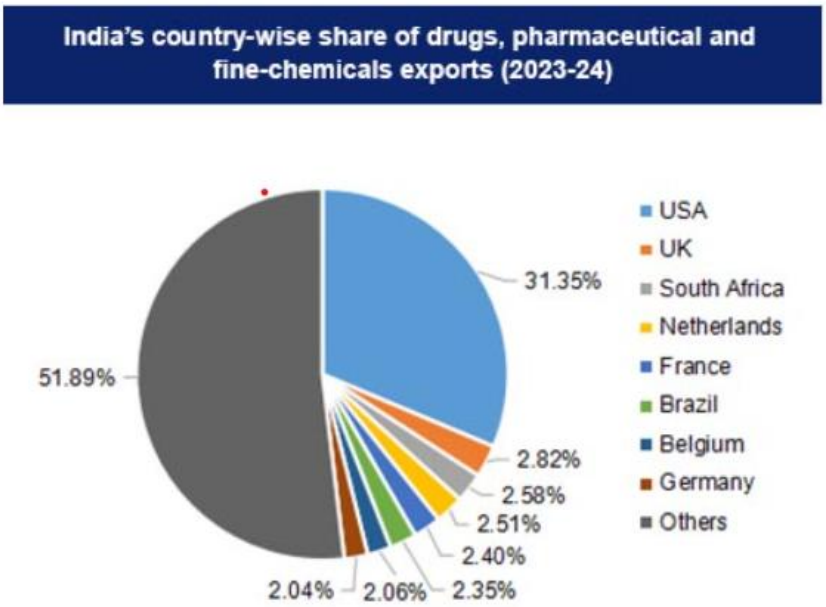
2.2 Global Regulatory frameworks governing Indian Pharmaceutical Exports

One of the most challenging factors in export of the generic drugs is the fact that different countries have different regulatory requirements for a drug to be sanctioned in their respective markets. For instance, in the EU, the European Medicines Agency (EMA) is the regulatory body which oversee the drug approval process while in the US, it is the Food and Drug Administration (FDA). Hence, a single drug cannot be manufactured which satisfies the regulations of all the global markets. Each country has set up guidelines that need to be followed from drug development to distribution and pharmaceutical legislations has not yet reached full harmonisation across the globe (Pezzola and Sweet, 2016).

Pezzola and Sweet (2016) effectively highlights the lack of uniformity in pharmaceutical legislations despite the global intellectual property (IP) harmonization through TRIPS which came into effect in 1995 (almost two decades back). The study argues that major regulatory agencies like the US FDA and EMA have little influence on the pharmaceutical legislations of developing countries. However, this is not true and that is evident from various warning letters and import bans issued by the US FDA. Also, the study doesn't consider the ICH guidelines and relies solely on the WHO data. This may be because the study is majorly focused on developing countries and at the time of the study, i.e in 2016, many of the developing countries were not integrating ICH guidelines into their regulatory frameworks. Also, the study doesn't specify how the lack of harmonization in these regulations creates barriers to international pharmaceutical exports and imports.

India's pharmaceutical industry has been a major player on global markets, exporting to North America, Africa, the EU, ASIAN, Latin America & the Caribbean (LAC), the Middle East, Asia, CIS, and other regions of Europe (Department of Commerce, 2024). The top five export destinations for Indian pharmaceuticals in 2023–2024 were the United States, United Kingdom, South Africa, the Netherlands, and France, indicating the nation's significant role in meeting global healthcare demands(IBEF, 2024).

Fig 2.1 India's country-wise share of drugs, pharmaceutical and fine-chemicals export (2023-24)(IBEF, 2024)



Indian generics are widely accepted and supplied to highly regulated markets such as United States, supplying almost 40% of the generic demand in the US markets (IBEF, 2025). Hence, understanding the regulatory frameworks is very crucial in sustaining the dominance in the international markets. Failure to comply with the regulations will lead to delays in product approval, import bans, and complete rejection of the drug to be sold in these markets. Recently, many Indian pharmaceutical companies have faced warning letters, import bans and product recalls due to regulatory violation such as non-compliance with cGMP.

In the fiscal year 2023, India accounted for almost 33% of the total drug recall second only to the US at 58%(FDA, 2023). Also, the number of non-compliance statements issued by the EMA to Indian manufacturers increased from 0 in 2020 to 4 in 2023(EMA, 2023). Despite these regulatory challenges, India maintains a strong presence in the EU market, ranking among the top countries to receive GMP certifications, with 101 issued in 2023, depicting strong presence in the EU markets as well(EMA, 2023).

Table 2.1: GMP certificates and non-compliance statements issued by EEA authorities(EMA, 2023)

	2019		2020		2021		2022	
	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement
EEA/EU	2,235	11	1,695	1	1,825	5	1,730	2
China	51	4	11	0	24	0	15	0
India	105	1	64	0	29	0	81	2
USA	127	0	35	0	52	0	118	0
Rest of the world	108	0	38	0	52	0	187	2
Total	**2,626**	**16**	**1,843**	**1**	**1,982**	**5**	**2,131**	**6**

Therefore, this research aims at understanding the regulatory hurdles the Indian generic manufacturers face and provide insights that can help them navigate the evolving regulatory standards across the globe.

2.3 Comparative Regulatory Analysis: India vs. EU vs. US

As mentioned above, different markets have different frameworks regarding generic drug approvals. The approval of a drug in one market doesn't guarantee the approval in the other. In the EU, a generic drug is approved into the market by European Medicines Agency (EMA) under the directive 2001/83/EC and regulation (EC) No. 726/2004. According the Article 3(3) of the regulation, if the reference medicinal product is approved by a centralized procedure, the generic counterpart can also avail marketing authorization via the same pathway(EMA, 2024). The manufacturers don't have to demonstrate the safety and efficacy of the generic through clinical and pre-clinical trials, since they have already been conducted for the reference medicinal product. Also, the marketing authorization application can only be filed after the market exclusivity of the reference product has expired, which is typically 10 years(EMA, 2012).

Now, in the US, the regulatory framework is carried out by Food and Drug Administration under the Hatch-Waxman Act of 1984 which established the Abbreviated New Drug Application (ANDA) pathway for generic medicines. These drugs are required to demonstrate a bioequivalence to the reference drug without the need for extensive and expensive clinical trials. The 21 CFR Part 314 and 21 CFR Part 320 are the federal code regulations(FDA, 2024). In India, the Central Drugs Standard Control Organization (CDSCO) heads the drug regulations, under the Drugs and Cosmetics Act of 1940 and Drugs and cosmetics rules of 1945(CDSCO, 2025). Comparing FDA and EMA regulations, the approval process of CDSCO is less complex and more cost-effective. The drug can enter the market relatively quicker when compared to the US and EU markets.

To address these kinds of regulatory disparities among international markets, international agencies like World Health Organization (WHO) and International Council for Harmonization (ICH) play a very important role in improving harmonization and establishing global standard for pharmaceutical laws. ICH is a collaboration between the regulatory bodies of the US, the EU and Japan, at an attempt to harmonize the pharmaceutical regulations to ensure GMP compliance and utmost quality in drug development processes(ICH, 2025). The adoption of ICH guidelines by Indian pharmaceutical companies helped many companies achieve an international standard.

2.4 Market Opportunities and Growth Drivers for Indian Generics

By the end of 2030, the Indian pharmaceutical business is expected to generate around US$130 billion at a compound annual growth rate (CAGR) of more than 10%(IBEF, 2025). A key driver for this growth is the significant increase in the number of small-molecule medications that are going off-patent which is predicted to nearly double between 2020 and 2026, rising from 190 in 2020 to 383 by 2026 along with 6 blockbuster drugs expiring in 2026 alone(KPMG, 2025). This presents a profitable opportunity to Indian generic manufacturers to introduce affordable medicines into international markets. Hence, the Indian pharmaceutical firms are in a good position to take advantage of new opportunities.

Along with that, the demand for high quality affordable generic medications is fuelled by the rising expense of healthcare globally, especially in developed countries like the US and the EU. Now, India has become the generic drugs market leader globally, producing nearly 20% of the volume of generic drugs in the world. Currently, ranked 3rd for pharmaceutical production by volume and 14th by value, India hosts around 3000 pharmaceutical companies and nearly 10,500 manufacturing facilities(India Briefing, 2023). Under the Generic Drug User Fee Act published by the FDA for the financial year 2024, India topped the list with the highest number of generic manufacturing facilities, with 376 registered facilities out of which 200 are API manufacturing facilities and 134 which produces finished dosage forms (Pharmacompass, 2025).

As a result of which, India has become a destination of Foreign Direct Investments (FDI).

2.4.1 Foreign Direct Investment (FDI)

Indian pharmaceutical firms get investments from foreign entities in the form of Foreign Direct Investment (FDI) inflows. These investments may take the shape of new production facilities, technological transfers, mergers and acquisitions, or

equity capital. Over the years, India's pharmaceutical sector has attracted a substantial percentage of FDI.

In greenfield projects (new investments), the Indian government permits 100% FDI, which exempts foreign investors from prior clearance. On the other hand, for the brownfield investments (acquisitions of already-existing companies), foreign companies are only allowed up to 74% of the company's share. Larger investments require additional government permissions (India Briefing, 2023).

Table 2.1: Pharmaceutical and Drugs FDI Inflows to India: Yearly Analysis (FY 2019-20 to FY 2021-22) (DPIIT, 2024)

Financial Year	FDI in INR (₹ Crores)	FDI in USD (Million)
FY 2019-20 (April-March)	3,650	518
FY 2020-21 (April-March)	11,015	1,490
FY 2021-22 (April-March)	10,552	1,414
FY 2022-23 (April-March)	16,654	2,058
FY 2024-24 (April-March)	8,844	1,064
FY 2024-25 (April-Sept)	4,349	520
Cumulative Equity Inflow (Apr 2000 - Sept 2024)	**139,230**	**23,048**

Between April 2000 and September 2024, the total foreign direct investment (FDI) equity inflow into India's pharmaceutical and drugs sector amounted to US$23.048 billion, or about 3% of total FDI inflows into all sectors(DPIIT, 2024). The COVID-19 pandemic is the major cause of the sudden increase in FDI in FY 2020–21, at US$1.49 billion. India contributed significantly to the global fight against the pandemic by providing vaccines, medicines, and necessary medical equipment(Statista, 2024). With major multinational pharma firms signing agreements for vaccine production and supply, the huge rise in the investment indicates the global acknowledgement of India's pharma sector as a vital participant in the global pharmaceutical world.

Moreover, the government of India, with their new schemes like Production Linked Incentive (PLI), brought about investments to reduce India's dependence on the import of critical raw materials all the while encouraging bulk production and increasing the manufacturing capabilities of domestic companies pushing export of pharmaceutical products worldwide (PIB, 2024).

In short, patent expiry of small-molecule drug and blockbusters and the rising need for affordable generic drugs across the world would drive the growth of the Indian pharmaceutical industry by 2030. India possesses the strength to fulfil the growing demand owing to its strong manufacturing units and dominance in the international generics market. The regulatory system of the country, including

support policies like 100% FDI for greenfield ventures, makes it more appealing for foreign investors. The government programs like the PLI scheme are predicted to improve indigenous manufacturing capacity and make India an important contributor in the global pharmaceutical sector.

2.5 Key Challenges to Regulatory Compliance in Indian Pharmaceutical Exports

Even though India leads the world in generic pharmaceutical sales, many of the manufacturers still struggle with regulatory compliance. To guarantee product safety, efficacy, and consistency, EMA and FDA have established extensive frameworks and requirements that businesses must adhere to. Although a few of Indian businesses have effectively adjusted to these changing demands, many still encounter operational and structural obstacles that limit their capacity to be compliant to international standards. These issues usually demonstrate systematic deficiencies in areas such as documentation, quality control, data governance, and inadequate training of the professionals.

In addition to the well-established fact that different regulatory requirements exist in different jurisdictions, one of the biggest operational challenges facing Indian pharmaceutical businesses is the difficulty of aligning internal systems to fulfil these changing standards at the same time. This leads to violations, inefficiencies, and redundant work, particularly for smaller businesses with less experience with international compliance. Another challenge is the limitations in infrastructure and automation. According to Ullagaddi (2024), modern data practices like real-time recording, automatic validation, and secure information transmission are frequently not supported by the outdated IT infrastructure that some of the pharmaceutical companies harbor. Continually depending on manual, paper-based procedures put regulatory compliance efforts at risk from things like errors, inconsistent data, and inadequate traceability (Ullagaddi, 2024). Lack of digitalization has been another issue as pointed out by Ullagaddi (2024).

2.5.1 The role of Data Integrity and Good Documentation Practices in Global Regulatory Compliance

In the pharmaceutical manufacturing sector, data integrity is the foundation for ensuring patient safety, product quality, and regulatory compliance. Over the recent years, organizations like FDA and EMA have increased their scrutiny regarding all the data operations during their inspections, which in turn shed light on the vulnerabilities pharma companies face especially in the production and quality assurance areas. Being one of the key suppliers of generic medications all around the world, for Indian generic manufacturers, data integrity has become a significant obstacle to market access. Hence, this section examines the

importance of data integrity and how it is a major regulatory concern and its effect on compliance.

According to the US FDA guidance (2018), data integrity is the completeness, consistency and accuracy of the data throughout the lifecycle of a drug. It ensures that all the cGMP records, whether manual or electronic, are reliable and accurate. FDA uses the **ALCOA** principles to uphold the data integrity (FDA, 2018) which are:

- Attributable: the data should be clear as to who recorded it and when
- Legible: The data should be in a readable format and it should be permanent
- Contemporaneous: The data should be recorded in real time when the activity occurs
- Original: The first record or a verified true copy must be retained
- Accurate: Data should not be altered or falsified and should reflect the actual observation and the result

This foundation and then evolved into ALCOA + incorporating additional requirements such as the data should be complete, consistent, enduring and readily available for inspection.

According to Gambhire et al. (2024), data integrity issues were among the top reasons why many Indian pharmaceutical companies got a warning letter from the US FDA. According to an EY (2018) analysis, many Indian pharmaceutical companies still do not have a validated digital system that is capable of keeping electronic records secure and maintain robust audit trails. According to the report, 21% of the organizations examined did not have audit trails enabled on lab equipment's, and almost 33% of them acknowledged sharing login credentials for laboratory systems— they both obviously violate 21 CFR Part 11 of the US FDA, which governs the use of electronic signatures and records. Additionally, according to the research, about 25% of the respondents said they were unaware of the requirements for complying with 21 CFR Part 11.

According to Alosert et al (2022), it is crucial that all the professionals involved in data management and processing undergo comprehensive training. The article highlights that training should cover each and every aspect from proper data storage to adherence to good documentation practices(Alosert *et al.*, 2022). Employees should be informed of the consequences of non-compliance as well as their specific roles and duties in preserving the integrity of the data. Similarly, for regulatory compliance in international markets, digital tools like Laboratory Information Management Systems (LIMS) and electronic batch records (EBR) facilitate better data control, lower human error, and enhance the overall quality

management process(Chingale *et al.*, 2024).

Lack of digitization increases the possibility of data manipulation in addition to paving way for non-compliance. According to Ullagaddi (2024), companies are unable to exhibit reliable traceability in the absence of automated data capturing systems and time-stamped audit trails. Fragmented quality systems, inadequate infrastructure, and a lack of proper validation systems all lead to a compliance environment that is vulnerable. Additionally, Ullagaddi (2024) points out that since 2014, data integrity has continued to rank among the most common violation categories, mostly as a result of repeated failures in analytical laboratories to properly document and maintain results.

2.5.2 The Role of Quality Management Systems (QMS) in Ensuring Regulatory Compliance

Regulatory compliance is essential for Indian pharmaceutical companies seeking entry into international markets, such as the US and the EU. The establishment of strong Quality Management Systems (QMS) is one of the most important means of accomplishing this. In simple words, a Quality Management Systems is made up of a set of practices and procedures designed to meet regulatory requirements, improve product quality, and minimize the risks of production(Choudhary, 2024). "The 'Quality System' of a QMS is of significant importance as it serves the supporting system for guaranteeing that all products are in compliance with the specifications required. A good QMS ensures adherence to internal and external regulatory requirements, such as those developed by the FDA and EMA, by putting in place an auditing quality system(Pratiksha *et al.*, 2018).

However, the lack of a robust QMS system can be assumed as a root cause for regulatory non-compliance among Indian pharmaceutical companies. From 2005 to 2018, a total of 8137 warning letters by the FDA worldwide of 85% of these warning letters were because of cGMP violations(Bablani and Janodia, 2020).

Table 2.2: Year wise record of total warning letters issues by FDA v/s warning letter issued to Indian companies(Bablani and Janodia, 2020)

Year	Warning Letters issued to Indian Companies	Total Warning Letters Issued	Total Number of FDA Audits Carried Out[a]
2005	0	506	NA
2006	2	467	NA
2007	2	375	NA
2008	2	435	2980
2009	4	565	18,986
2010	9	619	22,678
2011	6	756	26,108
2012	3	772	23,654
2013	8	680	20,805
2014	11	701	20,740
2015	11	694	20,160
2016	10	617	21,038
2017	14	536	22,121
2018	10	414	20,309

92 letters out of those 8137 letters were sent to pharmaceutical businesses in India. It is clear from the table that the number of companies receiving the warning letters increased over the years. While looking at the percentage of the FDA warning letters issues to foreign manufacturers, the number rose from 22.9 % in 2019 to 33% in 2020 with India and China receiving cGMP related citations(P. Ullagaddi, 2024). This trend of non-compliance essentially points to the gaps in the quality management system, poor documentation practices and data integrity failures. Between 2014 and 2016, a study analyzing 85 FDA issued warning letter found that 34% of those violations were due to quality system deficiencies and 24 % were because of data integrity breaches(Jain and Jain, 2018). The study also revealed that 30.6 % of the manufacturers who received the warning letters were placed on import alert. Out of those manufacturers placed on import alerts, 34 % of them were from India. Hence, the increasing number of FDA warning letters underscores the critical need to strengthening the QMS practices.

In the recent years, digital transformation is playing an important role in enhancing the Quality Management System by addressing key challenges like data integrity, process control and innovation(Pravin Ullagaddi, 2024). Data integrity, traceability, and effective process control are made possible by digitization which paves way for a strong QMS allowing Indian pharmaceutical companies to adapt to evolving regulatory requirements and helps them to be competitive and compliant on the global markets, and thereby to be in a position to provide safe, high-quality products.

2.7 Intellectual Property (IP) rights and Generic Drug Production

Intellectual property (IP) is a key factor in the international pharmaceutical industry, particularly for Indian pharmaceutical companies seeking to strengthen the presence in regulated markets like the United States and the European Union. Since the pharmaceutical industry is highly globalised, it requires strong intellectual property (IP) protection to safeguard investments and encourage innovation. Developing new drugs is an expensive process, costing anywhere from $300 million to $ 1 billion, and a large proportion of these expenses are incurred during the early research and development (R&D) phases. Therefore, to recover investments and enable pharmaceutical companies to profit from their breakthroughs, intellectual property protection is highly essential (Tenni et al., 2022).

However, strong IP laws can be a barrier to generic drug production. In 2005, India adopted the product patent system under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement(Prakash *et al.*, 2018). Before this, India's pharmaceutical sector thrived on the production of generic medicines, benefiting from the process patent system that allowed companies to develop alternative manufacturing methods for patented drugs. So, as long as the company developed a new process to make a drug, it could sell it as a generic version without infringing the original drug's patent. But post-TRIPS agreement, Indian pharmaceutical firms have had to adapt to stricter patent laws, impacting their ability to manufacture and export generics without facing legal and regulatory barriers.

Now, the generic manufacturers specifically need to handle data exclusivity, i.e the time frame during which only the original manufacturer of the drug may use the clinical trial data they filed to obtain regulatory approval and make sure their generics do not violate any existing patents. For instance, in the EU, the EMA has set the data exclusivity period to be 8 years after which the original manufacturer is obliged to release the clinical trials data to those manufacturers who wish to produce their generic counterparts (EMA, 2025a).

In addition to this, many companies also file for secondary patents to extend their protection (e.g., by seeking patents for small alterations to the original drug, like a different formulation) and makes the production and sale of generic drugs difficult (Sampat and Shadlen, 2017). Also, in the EU, the Supplementary Protection Certificates (SPCs) increase the marketing exclusivity for specific patented medications and plant protection products to a maximum of five years in order to compensate for lost time due to regulatory approvals (EMA, 2025b).

2.8 Strategies Adopted by Indian Pharmaceutical Firms to Strengthen Regulatory Compliance

Indian pharmaceutical manufacturers have shifted from a reactive, inspection-driven adjustments to more structured, proactive, compliance focused programs in response to more stringent regulations from the US FDA and the EMA. They have implemented a variety of strategies to enhance compliance and preserve access to international markets. The strategies listed below are a reflection of the industry's changing strategy for maintaining market access while maintaining product quality. Investing in digitalization, strengthening internal audits, forming collaborative partnerships, and taking advantage of government incentives are some of the important strategies. This section discusses these strategic adaptations, emphasizing the efforts being made by Indian manufacturers to address regulatory gaps and improve their competitiveness internationally.

1. **Digitalization**: The digitization of the major operational and documentation systems is a key strategy used by Indian pharmaceutical companies to improve regulatory compliance. This includes the adoption of digital tools like Laboratory Information Management Systems (LIMS) and TrackWise, Electronic Batch Records (EBR). According to Jayapala Reddy and Rao (2017), integrating domain-specific digital tools across quality, manufacturing and regulatory function increases operational efficiency. It also reduces compliance risks, especially in areas related to data integrity and documentation errors. The authors state that such systems significantly improve brand credibility and regulatory preparedness in global markets (Jayapala Reddy and Rao, 2017).

   According to Hole et al (2021), digitalization has several advantages for the pharmaceutical value chain. By facilitating structured, validated data flows, it increases deviation management, decreases batch release times, and improves process consistency in manufacturing. In quality assurance, it makes decision-making more efficient and enables the quick detection of quality problems, both of which are critical during audits or inspections. Crucially, digitalization makes it possible for departments to integrate seamlessly, enhancing cooperation and overall operational effectiveness.
   In addition to these benefits, recent literature further emphasizes the growing importance of digital transformation in improving regulatory compliance. Ullagaddi (2024) highlights the role of digital QMS systems in enhancing data transparency and ensuring audit-readiness. These technologies allow companies to respond more swiftly to regulatory requirements and improve overall compliance readiness. Digital tools such as TrackWise and LIMS were identified as key enablers in reducing compliance burdens, ensuring that companies meet the demanding

standards of global regulatory agencies.

The significance of digital transformation is further highlighted by recent studies on the application of cutting-edge technologies in the pharmaceutical industry, such as blockchain, artificial intelligence (AI), machine learning (ML), and the Internet of Things (IoT). The study conducted by Sugandha et al (2023) found that automation and digital tools have been essential in boosting operational efficiency, simplifying clinical trials, and preserving data integrity. For example, this article points out that blockchain technology is being utilized more and more to guarantee product traceability, which in turn helps to improve compliance and solve problems like counterfeiting(Sugandha *et al.*, 2023).

Even though big pharmaceutical companies have effectively incorporated these digital solutions, smaller sized companies still continue to face challenges due to the budget constraints. According to Ullagaddi (2024), smaller businesses have a harder time implementing digital technology because they have fewer financial resources. While digital transformation has been a game-changer for larger enterprises, smaller companies frequently struggle with the high initial expenses of installing digital QMS systems even though it's a worthwhile investment.

2. **Strengthening Internal Audits and Compliance Systems:** Many Indian pharmaceutical companies have concentrated on improving their internal audit and compliance systems in order to ensure strong regulatory compliance. Continual monitoring, early detection of deviations, and timely corrective action are all made possible by regular internal audits, which are crucial in identifying potential non-compliance risks before they are brought to the attention of external regulators like the US FDA and EMA during inspections.

   According to Agarwal and Mishra (2019), audits are essential for evaluating compliance and enhancing quality systems in the pharmaceutical sector. Internal audits play an important role in identifying the problems and areas for improvement in quality management systems, which supports regulatory compliance and continuous process improvement (Agarwal and Mishra, 2019). By identifying possible problems early on, audits can assist companies in addressing deficiencies before they are brought to the attention of external regulators, promoting a culture of improvement. This proactive approach guarantees that companies maintain high standards and comply with regulatory requirements.
   Implementing strong audit trails is another essential part of internal

auditing systems. Audit trails ensure transparency and traceability by offering a complete, chronological record of all data modifications. As per the guidelines established by the FDA and EMA, audit trails need to document who made modifications, when they were done, and what kind of changes they were. This degree of documentation ensures data integrity, and improve adherence to international regulatory standards(Huy, 2023).

3. **Collaborative Strategies:** Building collaborative partnerships with international pharmaceutical firms, universities, and research organizations is a key strategy for Indian pharmaceutical companies. According to Chokkakula et al (2018), collaborations in the form of in-licensing agreements, and contract research and manufacturing services (CRAMS) are vital to Indian pharmaceutical companies. These collaborations not only help these companies access newer technologies and products, but also help them speed up the regulatory approvals (Chokkakula *et al.*, 2018). For instance, when an Indian pharmaceutical company enters an in-licensing agreement with an MNC, these companies can market newly developed drugs at affordable prices while benefitting from the regulatory pathway already established by the MNCs in foreign markets. This approach streamlines the regulatory procedure, especially for generic medications.

4. **Enhancing employee training and awareness:**
   One other significant strategy used by Indian pharmaceutical companies do to ensure operational excellence and regulatory compliance is conducting extensive training initiatives. Pharmaceutical companies prioritize frequent training in data integrity, Good Manufacturing Practices (GMP), and changing regulatory requirements to guarantee that all employees are well-equipped to answer any questions directed towards them during an inspection.

   According to Bunn (2019), all the employees should be trained regularly and effectively and the training should be tailored to the specific duties they perform to ensure that they understand the critical task they perform and their impact on product quality and compliance. The training systems should also be monitored and assessed to ensure that it is effective and retraining should be implemented as necessary to address any performance gaps or in case of any regulatory changes(Bunn, 2019). Ankur Choudhary (2025) highlights how important ongoing training is to preserving regulatory compliance. He points out that one of the main reasons for non-compliance in the pharmaceutical sector is insufficient training. In his article, Choudhary proposes for structured training programs that are

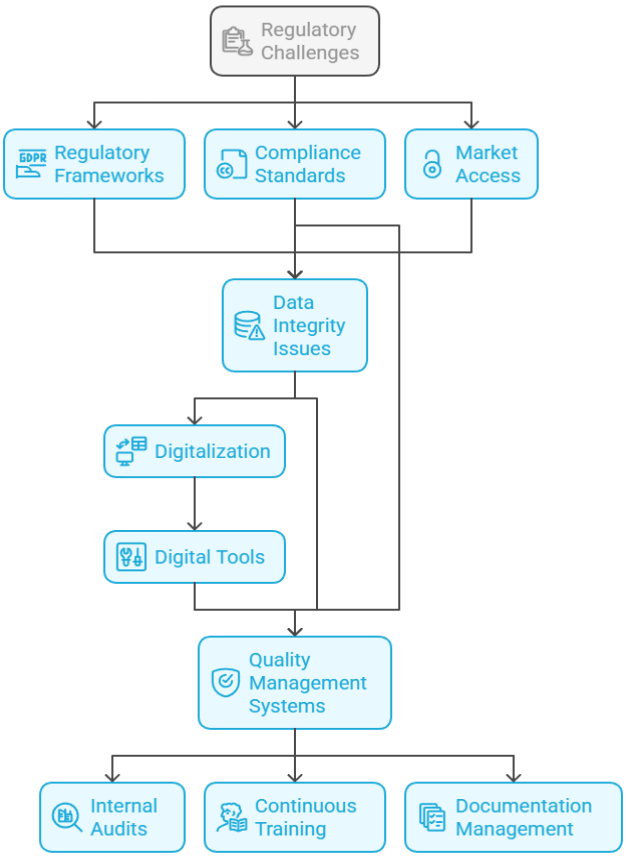
frequently updated to reflect the most recent regulatory standards, ensuring that all employees are competent and aware of their responsibilities (Choudhary, 2025).

2.9 Conceptual Framework

Indian pharmaceutical companies encounter a lot of hurdles when navigating through the global regulatory landscape. The regulatory frameworks differ from market to market, making it one of the challenges. Data integrity and compliance are closely related since if data integrity is kept throughout the manufacturing process, it's guaranteed that the data produced is accurate, complete and traceable. To meet these challenges, QMS plays a pivotal role as well. A strong QMS lowers the possibility of violations and promotes ongoing improvement. Digitalisation emerged as a key enabler in reducing compliance issues and improving operational efficiency.

The Figure 2.1 demonstrates how these crucial components—digitalization, data integrity, QMS, and regulatory challenges—are interconnected and how they all affect the compliance tactics used by Indian pharmaceutical businesses.

Fig 2.3 Conceptual Framework



2.10 Gaps in Literature

Even though the existing literature provides a lot of insights into the regulatory compliance issues faced by India in the global markets, there still exists several gaps. There is still a significant void in the literature about the actual use of digital technologies in Indian pharmaceutical companies. Although the potential advantages of digitization are widely known, there aren't many empirical studies looking at the actual difficulties and experiences faced by Indian pharmaceutical companies when implementing digital compliance solutions. Hence more thorough research is needed in this area focusing more on the Indian pharmaceutical perspective.

Additionally, there is a lack of information regarding the specific strategies used by Indian pharmaceutical firms to ensure compliance international regulatory expectations. Although several studies highlight the value of internal audits, digitization, and training, there are few in-depth descriptions of the real-world strategies and practices that these companies use. Therefore, it is essential that this study investigate these strategies and offer insights into how Indian pharmaceutical companies can more effectively negotiate the changing regulatory environment.

In summary, this study attempts to fill these gaps by investigating the practical

challenges and strategies employed by Indian pharmaceutical firms to improve their compliance and navigate the changing regulatory environment.

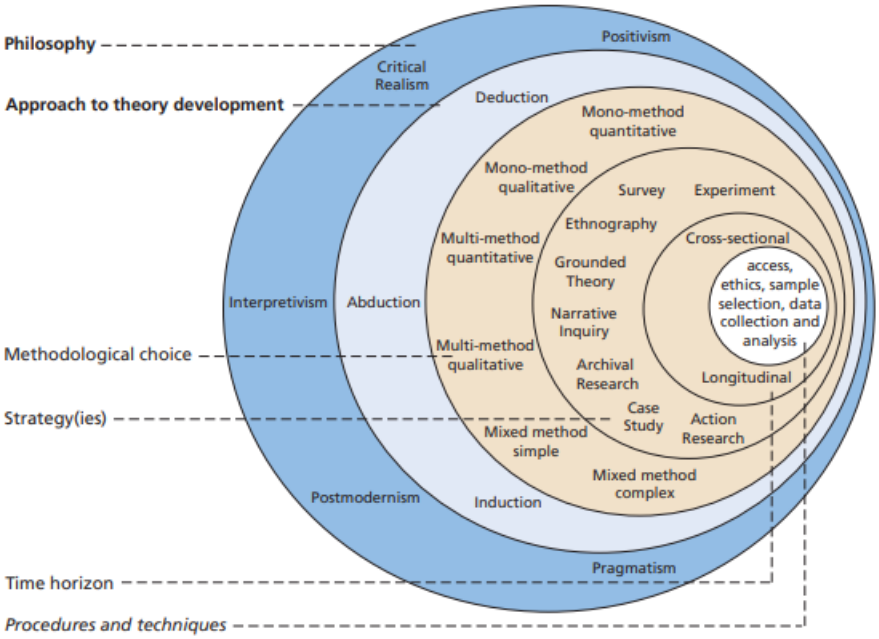
CHAPTER 3: RESEARCH METHODOLOGY

3.1 Overview

This chapter details the research methodology adopted for this study and specifies the systematic approach employed to investigate the challenges faced by Indian pharmaceutical companies, manufacturing generic medicines, in ensuring compliance with regulatory requirements, specifically focusing on the US FDA and European Medicines Agency (EMA) standards. The research adopts a qualitative approach, aiming to explore the experiences, strategies, and challenges encountered by industry professionals working in the QA/QC, regulatory affairs and export offices in the Indian pharmaceutical companies. This chapter outlines the justification for the chosen methodology, the design of the research, the process of data collection and analysis, and the ethical considerations that guided the research.

This study is guided by the Research Onion framework proposed by Saunders et al. (2023), which provides a structured and systematic approach to selecting appropriate research methods.

Figure 3.1 The research Onion (Saunders *et al.*, 2023)



3.2 Research Philosophy

In his book, Saunders et al. (2023) describes three assumptions namely ontological, epistemological and axiological. They point out that the differences in these assumptions give rise to various research paradigms such as positivism, interpretivism, relativism, critical realism and pragmatism. These paradigms are

responsible for how the researchers understand the reality and approach the research process.

An Interpretivism philosophical approach is intended to be carried out for this research. Interpretivism emphasizes on understanding the multiple subjectivities(Saunders *et al.*, 2023). This approach is more suited for this research since the core aim of this research is to delve into the complex challenges Indian generic manufacturers have to face in the context of the US FDA and EMA regulatory frameworks. Hence, a deep understanding of different perspectives of professionals within these companies is essential and the data obtained will be purely subjective and focuses more on their experiences and viewpoints. The participants can share valuable insights on the challenges and concerns they come across in the industry and shed light upon the adaptation strategies they follow.

Comparing it with the positivist approach which aims to generalize findings through quantifiable data, interpretivism is mainly about gathering detailed insights that emerge from human interaction and experiences. Also, the challenges faced in regulatory compliance are not uniform across all companies; they vary depending on company size, infrastructure, regulatory history, available resources, and market focus. Hence, this approach will help to explore these differences rather than relying solely on objective facts.

3.3 Research Approach

This study follows an inductive research approach, which is in close alignment with interpretivist research philosophy. As Easterby-Smith et al. (2012) suggest, the choice of approach is not only about data collection and analysis, but also about the general research design setup, such as how evidence is gathered and interpreted to answer the research question.

Because this research is targeted at comprehending the perceptions and experiences of professionals working in the QA/QC, regulatory affairs, and export offices in the generic manufacturing facilities in Indian pharmaceutical companies, an inductive approach is most suitable. It enables the development of novel knowledge and theoretical understanding from scratch, especially in cases where there is no literature or where such literature does not effectively outline the specific environment under consideration.

Also, as Easterby-Smith et al. note, induction is particularly suitable when the research aims to find out why something is happening, rather than just explaining what is happening. In the case of this research, the aim is to find out why certain compliance problems happen, how professionals respond to such challenges, what are the strategies they use and why they resort to such strategies, why some

strategies are better than the others, etc. rather than experimentally testing a hypothesis.

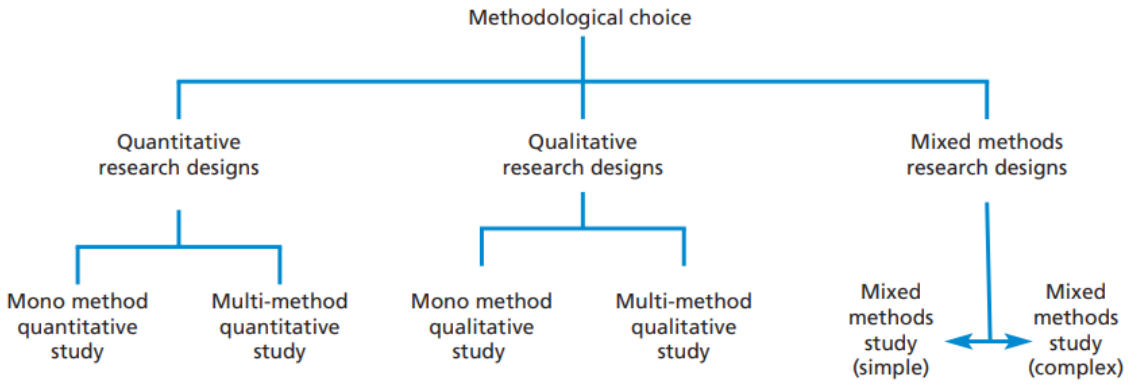
In line with this, the inductive approach allows themes and patterns to emerge from the data over time. This is especially relevant to a topic like this, where there is a lot of regulatory literature available globally, but relatively less real-life data on how these Indian pharmaceutical firms experience and negotiate compliance in practice. The flexibility and openness of the inductive approach thus make it the most suitable choice for uncovering rich, contextual results with potential to inform future practice and research.

3.4 Research Methodology

3.4.1 Design of Methodology

The design of the research follows a qualitative approach based on semi-structured interviews.

Figure 3.2: Methodological choice(Saunders *et al.*, 2023)



Saunder's research onion also discuss whether the research opt for a mono, multi or mixed methods. This study follows a mono method qualitative study.
The semi-structured interview format was chosen because it allows for both flexibility and focus. This approach guarantees that important research issues are covered in every interview while allowing the researcher to pose open-ended questions that encourage thorough answers from participants. Semi-structured interviews offer the opportunity to explore individual experiences and viewpoints in-depth, providing rich qualitative data that can be analyzed for recurring patterns and themes.

The research design also includes the use of purposive sampling, which is a non-random technique used to select participants who possess specific knowledge or experience related to the research topic. In this study, participants will be selected

based on their roles within the pharmaceutical industry, such as regulatory affairs managers, compliance officers, business development executives, and other professionals involved in the exportation of pharmaceutical products to highly regulated markets. A purposive sampling technique ensures that the research focuses on individuals who can provide relevant, detailed, and informed perspectives on the regulatory challenges faced by Indian pharmaceutical companies.

The interviews will be conducted remotely, allowing for a broader reach of industry professionals, irrespective of their geographical locations. This approach ensures that the sample is diverse, capturing insights from different pharmaceutical companies and sectors within the industry.

3.4.2 Data Collection

Conducting Semi-Structured Interviews

The semi-structured interviews will be the primary data collection method. Interviews will be conducted with key professionals in the Indian pharmaceutical industry who have direct experience with regulatory compliance for exports to the US and the EU. This approach is suited for exploring their views and experiences in complex fields such as pharmaceutical regulatory compliance(Gill *et al.*, 2008). The interviews will be structured around a core set of open-ended questions designed to gather insights into the following areas:

- The primary regulatory challenges faced by Indian pharmaceutical companies in the US and the EU markets.
- The strategies used by companies to ensure compliance with evolving regulations from the US FDA and EMA.
- The role of regulatory bodies and how they influence companies' compliance practices.
- The impact of regulatory non-compliance, both in terms of financial penalties and reputational damage.
- How Indian pharmaceutical companies are adapting to new or changing regulatory standards.

Example interview questions include:

- "What are the major compliance challenge your company faces in ensuring adherence to US and EU regulatory requirements?"
- "How does your company stay updated with the changing regulatory environment in these markets?"

- "Can you share any strategies that have been particularly effective in managing regulatory compliance?"

The interview will last 15-20 minutes via zoom platform and the meeting will be recorded with the participants consent and then transcribed for analysis. By adopting semi structured interview design, the study ensures that while core areas are addressed across all interviews and the participants had the freedom to highlight their experiences which in turn would enrich the overall depth and quality of the research.

3.5 Pilot Study

Before the main data collection, a pilot interview was conducted as part of the research to assess the clarity, structure and relevance of the semi-structured interview questions. Conducting a pilot interview is a well-defined approach in qualitative research to refine the questions, improve structure and identify possible drawbacks of the set questionnaire before engaging in full data collection(van Teijlingen and Hundley, 2001).

The pilot study was carried out with a participant who had professional experience in pharmaceutical quality assurance for over three years, aligning with the target respondent profiles. The feedback from this session indicated that while most of the questions were clear and relevant, some questions needed rewording. Conducting the pilot study also confirmed that the average time for each interview is around 15-20 minutes, and the semi structured format allowed for both focused and flexible discussion. The data collected during pilot study was not included in the final analysis, but was necessary in refining the interview question and improve the data collection process.

3. 6 Time Horizon

The current study employs a cross-sectional time frame, i.e., collecting data at a single point in time or a short interval of time(Saunders *et al.*, 2023). Since the dissertation involves time constraints and aims to capture the snapshot of regulatory compliance initiatives of Indian exporters at this moment in time, the best and most feasible one is the cross-sectional design. It gives a snapshot of compliance issues of Indian pharmaceutical companies in international markets particularly the regulations set forth by the FDA and EMA. Although a longitudinal study might offer insight into the progression of compliance issues over a long period of time, it is beyond this dissertation's scope and timescale.

3.7 Data Analysis Approach

For analyzing the data collected through interviews, a thematic analysis is used,

which is essentially a systematic method for identifying patterns and key themes widely used in qualitative methods. It is a well-recognized method used my many researchers to systematically identify, organize and interpret the qualitative dataset by searching for meaningful patterns. This method is particularly well-suited for this research because it helps in identifying recurring themes, insights and different point of views across different interviews.

This method provides a lot of flexibility to capture and understand the complex realities and perspectives that surround different participants, while giving a structured and transparent process of analysis. It supports the inductive approach which allows the researcher to remain open to emerging insights while analyzing how everything aligns with the research objectives.

The thematic analysis is guided by the framework proposed by Braun and Clarke (2006), who outlined a six-phase process for conducting a thematic analysis. Even though this method was initially developed within the psychology, it is widely adopted across disciplines including business and healthcare research due its adaptability.

The six phases are:

1. Familiarisation with the Data: The first step is transcribing the interviews and then reading the scripts several times to familiarise with the dataset. During this phase, preliminary observations are noted and attention is paid to the patterns or repeated points raised by the participants. This would help build an overall understanding of the data set.
2. Generating Initial Codes: The next step is to systematically identify and code the data that is relevant to the research question. Coding is carried out manually, making a note of the recurring phrases, ideas, and experiences related to regulatory compliance challenges, adaptation strategies etc.
3. Searching for Themes: After the initial coding, the codes are reviewed and analysed to correlate with potential themes. After the key themes are identified, they will be grouped under broader themes like regulatory complexity, compliance challenges, adaptation strategies, impact of evolving regulations, etc.
4. Reviewing themes: This phase focuses to assess whether they accurately represent the coded data set. Some themes were refined, merged or discarded depending on the relevance of the data.

5. Defining and naming themes: Here, each theme is clearly defined and finalised, capturing the essence of the participants experiences and viewpoints.
6. Producing the Report: The last and final phase is writing an analytical narrative incorporating the quotations from the interviews. Themes are presented systematically and connections to existing literature is pointed out and analysed(Braun and Clarke, 2006).

For example, Hamill et al. (2023) conducted a qualitative study on the procurement and manufacture of APIs in India and used thematic analysis to identify institutional and operational challenges in the supply chain. Similarly, a study done by Tauqueer et al. (2019) also used a thematic approach to analyse the data. Hence, these studies reinforce the methodological credibility and relevance of thematic analysis in pharmaceutical regulatory research.

A cross analysis will also be done to compare the response from different companies and evaluate if they have the same problems and strategies when it comes to regulatory bodies such as FDA and EMA. This would explore how different companies with different levels of experience address the same regulatory issues. Hence, similarities and differences can be identified to help the companies navigate the changing regulatory landscape better.

By this systematic analysis, and incorporating experiences of people from different companies, the study will provide practical insights for those companies looking to improve their regulatory compliance.

3.8 Ethical Implications

This research involves qualitative interviews of corporate professionals, i.e., professionals working in the Indian pharmaceutical companies. This research has been planned in a way that it does not involve any significant ethical implications, and all ethical practices have been used to protect the rights, dignity, and privacy of the research respondents. The key aim is to obtain professional opinions about regulatory compliance without asking for any sensitive or proprietary information that could potentially damage the reputation of the company or the individual.

Full and informed consent forms will be distributed to all participants before the interview, explaining the purpose of the research, the nature of their involvement, how their responses will be used, and their freedom to withdraw from the research at any time. The involvement of the participants is entirely voluntary. No company names or personal identifiers will be recorded in the final report. All responses will be anonymised and stored safely, with access only available to the

researcher. Data will only be used for academic purposes and that too in line with ethical principles.

Though there are no major ethical risks for this study, some practical concerns can be predicted. One such is the availability of respondents, as working professionals may have tight schedules. This will be tackled by approaching more respondents than required to account for potential non-responses. Another issue that can arise is that some respondents may hesitate to talk freely due to company policies. However, the assurance of confidentiality and anonymity will create a safe environment for them to open up and engage in an honest conversation.

Overall, the research is carried out following high ethical standards in terms of a responsible and respectful approach to data collection. The ethical strategy is directed towards ensuring the privacy of participants and maintaining the integrity of the research process without imposing any harm or risk on the participants or their organization.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Overview

This section is dedicated to the analysis of the qualitative data collected through semi structured interviews with the professionals working in the regulatory affairs, quality control/quality assurance departments in the Indian pharmaceutical industry. The primary aim of this research is to explore the compliance challenges faced by Indian pharmaceutical companies manufacturing generic medicines exporting to the US and EU markets. This research also aims to shed light of various adaptation strategies and how these companies adapt to evolving regulatory requirements and manage limitations to remain competitive in international markets.

A total of 8 professionals took part in this research. The professionals that were interviewed held a variety of positions in the pharmaceutical industry and had a wide range of experience in supply chain management, pharmacovigilance, quality assurance, supplier qualification and regulatory affairs. These experts offered insightful information about the challenges, strategies, and adaptations associated with international regulatory compliance in the pharmaceutical industry. The sociodemographic statistics of the participants and essential characteristics of the research study context are given in the table below:

Table 4.1: Sociodemographic details

Respondent characteristics	**Sample size: 8**
1. Role	
Regulatory affairs specialists	3
Quality Assurance specialist	3
Team Lead global supply quality	1
Pharmacovigilance	1
2. Experience level (years)	
3-5	3
6-10	3
>10	2

A thematic analysis is adopted for this research to interpret the interview data. This method is widely used in qualitative research to identify and organize recurring patterns or 'themes' within textual data(Braun and Clarke, 2006). This method of analysis was chosen for the flexibility it provides when it comes to extracting rich, detailed insights from open ended answers, especially useful when examining experiences, viewpoints and challenges faced by the

professionals in a regulatory context. The coding process involves initial familiarization with the data, generation of preliminary codes, clustering of the codes into broader themes, and finally reviewing and refinement of those themes.

The participants interviewed for this research are people with diverse professional roles, including people working in regulatory affairs, quality assurance managers, pharmacovigilance professionals with experience ranging from 3 to over 10 years in the pharmaceutical sector. These varied perspectives enhance the depth of analysis and allow to understand the regulatory compliance challenges even better and how they manage across different functions and company sizes.

In line with the guidelines provided in the handbook, the discussion is integrated within the data analysis. Each theme is analyzed in correlation with existing literature, regulatory context and theoretical relevance. This integrated approach offers a more detailed view of the processes influencing Indian pharmaceutical exports to regulated countries and enables a more coherent narrative.

The analysis is structured around three key themes:

1. Regulatory Challenges
2. Adaptation Strategies
3. Risk management and Global Regulatory Compliance

Each theme is supported by relevant subthemes and direct quotes from the participants, offering a clear picture of the stakeholder experiences and perceptions.

4.2 Research Question and Objectives

Research Objectives:
To this study is guided by following objectives:

Objective 1: To identify and analyze the key compliance challenges faced by Indian generic drug manufacturers in global markets, specifically focusing on regulations from the US FDA and EMA.

Objective 2: To identify the challenges faced by these companies in adapting to the regulatory changes, such as evolving pharmacovigilance and data integrity standards, and the impact of non-compliance and analyze how generic manufacturers adapt to such changes.

Objective 3: To assess the effectiveness of current strategies and practices employed by Indian pharmaceutical generic manufacturers to meet these regulatory expectations and explore potential improvements for enhanced market

access and compliance.

Research Question:
The following are the research questions intended to help reach the objectives:

1. What are some of the major compliance challenges faced by Indian pharmaceutical manufacturers in order to meet the regulatory requirements set up by the US FDA and EMA
2. How do the evolving regulatory requirements in the US and EU affect the Indian generic drug manufacturers
3. What are some of the measures these companies have taken to enhance the regulatory adherence, and to what degree have they succeeded?
4. What are some of the recommendations to strengthen the compliance for Indian manufacturers exporting to international markets?

Every theme that is discussed in this chapter has been created in order to answer these research question and achieve these goals.

4.3 Thematic Discussion

Theme 1: Regulatory Challenges

One of the most frequently recurring themes across all the interviews was the persistent struggle to meet with the regulatory requirements of global markets, particularly when it comes to US FDA and EMA. Participants consistently stated that compliance with evolving Good Manufacturing Practices (GMP), maintaining data integrity, ensuring robust documentation practices and keeping up with changing expectations as critical issues that affect the export readiness of these companies. This theme emerged with the consistent references to issues with data integrity, poor documentation practices and non-compliance with manufacturing standards, as discussed by the participants.

This theme addresses the first objective of the study: To identify and analyze the key compliance challenges faced by Indian generic drug manufacturers in global markets, specifically focusing on regulations from the US FDA and EMA. This theme highlights how regulatory compliance in the pharmaceutical export industry is dynamic and demanding, and it offers insight into how organizational and systemic flaws can lead to serious non-compliance risks.

Subtheme 1.1: Data integrity concerns

In this theme, the most recurrent subtheme was data integrity. All the participants brought up the growing regulatory scrutiny of data handling procedures, especially with regard to audit trails, electronic records, and real-time data

entering. According to the US FDA guidance (2018), data integrity is the completeness, consistency and accuracy of the data throughout the lifecycle of a drug. It ensures that all the cGMP records, whether manual or electronic, are reliable and accurate.

One of the respondents commented that,

> *"Data Integrity has evolved like anything."*
> capturing the growing expectations from regulatory agencies such as the US FDA and EMA.

Concepts like ALCOA (Attributable, Legible, Contemporaneous, Original, and Accurate) and ALCOA+, helped organizations like the US FDA and EMA increasingly demand full traceability of data. This is in line with the larger regulatory trend that has made data integrity a necessity for compliance rather than just a best practice. Hence, now these standards are no longer optional, instead regarded necessary for keeping accurate and transparent records throughout the product lifecycle.
According to one respondent,

> "*Data integrity is a major concern. Everything is being scrutinized, including audit trails, batch records, and even metadata. If anything is incomplete or missing, it immediately becomes a finding."*
> This is a reflection of the regulators move toward forensic-level examinations, which assess the legitimacy and traceability of presented data

This stresses the importance of data integrity and how it becomes a challenge. Literature data also supports these concerns. According to Gambhire et al (2024), data integrity violations are one of the major reasons stated in USFDA warning letters sent to Indian pharmaceutical companies, reflecting widespread challenges in maintaining audit-ready records and reliable documentation practices. Ullagaddi (2024) similarly notes that data integrity emerged as a major regulatory concern around 2014–2015 and continues to be one of the top violation categories, with specific breaches including non-compliance with 21 CFR Part 11, and manipulation of analytical data(P. Ullagaddi, 2024). The 2015 EU ban on 700 generic medications manufactured in India due to suspected clinical trial data manipulation further demonstrates this finding(Pérez, 2017).

According to these results, issues with data integrity are more systemic. They are frequently made worse in establishments with weak electronic systems or a heavy reliance on paper-based documentation. Thus, this subtheme illustrates how data integrity continues to be a crucial yet continuous obstacle for Indian pharmaceutical companies attempting to satisfy global regulatory requirements.

Subtheme 1.2: Poor Documentation Practices

The challenge of keeping accurate and thorough documentation was another frequent concern brought up by the participants. Poor documentation methods are a major risk factor for not meeting the regulatory standards imposed by the US FDA and EMA. As one of the interviewees mentioned:

> *"Many compliance issues arise from poor documentation"*

Participants responded that this problem is more noticeable in businesses with poor electronic documentation systems or those that still keep records on paper. Documentation is a very important aspect in the pharmaceutical industry. As one of the respondents commented:

> *"if you have not documented (any activity), then it is not done"*

These procedures often lead to missing documentation, outdated Standard Operating Procedures (SOPs), and inconsistent batch records—all of which are significant issues during regulatory inspections. The FDA and EMA, among other regulatory agencies, place a high value on accurate documentation and frequently mandate that businesses keep a thorough audit trail for all their operations. The substantial effect of poor documentation processes on compliance was one of the main conclusions drawn from the interviews. One participant explained:

> *"If there's a deviation or an issue during manufacturing, having the right documentation at the right time is crucial. If records are lost or poorly maintained, it can lead to severe delays in the approval process or, worse, product recalls."*

According to Rodríguez Pérez (2017), data integrity problems are often cause due to poor documentation practices or incidents which cause data loss which may often come across as fraudulent intent. As per Ullagaddi (2024), documentation errors can also occur where companies are still depending on manual paper-based procedures. The literature review findings back up this fact. Hence, we can conclude that issues related to documentation directly affects data integrity.

Subtheme 1.3: Quality Management System

In every interview, Quality Management System (QMS) was recognized as a fundamental component in guaranteeing regulatory compliance. Participants underlined the significance of having a strong QMS in place, stating that it has a direct impact on the company's capacity to satisfy the stringent requirements of the US FDA and EMA. One interviewee stated

> *"The presence or absence of a robust quality management system, it's like a make-or-break factor in a regulatory compliance environment"*

A quality management system (QMS) can be defined as an organized framework that pharmaceutical companies use to manage their processes, and ensure product quality, safety, and regulatory compliance and includes protocols for manufacturing, documentation, testing, risk management, and ensuring continuous improvement(ISO, 2025).

This sub theme emerged as a critical challenge when interviewees described how inadequate or outdated systems hindered their ability to maintain compliance with the regulations, especially in upholding GMP which is crucial in ensuring compliance. This is well in line with the literature review finding. Choudhary (2024) highlighted that a well implemented QMS is essential for meeting the regulatory requirements of FDA and EMA. Several participants were also of the opinion that implementation of a robust quality management system was integral to avoiding audit failures and ensuring product quality in highly regulated markets. One of the participants commented:

> *"A good quality management system is at the heart of compliance, but we often see gaps between what companies promise in policy and what they deliver in practice. If a company fails to implement its QMS properly, the risks of non-compliance multiply"*

This is backed by Bablani and Janodia (2020), who show that 85% of FDA warning letters from 2005 to 2018 were related to cGMP violations, with many companies cited for QMS deficiencies. This trend points to the critical need for stronger QMA practices. Ullagaddi (2024) also noted that weak QMS systems contribute significantly to regulatory violations. He also discusses how digital transformation enhances QMS by improving data integrity and process control, helping Indian companies meet evolving regulatory standards. As one of the interviewees responded,

> *"So, one of the best things a company could do in the present scenario is to invest in a digital quality management system, you know, like TrackWise, or LIMS"*
>
> This suggestion is aligned with Pravin Ullagaddi (2024), who highlights how digital transformation has enhanced QMS enabling companies to meet evolving regulatory standards.

In summary, implementing a strong and robust Quality Management System (QMS) is essential for ensuring compliance and operational efficiency. However, establishing a QMS that satisfies the requirements of international markets is still a difficulty for many Indian pharmaceutical companies, especially for small scale enterprises.

Analytical Considerations

Relevance to research Question:

This theme directly responds to first research question by highlighting the major compliance issues that Indian pharmaceutical companies have while trying to meet the regulatory standards set by FDA and EMA. It highlights the critical challenges such as data integrity, documentation practices, and weak QMS. The interviewees repeatedly highlighted the ways in which weak QMS and inadequate documentation hinder compliance and these findings align with the study's aim of examining the difficulties Indian companies encounter in maintaining regulatory compliance in international markets.

Complexities:

Although most participants stressed the value of data integrity and QMS, a conflict surfaced when talking about the size and resource allocation of the companies into account. All the interviewees were of the opinion that majority of the issues with data integrity, documentation and QMS happens with smaller companies who suffered from outdated systems, limited resources and lack of digital solutions. One participant mentioned

> *"Implementing a proper QMS takes time and investment, which is difficult for smaller companies to manage."*

This draws attention to a tension in the pharmaceutical sector, where smaller companies find it difficult to meet international regulatory requirements due to resource differences. However, this doesn't mean that larger firms are without any challenges, they too must adapt to evolving regulations and invest further in technologies to meet the ever-increasing demands as one of the participants suggested:

> *"Regulators want to see that you're constantly improving your systems. They don't just want a fixed set of processes; they want to know that you're evaluating and improving your practices regularly to stay compliant"*

Participant Consistency:

The interviews had a remarkable consistency where the participants identified nearly the same challenges, with data integrity being major challenge to regulatory compliance by all of them.

Theme 2: Adaptation Strategies

Indian pharmaceutical companies encounter a lot of challenges in maintaining

compliance as regulatory bodies like US FDA and EMA continue to evolve their regulations. The development and implementation of successful strategies has been one of the main responses to these challenges. Companies employ a variety of tactics to meet quality standards, keep in line with evolving regulations, and preserve their competitive positions in international markets. The majority of the strategies that were found were intended to address issues with data integrity, documentation procedures, quality management systems (QMS), and general operational effectiveness. The most often mentioned adaptation tactics used by Indian pharmaceutical companies are examined in this section, with an emphasis on digital transformation, regulatory knowledge and training, and cooperative collaborations.

Subtheme 2.1: Digital Transformation and Technological Integration

Digital transformation was one of the most discussed adaption strategies. Majority of the participants mentioned that pharmaceutical companies were investing in automated data management systems, electronic batch records, and digital QMS platforms. Data integrity, documentation problems, and audit readiness were among the difficulties that were effectively resolved by the move to automated systems and the digitalization of documents. Participants consistently cited those digital solutions such as TrackWise, LIMS, RIMS and VEEVA, allowed them to enhance data integrity and helped them maintain audit-ready records. When asked to one participant about digitalization in their company, they responded with:

> *"Yes, it significantly enhanced compliance by improving your accuracy, maintain data integrity and efficiency… we have advanced data management systems like RIMS and VEEVA… they streamline the process, 60% of it is streamlined. We don't search for any document... you have all those documents categorized properly, standardly, which simplifies and streamlines the process"*

Another participant responded with:

> *"So, over the past few years, we have shifted from largely paper-based systems to integrate the digital forms, and it has significantly improved both efficiency and audit readiness"*

The transition from paper-based to digital system is an excellent example of how compliance is facilitated by technological integration. The role of digital transformation in improving regulatory compliance is well documented in the literature review. Ullagaddi (2024) stated that digital solutions enhance traceability and improve reliability of records. This was backed by one of the respondents when they commented:

> *"It's easily traceable, and its more secure, and there's like, chance for less human error"*

Due to automation in key processes such as batch record management and audit trails, these companies can reduce the risk of non-compliance due to documentation errors. This change in technology is particularly important when it comes to addressing challenges mentioned previously like data integrity, documentation errors and establishing a robust QMS. Participants frequently mentioned how they were able to improve data integrity and guarantee that records are always audit-ready by using digital solutions such as TrackWise, LIMS, RIMS, and VEEVA.

Subtheme 2.2: Regulatory Knowledge and Training

In order to keep up with the evolving regulations, one key strategy mentioned by the majority of the participants is continuous investment in regulatory knowledge and training programs. Many participants commented that ensuring staff competence is very crucial when it comes to maintaining regulatory compliance. When asked about the training culture, one of the participants responded with:

> *"The company have a dedicated team for this, a training centre to ensure all employees are, you know, covered on up-to-date regulations"*

As highlighted by several participants, human resources are central to a company's ability to navigate through the complex regulations set forth by the FDA and EMA. Continuous investment in regulatory knowledge and training programs is must to keep the employees updated with new regulations and ensure staff competence.

> *"So we need to be having the continuous training and proactive strategies to ensure the compliance is up to the mark"*

Participants also emphasized the importance of staying ahead of the regulatory changes. By staying updated on new regulations as they emerge, these companies can ensure they are prepared well in advance even before the regulation has become official. This proactive approach is vital for companies especially exporting to stringent markets like the US and EU. When asked how they stay updated with the regulations, one of the interviewees responded:

> *"Yeah, so we have a dedicated regulatory Intelligence Team, actually, so they monitor changes through regulatory databases like TOPRA, regulatory newsletters and direct communications with consulting partners"*

A proactive regulatory intelligence helps companies anticipate these changes, ensuring they can implement the required adjustments quickly and effectively, reducing a potential disruption in operations that can arise due to a change in

regulation. One of the respondents commented:

> *"What helps is that we treat regulatory updates not as disruptions, but as opportunities to strengthen our system, that mindset keeps us ahead of the curve"*

A key component of developing a robust compliance culture is adopting this mentality, which sees regulatory changes as opportunities rather than challenges. By incorporating regulatory updates and knowledge into day-to-day operations, companies can cultivate an adaptable culture that sees change as an essential and unavoidable part of growth. Additionally, by providing regular trainings, the company can guarantee that the employees are actively remaining in compliance with changing regulatory requirements rather than only responding to them. This is in alignment with Choudhary's (2025) findings, participants consistently highlighted the importance of continuous investment in training programs.

Subtheme 2.3: Co-operative Collaborations

For Indian pharmaceutical businesses, navigating the increasingly complicated regulatory framework requires not only regulatory intelligence and internal training, but also cooperative collaboration. One interview mentioned that many companies are hiring people who previously used to work as an auditor for the regulatory bodies. They commented:

> *"They'll take their suggestions... will help them to meet the regulatory standards, and also it will help them meet the regulatory expectations during the audit and these ex-auditors will guide the company"*

This method not only helps companies comply with regulations, but it also makes them audit-ready by preparing them for regulatory audits. By taking advantage of the former auditor's experience, companies can reduce the possibility of non-compliance during an actual audit.

Collaborating with local experts who are aware of the specific regulatory requirements in different regions is another strategy used by some companies. This point was highlighted by one participant:

> *"If you can collaborate with the local experts and you get what exactly the requirement is, you can align easily by communicating with the local experts and implementing proactive risk management strategies"*

Hence, communication with regulators, hiring the consultants, subscription to the databases, professional memberships, all these strategies are adopted

Analytical Considerations

Relevance to Research Question:

One of the research questions is to understand how Indian pharmaceutical companies overcome compliance challenges while adhering to regulatory standards set by bodies like the US FDA and EMA. This theme directly addresses the strategies used by Indian pharmaceutical companies to adapt to evolving regulatory requirements.

The strategies covered in this section, including digital transformation, regulatory knowledge and training, and cooperative collaborations, directly contribute to overcoming important compliance challenges such as data integrity, documentation practices, and quality management systems (QMS). The emphasis on proactive regulatory intelligence and investment in digitalization shows how companies are overcoming regulatory challenges in a world that is becoming more digital and interconnected.

Complexities:

Even though digitalization is viewed as an essential component for regulatory compliance in this era, the process of integrating digital tools can be complex and expensive. Integrating new digital systems can be difficult for some companies which have older, legacy systems which may be incompatible with the modern digital solutions, requiring substantial investment to bridge this gap.

Moreover, many companies also find complexity in adhering to different regulatory requirements across different global markets. For instance, if a company is manufacturing for both the US and EU markets, they must ensure distinct regulatory requirements, particularly in terms of documentation, data integrity and audit trails, all can be difficult. Because the norms in one market may differ from those in another, it becomes more difficult to ensure compliance across these different regulatory environments, requiring additional strategies to satisfy both sets of regulations.

Participant Consistency

Participants were consistent during the interview, especially when it came to significance of proactive strategies like investing on digital technologies, establishing regulatory intelligence team and focusing more on training the employees and fostering a culture of compliance. Participants emphasized the need for these strategies to maintain compliance in a highly regulated global pharmaceutical market, regardless of the size of the organization.

Theme 3: Risk Management and Global Regulatory Compliance

Companies in the pharmaceutical sector must proactively manage the risks of non-compliance as well as adjust to various regulatory frameworks as the industry continues to evolve over time. Hence this theme focuses on how companies deal with the regulatory diversity across different markets, like the US, the EU and other international organizations, and how they employ risk management techniques to minimize any non-compliance issues. It also emphasizes how crucial it is to have an operational framework that is robust enough to adjust to changes in regulations, ensure compliance and reduce interruptions to company operations.

Subtheme 3.1: Impact of Regulatory Diversity and Global Compliance

Although Theme 1 covered the main regulatory challenges that Indian pharmaceutical companies face in the present scenario, the complexity that arises because of lack of harmonization of the regulations worldwide needs to be further discussed. When exporting multiple international markets, Indian pharmaceutical companies have many difficulties, especially with the US FDA and EMA whose regulations are getting more stringent day after day. Participants in this study highlighted the additional challenges they face as a result of having to adhere to different regulatory frameworks when exporting to different markets. As one participant explained:

> *"We have a huge regulatory team... we have three to four different teams in regulatory again, okay, one team is completely dedicated to US, the other team is completely dedicated to EU. One team is completely dedicated to ROW... so any changes varying between the regulatory are being easily communicated between the teams. So, this can only happen if you have a dedicated regulatory team in place"*

For companies that manufacture drugs for more than one market, must comply with different regulations, which include variations in GMP standards, documentation, and data integrity.

> *"We tailor our regulatory, submissions, labelling, PV and documentation practices based on the requirements of each target market, like whether it's a US, or EU"*

Large companies often have resources to manage these kinds of requirements. However, when it comes to SMEs, it can possess a great challenge because they might not have the budget or human resource to establish individual regulatory teams for each region. However, to remain competitive, these companies have no choice but to fulfil all of these demands.

For companies that operate in several different locations, these differences in regulatory requirements pose a serious challenge. They are required to keep

separate sets of records, adhere to various reporting standards, and make sure that every procedure satisfies the regulatory expectation of every market. The risk of non-compliance is further increased by the global variation in regulatory processes. In order to satisfy these evolving standards, companies must stay up to date on these changes and modify their compliance processes accordingly. When asked to a participant how they overcome such challenges, they replied with:

> *"So global process with local adaptions, yeah, and conduct regular training programs to keep employees updated on regulations, these strategies will collectively, altogether help maintain the compliance and they ensure smooth market access across different regions"*

From the literature review according to Pezzola and Sweet (2016), one of the biggest obstacles facing multinational pharmaceutical companies is the absence of regulatory harmonization among major markets. This means that local regulatory requirements must be accommodated while maintaining a global compliance framework.

Subtheme 3.2: Risk Management and Mitigation in Regulatory Compliance

For Indian pharmaceutical companies to successfully negotiate the challenges of international regulatory compliance, risk management is very essential. Participants pointed out the importance of proactive risk management techniques in preventing compliance errors and ensure audit readiness.

> *"And if, if you do not have a proper risk management in place, and if you have failures in implementing the changes... then that will also have a compliance issue."*

These companies are now focusing more on identifying and addressing potential compliance risks early on, before they lead to any regulatory violations. Regular risk assessments help these companies identify gaps in their compliance systems and implement corrective actions in place to lower the chance of non-compliance. Another strategy some companies use is to monitor the other companies. One participant was of the opinion that:

> *"So, then you will understand what happening exactly in the other companies, whether we are also running the business in a similar way, or we are doing we? Are we? Are we are working in a better way? Or is there any chance or a scope to improve our procedures"*

Developing a proactive risk management culture within the company is also essential. This was highlighted by almost all the respondents.

> *"What really helps is creating a proactive compliance culture where every department sees compliance as their responsibility, not just QAs and people understand the why behind regulations"*

Furthermore, another crucial component of risk management is crisis management during regulatory audits or inspections. Companies should be ready to react quickly and effectively to audit results by putting corrective actions into place and enhancing their compliance systems to stop recurrence.

Additionally, creating a compliance culture that emphasizes regulatory conformity in every department is essential to creating a risk-resilient company. Companies can lower their risk of regulatory penalties and improve their capacity to adapt to changing regulatory requirements by integrating compliance into their company culture.

Analytical Considerations

Relevance to Research Question:

The main goal of the research is to investigate how Indian pharmaceutical businesses manage compliance issues while following international regulatory requirements, like those established by the US FDA and EMA. This is specifically addressed in Theme 3, which looks at how companies manage regulatory diversity and apply risk management techniques to guarantee compliance in strictly regulated markets. The results show that Indian pharmaceutical companies, especially those exporting to the US and EU, created region-specific regulatory teams, and keep up-to-date compliance systems to meet changing standards in the response to non-harmonized regulations. As addressed by the participants, these strategies show how companies are proactively implementing robust systems and adopting a methodical approach to successfully manage the risks associated with worldwide compliance.

Complexities:

There are several challenges to look after when a company is involved in export to different countries with different regulations, especially when GMP rules, documentation standards, and pharmacovigilance. For example, organizations manufacturing for both the US and EU must align with separate standards for data integrity, documentation, and audit readiness. Particularly for SMEs who lack the resources to keep specialized teams for each country, this dual compliance burden adds a significant amount of complexity. Furthermore, maintaining current knowledge of evolving regulations and integrating them into business operations necessitates ongoing regulatory intelligence and training, which can be resource-intensive.

Participant Consistency:
All the participants were in agreement about the necessity of strong regulatory frameworks and proactive risk mitigation. To remain in compliance with a variety of international rules, some respondents underlined the significance of having specialized regulatory teams, region-specific submission procedures, as well as regular training for employees. In addition, almost every participant acknowledged the importance of developing a compliance culture across the entire organization, where each and everyone involved is accountable.

Discussion Summary

The results of this study offer a thorough understanding of how Indian pharmaceutical companies deal with the increasing complexity of international regulatory compliance, especially with regard to the requirements of the US FDA and EMA. A recurring theme in all three themes was that Indian pharmaceutical companies are actively creating strategic solutions to the complex compliance issues they face in order to maintain their competitiveness in regulated global marketplaces and retain their position.

Data integrity violations, inadequate documentation procedures, and gaps in Quality Management Systems (QMS) are among the primary compliance challenges that were addressed in Theme 1. Small and mid-sized companies face particular difficulties since they frequently lack the digital tools and infrastructure needed to satisfy the stringent international regulations. According to the interviews, issues with inconsistent SOPs, audit trails, and real-time data entry directly affect compliance raise the possibility of regulatory penalties. These observations support findings in recent literature and are consistent with the study's primary goal of identifying the major compliance issues faced by Indian generic producers.

The second theme moved the spotlight to adaption strategies that companies are using to get beyond these challenges. Digital transformation was mentioned as a key facilitator for enhancing data traceability and documentation quality, including the use of digital QMS platforms (e.g., TrackWise, LIMS, VEEVA). The establishment of regulatory intelligence teams that keep an eye on changing needs and investments in regulatory expertise and training were equally crucial. The significance of proactive compliance—staying ahead of changes rather than responding after a failure—was repeatedly underlined by participants.

For theme 3, the focus was fully on risk management. Companies are forced to design region-specific compliance strategies due to the operational difficulty caused by the lack of standardized global regulations. Due to their limited resources, SMEs continue to be at a disadvantage, even though larger

organizations are better able to manage this diversity through dedicated teams. However, one of the most important findings that emerged from the interviews was development of a compliance culture, in which all departments was held responsible for being compliant. Below is a thematic snapshot of the study.

Table 4.2: Thematic Table Snapshot

Theme	Sub-theme	Definition	Example Quote	Link to RQ
Regulatory Challenges	Data Integrity Concerns	The need to maintain the accuracy, consistency, and completeness of data to meet regulatory standards.	"Data integrity is a major concern. Everything is being scrutinized, including audit trails, batch records, and even metadata. If anything is incomplete or missing, it immediately becomes a finding."	Yes
	Poor Documentation Practices	The impact of poor documentation systems or outdated SOPs on regulatory compliance.	"Many compliance issues arise from poor documentation"	Yes
	Quality Management System (QMS)	The importance of having an integrated, compliant QMS to ensure product quality and regulatory compliance	"A good quality management system is at the heart of compliance, but we often see gaps between what companies promise in policy and what they deliver in practice."	yes
Adaptation Strategies	Digital Transformation and Technological Integration	The use of digital tools to streamline compliance processes, improve data traceability, and ensure audit-readiness.	"Yes, it significantly enhanced compliance by improving your accuracy, maintain data integrity and efficiency… we have advanced data management systems like RIMS and VEEVA."	yes
	Regulatory Knowledge and Training	The role of continuous employee training and importance of regulatory intelligence teams to stay ahead of regulatory changes.	"Yeah, so we have a dedicated regulatory Intelligence Team, actually, so they monitor changes through regulatory databases like TOPRA, regulatory newsletters and direct communications with consulting partners"	yes
	Cooperative	Collaborating with local	"They'll take their	

	Collaborations	experts and former regulatory auditors to improve compliance processes.	suggestions... will help them to meet the regulatory standards, and also it will help them meet the regulatory expectations during the audit."	yes
Risk management and regulatory compliance	**Proactive Risk Management**	Identifying potential risks in advance and implementing strategies to mitigate them, ensuring a proactive approach to compliance.	"And if you do not have a proper risk management in place, and if you have failures in implementing the changes... then that will also have a compliance issue."	Yes
	Compliance Culture	Building an organizational culture where every department takes ownership of regulatory compliance, integrating it into daily operations.	"What really helps is creating a proactive compliance culture where every department sees compliance as their responsibility, not just QAs and people understand the why behind regulations."	yes

The results collectively highlight how dynamic and complex regulatory compliance is in the Indian pharmaceutical export industry. In addition to addressing the main research question, the thematic analysis draws attention to the changing demands of international regulators as well as the increasing demand for digital innovation, agility, and nurturing a compliance culture.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

This chapter will summarize the key findings, offer strategic conclusions and provide recommendations based on the results from data analysis and research questions explored throughout this thesis. The key focus of this research was to examine the compliance challenges Indian generic manufacturing companies is facing while exporting to regulated markets like the US and the EU.

4.1 Research Conclusion

The findings from the analysis directly address the research questions and shed light on the major compliance challenges, adaptation strategies, and limitations faced by these companies. The following conclusions were made:

- Data Integrity: Data Integrity remains a core challenge with Indian pharmaceutical companies frequently struggling to meet the rising expectations around electronic records, data transparency and data traceability.
- Documentation Practices: Poor documentation practices, especially in companies still relying on manual paper-based systems, significantly hinder regulatory compliance and increase the risk of audit failures.
- Poor Quality Management Systems (QMS): The lack of a robust QMS is another factor that prevents a company from meeting the stringent regulatory standards. A strong QMS guarantees regulatory compliance, emphasizing the need for digital transformation.
- Regulatory Intelligence: Proactive regulatory intelligence is important in adapting to regulatory standards that change constantly. Companies need to stay ahead of regulatory changes by establishing regulatory intelligence teams and continuously train the professionals to cultivate a culture of compliance.
- Risk Management and Regulatory Diversity: Effective risk mitigation strategies are necessary to manage compliance across several regulatory frameworks, including those of the US FDA and EMA.

4.2 Strategic Conclusions

As mentioned in Chapter 1, Indian pharmaceutical industry has long been considered the pharmacy of the world, making a substantial contribution to the production and supply of affordable medications worldwide. Despite this success, exporting to regulated markets like the US and EU presents significant challenges for Indian generic producers, mostly because of the strict regulations imposed by FDA and EMA. In this situation, maintaining market access is largely dependent on implementing strategic adaptations. Based on the findings and

conclusions drawn, the following are an overview of the actions that should be taken to address the issues:

- Increase focus on digitalization: Pharmaceutical companies should prioritize transformation of their current systems and invest in automated data management systems, electronic batch records, and digital QMS platforms to ensure data integrity and audit readiness.
- Strengthen QMS: A QMS is the backbone of all the process happening in that company. Implementing a robust QMS that aligns with global standards will be crucial for meeting GMP requirements and preventing audit failures.
- Establishing Regulatory Intelligence Team: Establishing a dedicated regulatory intelligence team will enable companies to proactively monitor and prepare in advance to any upcoming regulatory changes and remain compliant across multiple markets.
- Foster collaborations: Strategic collaborations with regulatory experts, consultants and former auditors will help companies stay compliant with the increasingly complex regulatory requirements across different markets.
- Proactive Culture: Companies need to develop a culture where compliance is a shared responsibility across all divisions, proactively identify risks, and customize compliance procedures for each market.

4.3 Recommendations

The strategic conclusions presented in this thesis highlight how important quality is an enabler of market access. In addition to meeting regulatory requirements, Indian pharmaceutical companies can establish themselves as reliable suppliers in highly regulated markets by putting in place a strong QMS, improving data integrity through digital transformation, and guaranteeing ongoing training. Some practical recommendations for addressing the compliance challenges and improving regulatory readiness include:

- Invest in technology: Especially companies still reliant on manual processing should start consider to invest in automated systems and digital tools to improve data management and documentation practices. Tools like TrackWise, LIMS, RIMS, etc. can significantly enhance audit preparedness and reduce the risk of non-compliance.
- Implement continuous training: Regulatory training should be integrated into the company culture to ensure employees are always up to date with evolving regulations. Employees should be trained frequently and they should be able to understand the ‘why’ behind every task they are doing

rather than just the ‘how’. This deeper understanding fosters greater compliance and helps the employees to perform well during an audit or inspection.

- Proactive Risk Management: Pharmaceutical companies should adopt proactive risk management strategies rather than reactive ones. This involves identifying potential compliance risks and regulatory changes before they become a critical issue. This way, companies can implement corrective actions and adjust processes to stay compliant.
- Establish a robust QMS: A strong QMS which is regulatory updated and integrated with digital solutions can significantly enhance regulatory compliance and audit readiness by ensuring that all processes are consistently aligned with GMP and global regulatory standards. Regular reviews and updates of QMS in line with changing regulatory requirements ensures that the company is always ready for inspections, with real-time access to complete and accurate data.
- Changing Mindset: View inspections as opportunities for continuous improvements and self-assessments. This change in mindset can foster transparency and commitment to quality, ultimately enhancing audit readiness and strengthening relationships with regulatory bodies.

4.4 Limitations of this Research

This study majorly has three limitations:

- Sample size: This study has relatively small sample size with just 8 participants, which limits the ability to generalize the findings across the entire industry.
- Geographical Focus: This study is primarily focused on Indian pharmaceutical companies exporting to the US and EU markets, limiting the broader applicability to other regions or markets.
- Time Constraints: The study was conducted over a limited timeframe, and may not account for emerging trends or recent regulatory changes in the industry.

4.5 Contribution of the Research

Indian pharmaceutical companies, especially in the generic medicines sector, are global leaders in terms of production capacity and cost efficiency. However, despite their dominance, these companies frequently face regulatory challenges, often receiving warning letters from regulatory bodies such as the US FDA and EMA due to issues like data integrity violations, poor documentation practices, and weaknesses in their Quality Management Systems (QMS).

This study highlights these critical compliance challenges and provides valuable insights into how Indian generics manufacturers are adapting to evolving regulatory standards. The research emphasizes the need for digital transformation, the implementation of proactive regulatory intelligence, and the fostering of collaborative partnerships with regulatory experts to enhance compliance and reduce the risk of regulatory setbacks.

4.6 Suggestions for Further Research

Further research could explore:

- Comparative Studies: Future research could compare the compliance challenges and strategies of Indian pharmaceutical companies with those in other emerging markets. Comparing and contrasting strategies can help gain valuable insights.
- Impact of Digitalization: Additional studies could focus on the long-term impact of digital transformation on regulatory compliance and how it affects companies' ability to meet global standards. Most studies only talk about how digitalization is a boon, and not about what changes digitalization bought about.
- Being self-sufficient: Further research could investigate how Indian pharmaceutical companies can lessen dependency on external auditors and consultants and on how to become self-sufficient.

4.7 Final Reflection

Completing this dissertation has deepened my understanding of the regulatory challenges faced by Indian pharmaceutical companies in a global context. This research helped me to comprehend the need for developing and adapting different strategies in this world where regulations are evolving like anything. The research has reinforced the importance of proactive strategies, including digital transformation and regulatory intelligence, in maintaining compliance with increasingly stringent global standards. This research also portrayed how important digitalization is, and how technology is actually a competitive advantage. The study also emphasizes that quality is non-negotiable and that it is an enabler for market access. The process of conducting this research has also provided valuable insights into the role of continuous training and collaborative partnerships in fostering a culture of compliance. Thus, the study offers conclusions which can be used as a road map for Indian pharmaceutical companies who wish to strengthen their compliance in global markets.

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APPENDIX A: ETHICS FORM

Ethics Application & Declaration Form

DISSERTATION TITLE: COMPLIANCE CHALLENGES OF INDIAN PHARMACEUTICAL COMPANIES IN GLOBAL MARKETS: NAVIGATING REGULATORY REQUIREMENTS AND ADAPTATION STRATEGIES

RESEARCHER'S NAME: SWATHIKEDINI SUBRAMANNYAN

PROGRAMME OF STUDY: MSC IN PHARMACEUTICAL BUSINESS AND TECHNOLOGY

SUPERVISOR'S NAME: MARY O'DRISCOLL

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

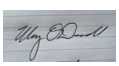
For Student:

STUDENT SIGNATURE: 

DATE: 21/03/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes [ ] No [X]

SUPERVISOR SIGNATURE: 

DATE: 21 March, 2025

For Ethics Committee (if required): NA
Ethics Committee Approval Given: Yes [ ] No [ ]

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

Indian pharmaceutical industry has emerged as a global leader in the production and export of generic medicines, supplying affordable, high-quality drugs to international markets. However, entry into highly regulated markets such as the US and the EU comes with significant compliance challenges. Regulatory authorities like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) strictly implement Good Manufacturing Practice (GMP) requirements, data integrity expectations, and evolving pharmacovigilance expectations that the manufacturers need to strictly follow. In the past, non-compliance with these regulations has led to warning letters, product recalls, import bans, and reputational loss for numerous Indian pharmaceutical companies.

The research aims to explore the significant regulatory challenges for Indian generic drug manufacturers in global markets and examine their compliance strategies for addressing international regulatory standards. By conducting qualitative interviews with export officers, regulatory experts, and quality assurance experts, the research will identify how effective are the existing compliance strategies are and where they need more focus.

By comparing regulatory requirements in India, the US, and the EU, this research will bring explore the differences in approval processes and how Indian manufacturers accommodate to these differences. The research will also delve into the consequences of regulatory non-compliance, such as economic implications and restrictions on market access.

Lastly, the findings will have a significant and useful impact for Indian pharmaceutical companies to strengthen their regulatory compliance system, expand market access worldwide, and reduce the risk of regulatory non-compliance. By eliminating the compliance barriers, Indian manufacturers can maintain their competitiveness in the global pharmaceutical marketplace while upholding patient safety and product quality.

1.2 Research methodology

This study will adopt a qualitative research approach to explore the compliance challenges faced by Indian pharmaceutical companies in global markets. The primary data will be collected through semi-structured interviews with professionals in the pharmaceutical industry, including regulatory affairs specialists, quality assurance managers, and industry consultants.

The Semi-structured interviews will be conducted with participants selected through purposive sampling, ensuring they have relevant expertise in pharmaceutical regulations, export compliance, and quality management. These interviews will be conducted online via video conferencing platforms to facilitate participation from experts based in India. The interviews will focus on understanding regulatory hurdles, strategies for compliance, and the impact of regulatory changes on Indian generic pharmaceutical exports.

Interview transcripts will be thematically analysed to identify key patterns related to compliance challenges, regulatory adaptations, and strategic responses. Ethical considerations, including informed consent and participant confidentiality, will be maintained throughout the research process.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	Yes
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	Yes

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	Yes
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:	
People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.

Since the research involves senstitive themes like compliance failures and regulatory breaches, the following steps are included in the action plan:

1. Participants will be assured of **anonymity and confidentiality** to encourage honest responses without fear of professional or legal repercussions.

2. Participants will have the **right to withdraw** at any stage of the study without providing a reason.

3. All data will be **securely stored** and used solely for research purposes. No personally identifiable information will be disclosed in the final dissertation.

3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

To ensure ethical data collection and processing, the research will follow best practices in consent and data protection:

1. **Informed consent** will be obtained from all participants before interviews ensuring they understand the study's purpose, their role, and their rights.
2. All data will be **securely stored** and used solely for research purposes. No personally identifiable information will be disclosed in the final dissertation.

3. Participation will be entirely **voluntary**, and no participant will face pressure to take part or answer any question they are uncomfortable with.

3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study

This study will involve professionals working in the pharmaceutical industry, specifically those engaged in regulatory compliance, quality assurance, and export management. Participants will be selected based on their expertise and direct involvement in navigating regulatory challenges in global markets, particularly in the EU and US. Their insights will provide valuable perspectives on the difficulties faced by Indian generic pharmaceutical companies in meeting international regulatory requirements and adapting to evolving standards.

The participant sample will include Regulatory Affairs Specialists, who are responsible for compliance with international regulatory authorities such as the US FDA and EMA. Their feedback will be highly relevant in establishing the specific regulatory issues Indian companies face when exporting generic medicines. Compliance and Quality Assurance (QA) Managers will be included as well, since they oversee Good Manufacturing Practices (GMP), regulatory audits, and quality management systems (QMS) and hence are key stakeholders in maintaining international standards compliance. Industry Consultants and Policy Experts will also be approached to view the situation from outside and offer ideas on how best companies can embrace international regulatory structures.

These participants have been chosen because they offer firsthand experience with regulatory process and measures of compliance. The inclusion of professionals with varied functional expertise will allow the research to draw upon a broad range of perspectives for regulatory adaptation. Their knowledge will be essential in fulfilling the goals of the research, which address the Indian pharma industry's challenges and measures taken by such firms to secure compliance in the competitive global market.

4.2 How do you plan to gain access to/contact/approach your participant(s).

The respondents will be contacted using a combination of professional networking and direct outreach strategies. One of the primary networking strategies will be the use of LinkedIn platform. Professionals who have experience in the fields of compliance, quality assurance, and pharmaceutical exports will be contacted. Additionally, professional networks and referrals will be utilized to establish contacts with the potential participants. In order to establish direct contact, email invitations will be sent to potential participants with the objective of clarifying the purpose of the study, the voluntary nature of the study, and the strategies for confidentiality.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	N/A

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research

e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

All research data will be securely stored in compliance with ethical and data protection guidelines. Interview recordings, transcripts, and survey responses will be stored in **password-protected digital files** on a secure cloud storage platform and a **hard drive** to prevent unauthorized access. The data will be retained for a period of **24 months after the completion of the research** to allow for verification and potential future academic use. After this period, all digital files will be permanently deleted.

To manage **data protection issues**, participants' identities will be anonymized, and all identifiable information will be removed from transcripts and reports. Access to the data will be strictly limited to the researcher and, if necessary, the dissertation supervisor. Informed consent will be obtained before data collection, and participants will be made aware of their rights, including the right to withdraw their data at any stage before final analysis.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes No

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	Yes
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE: 21/03/2025

SECTION 10: APPENDIX

QUESTIONNAIRE

1. What are the biggest compliance challenges Indian pharmaceutical companies face when exporting to regulated markets like the US and EU?
2. In your opinion, has the regulatory audits (e.g., US FDA, EMA) become more stringent in recent years? If so, in what respects?
3. In your experience, do smaller pharmaceutical companies face more compliance challenges than larger firms? If so, why? In your experience, how do compliance challenges differ between smaller and larger pharmaceutical companies? What unique obstacles or advantages have you observed for each?
4. Can you cite any instances where compliance issues resulted in product recall, warning letter, or import ban?
5. How do Indian pharmaceutical companies adapt to evolving regulatory expectations, particularly in areas like pharmacovigilance and data integrity? Can you share specific examples of successful or challenging adaptations?
6. What strategies, in your experience, have been the most effective in maintaining compliance with International regulatory requirements?
7. How does your company stay informed about upcoming regulatory changes, and what internal processes are used to assess, plan, and implement those changes? Can you give an example of how far in advance you typically become aware of such updates and how your team responds?

8. To what extent do you believe the presence or absence of a robust Quality Management System (QMS) impacts regulatory compliance? Can you share any experiences or examples where a well-implemented QMS helped ensure compliance, or where the lack of one led to challenges?
9. In your experience (or opinion), what common gaps or weaknesses cause pharmaceutical companies to fall short of regulatory compliance—even when formal compliance programs are in place? Can you share specific examples or patterns you've observed?
10. Given that full harmonization of global regulations is unlikely, how does your company navigate the challenges of complying with varying regulatory requirements across different markets?
11. How has digitalization influenced regulatory compliance in your company?
12. What recommendations would you make to companies wishing to strengthen their compliance with the US FDA and EMA rules?

APPENDIX B: CONSENT FORM

GRIFFITH COLLEGE

Consent to take part in research

COMPLIANCE CHALLENGES OF INDIAN PHARMACEUTICAL COMPANIES IN GLOBAL MARKETS: NAVIGATING REGULATORY REQUIREMENTS AND ADAPTATION STRATEGIES

The researcher retains one copy signed by both themselves and the participant. The participant should also receive a copy of consent form as a record of what they have signed up to.

1. I [*insert participant name*] voluntarily agree to participate in this research study
2. I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
3. I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
4. I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
5. I understand that participation involves taking part in a semi-structured interview, where I will be asked questions about regulatory compliance challenges faced by Indian generic pharmaceutical companies in global markets. The interview/survey will focus on my professional experiences and perspectives regarding regulatory hurdles, quality management, and adaptation strategies. My participation is voluntary, and I can choose to withdraw at any time without providing a reason. All responses will be kept confidential and used solely for academic research purposes.
6. I understand that I will not benefit directly from participating in this research
7. I understand that all information I provide for this study will be treated confidentially
8. I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
9. I agree to my interview being audio-recorded.
10. I understand that disguised extracts from my interview may be quoted in dissertation
11. I understand that I will adhere to all of the codes of conduct and employee confidentiality for company XXX and there is no expectation to breach these by partaking in this research.

12. I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission

13. I understand that signed consent forms and original audio recordings will be retained inside password-protected digital files on a secure cloud storage platform and a hard drive to prevent unauthorized access until 24 months after the completion of the research to allow for verification and potential future academic use.

14. I understand that a transcript of my interview in which all identifying information has been removed will be retained for 24 months after the completion of the research.

15. I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.

16. I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details
Name: Swathikedini Subramannyan
Degree Programme: MSc in Pharmaceutical Business and Technology
College Details: Griffith College
Contact number: +353 894000918
Contact mail

Signature of participant
[Full Name – Printed]
Signature of research participant

---------- ---------- Date

Signature of researcher
I believe the participant is giving informed consent to participate in this study

21/03/2025
---------- ---------- Date
Signature of researcher

APPENDIX C: PARTICIPANT INFORMATION LETTER

Participant Information Letter

COMPLIANCE CHALLENGES OF INDIAN PHARMACEUTICAL COMPANIES IN GLOBAL MARKETS: NAVIGATING REGULATORY REQUIREMENTS AND ADAPTATION STRATEGIES

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

I am a postgraduate student conducting this study as part of my Master's degree in Pharmaceutical Business and Technology. This research is being carried out as a requirement for my dissertation, which will contribute to my final qualification.

I am doing this study to explore the compliance challenges faced by Indian generic pharmaceutical companies in global markets, with a focus on the regulatory requirements of the EU and the US. The study aims to understand the key regulatory hurdles, how companies adapt to evolving compliance standards, and the impact of these regulations on pharmaceutical exports.

This research is purely academic and does not assume any predetermined outcomes. The goal is to gather insights from industry professionals to provide a balanced and objective analysis of regulatory compliance in the Indian pharmaceutical sector. The findings will contribute to a broader understanding of the challenges and potential strategies for improving regulatory adherence and market access.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part in this study, you will be asked to participate in an interview about your experiences with regulatory compliance in the pharmaceutical industry. The interview will be semi-structured, meaning that while there will be key questions, you will have the opportunity to share your insights freely. The discussion will focus on regulatory challenges, quality management practices, and how companies adapt to evolving compliance requirements in global markets, particularly in the EU and the US.

Interviews will be conducted online via a secure video conferencing like zoom. The interview is expected to last approximately 30–45 minutes. With your permission, the conversation will be audio-recorded to ensure accuracy in transcribing your responses. If you choose not to be recorded, handwritten notes will be taken instead. All recordings and transcripts will be kept confidential and used solely for research purposes.

Participation is entirely voluntary, and you can choose to withdraw at any time before the data is analysed, without giving a reason. Your responses will be anonymized, and no personally identifiable information will be included in the final research. The study is designed to minimize any potential inconvenience, and your participation will contribute valuable insights to understanding the regulatory landscape for Indian pharmaceutical exports.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in this research because of your expertise and experience in the pharmaceutical industry, particularly in areas related to regulatory affairs, quality assurance, and export management. Your role involves direct involvement in navigating regulatory challenges and ensuring compliance with international standards, such as those set by the US FDA and EMA. This makes you uniquely qualified to provide valuable insights into the compliance challenges faced by Indian generic pharmaceutical companies in global markets.

I identified you as a potential participant through professional networks, including LinkedIn, where your role and experience were highlighted. Additionally, I have received recommendations from industry contacts who believe your expertise would be particularly relevant to this study.

Your input will help deepen the understanding of regulatory hurdles and adaptation strategies used by Indian pharmaceutical companies to meet global compliance standards. Your perspective will contribute to a comprehensive analysis of the regulatory landscape and the challenges in ensuring compliance with evolving standards.

DO YOU HAVE TO TAKE PART?

Participation in this study is completely voluntary. You are under no obligation to take part, and you have the right to refuse participation at any time without any consequences whatsoever. If you choose to participate, you are also free to refuse to answer any question that you are not comfortable with, and you can withdraw from the study at any point before the data is analyzed, with no impact on your relationship with the researcher or any affiliated institutions.

Your decision to take part, or not, will not affect your professional standing or any future interactions with the researcher. Your participation is entirely at your discretion, and your rights will be respected throughout the process.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

By taking part in this study, you will have the opportunity to provide valuable insights into the regulatory challenges faced by Indian pharmaceutical companies in global markets, which could contribute to improving regulatory practices in the industry. However, there are some potential risks to consider. There is a minimal risk to confidentiality, despite all data being

anonymized and securely stored in password-protected files. While the study is unlikely to cause distress, discussing regulatory challenges could bring up feelings of frustration or stress, especially if you've faced significant hurdles in your career. If this occurs, you can stop the interview or survey at any time, skip questions, or withdraw from the study without any consequences. Additionally, while there is a very low risk of professional implications, all responses will be anonymized, ensuring that neither you nor your organization will be identifiable in the final research. Measures to protect your confidentiality and ensure your comfort throughout the study will be in place, and you are encouraged to raise any concerns as they arise.

WILL TAKING PART BE CONFIDENTIAL?

Yes, taking part in this study will be completely confidential. All efforts will be made to ensure that your identity, as well as any company-specific information you share, remains anonymous. During the research process, all personal and organizational details will be removed from any transcripts or reports. Any data shared will be stored securely in password-protected files and will only be accessible to the researcher and the dissertation supervisor. Audio recordings, consent forms, and other non-anonymized data will be securely stored and retained for a period of 12 months after the completion of the research for verification purposes. These records will never be shared without your explicit consent.

If any company data is used, authorization will be sought from the appropriate parties, and any confidential company information will be handled according to the permissions granted. No identifiable company data will be included in the research report without proper consent.

There are some rare circumstances in which confidentiality may need to be breached. If, during the research process, the researcher has strong reason to believe that there is a serious risk of harm to you or someone else (such as in cases of physical harm, emotional abuse, self-harm, suicidal intent, or criminal activity), confidentiality may be broken. In such cases, the researcher may need to report this information to the appropriate authorities to ensure safety. However, this is only done if the researcher believes that there is a significant threat of harm or danger.

By participating, you acknowledge that, although your responses will be kept confidential, there are exceptions in extreme situations to ensure the safety and well-being of individuals. If you have any questions about confidentiality or data usage, please feel free to ask at any time.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings will be securely stored in a password-protected cloud storage platform and on an encrypted local hard drive. Only the researcher and the dissertation supervisor will have access to the data. These documents will be retained until after my degree has been conferred. Following this, a transcript of interviews, with all identifying information removed, will be stored for an additional two years.

Under freedom of information legislation, you are entitled to access the information you have provided at any time. If you wish to request access to your data, you may contact the researcher.

For verification purposes, the signed consent forms, audio recordings, and other primary research data will be stored on Moodle in the primary data folder. The data can be accessed by

Innopharma staff, as well as any Griffith staff members who need to verify the authenticity of the research carried out and the data collected. This ensures that the data remains accessible for review while being kept secure and confidential.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this study will primarily be used to fulfill the requirements of my Master's dissertation. Upon completion, the final research product will be submitted as part of my course requirements. As part of the academic process, the dissertation will be made accessible in the Griffith College library, where it will be available for students and faculty to review.

Additionally, the dissertation could potentially be made available in online e-journals or a research repository, subject to the college's policies and any relevant permissions. At this time, my plan is to submit the research solely for my dissertation and not for external publication. However, if future opportunities arise, such as presenting at academic conferences or publishing in journals, I may consider sharing the findings more widely.

The results will remain within the academic context, and I do not plan for the research to be used outside of this scope unless further opportunities for dissemination arise.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

For further information about this research study, you can contact:

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THANK YOU

APPENDIX D: INTERVIEW QUESTIONNAIRE

1. What are the biggest compliance challenges Indian pharmaceutical companies face when exporting to regulated markets like the US and EU?
2. In your opinion, has the regulatory audits (e.g., US FDA, EMA) become more stringent in recent years? If so, in what respects?
3. In your experience, do smaller pharmaceutical companies face more compliance challenges than larger firms? If so, why? In your experience, how do compliance challenges differ between smaller and larger pharmaceutical companies? What unique obstacles or advantages have you observed for each?
4. Can you cite any instances where compliance issues resulted in product recall, warning letter, or import ban?
5. How do Indian pharmaceutical companies adapt to evolving regulatory expectations, particularly in areas like pharmacovigilance and data integrity? Can you share specific examples of successful or challenging adaptations?
6. What strategies, in your experience, have been the most effective in maintaining compliance with International regulatory requirements?
7. How does your company stay informed about upcoming regulatory changes, and what internal processes are used to assess, plan, and implement those changes? Can you give an example of how far in advance you typically become aware of such updates and how your team responds?
8. To what extent do you believe the presence or absence of a robust Quality Management System (QMS) impacts regulatory compliance? Can you share any experiences or examples where a well-implemented QMS helped ensure compliance, or where the lack of one led to challenges?
9. In your experience (or opinion), what common gaps or weaknesses cause pharmaceutical companies to fall short of regulatory compliance—even when formal compliance programs are in place? Can you share specific examples or patterns you've observed?
10. Given that full harmonization of global regulations is unlikely, how does your company navigate the challenges of complying with varying regulatory requirements across different markets?
11. How has digitalization influenced regulatory compliance in your company?
12. What recommendations would you make to companies wishing to strengthen their compliance with the US FDA and EMA rules?