# ASSESSING THE EFFECTIVENESS OF PHARMA BUSINESS BY OPTIMUM RESOURCES MANAGEMENT

by

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## **DISSERTATION**

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# ASSESSING THE EFFECTIVENESS OF PHARMA BUSINESS BY OPTIMUM RESOURCES MANAGEMENT

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## **Dedication**

To my parents, the roots of my wisdom, who nurtured my curiosity and taught me the strength of unwavering values.

To my wife, my unwavering partner and compass, whose belief in my journey has been both my anchor and my sail.

To my daughters, my sparks of endless wonder, whose giggles and dreams inspire me to imagine a brighter tomorrow.

This work is for you all, my past, my present, and my future.

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Finally, I express my gratitude to the participants of this research for their time, and patience in completing those long surveys, and to all those who, in ways big or small, contributed to its completion. This thesis is a testament to your collective support and encouragement.

#### **ABSTRACT**

## ASSESSING THE EFFECTIVENESS OF PHARMA BUSINESS BY OPTIMUM

## RESOURCES MANAGEMENT

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Pharmaceutical companies operate in an environment characterized by swift technological advancements and intense market rivalry, playing a key role in meeting critical healthcare challenges. However, with this innovation comes the challenge of managing resources effectively while maintaining cost efficiency, regulatory compliance, and sustainability concerns. This research critically examines these obstacles and formulates actionable solutions to address them. It further delineates implementation barriers and advances industry-aligned best practices derived from scholarly evidence and real-world applications. The research adopts a mixed-methods approach, combining a comprehensive literature review, surveys with industry experts, and quantitative data analysis to provide holistic insights into the subject matter. The findings of this research will contribute to the development of best practices and strategies in pharmaceutical operations, offer actionable recommendations for pharmaceutical companies, and

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contribute to the advancement of optimized resource management practices in the industry.

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## **CHAPTER I:**

## **INTRODUCTION**

## 1.1. Introduction

The pharmaceutical sector is widely regarded as a rapidly evolving, high-stakes, and pioneering force within the global economy. It also has a big impact on society and is an indicator of the healthcare system (Szmelter-Jarosz, 2019). Effective resource management is critical for the success of pharmaceutical companies. The pharmaceutical industry faces significant challenges in terms of cost reduction and process optimization due to increasing competition, regulatory requirements, and sustainability concerns. This research aims to investigate the optimization of resource utilization in the pharmaceutical industry to improve operational efficiency and reduce costs. The research will be conducted through a comprehensive literature review, followed by a quantitative research approach utilizing data collection and analysis. The findings of this research will contribute to the development of best practices and strategies for optimizing resource utilization in the pharmaceutical industry.

## 1.2. Pharmaceutical Industry

The pharmaceutical industry is mainly classified into two categories.



Figure 1 Categories of Pharmaceutical Industries

#### **Innovators**

An innovator drug is a drug that was the first to be approved for use containing a specific active ingredient. It is usually the product whose efficacy, safety, and quality have been proven. In most cases, a company that produces a new drug acquires a patent when it makes the drug for the first time. It is common for drug patents to last for up to 20 years. Patents prevent other companies from making or selling the same drug during the patent period.

#### Generics

The same active component is used to make generic drugs as the original drug. The molecules in a drug that gives it its effects are known as active ingredients. To put it another way, a generic drug has the exact same pharmacological effects as its brand-name counterpart. Once the patent on a drug expires, other businesses can produce generic versions.

Innovator drugs are more precious because the company that first manufactures the product spends a large quantum of plutocrats in exploration to develop the drug which includes clinical trials, marketing, and creation of drugs.

Innovators focus on drug discovery and bring new drugs into the marketplace after filing an NDA - a new drug application. In contrast, generics enter the market by marketing a product bioequivalent to those of the innovators by filing an ANDA -abbreviated new drug application (Kiran et al., 2019).

The scope of this research centers on optimizing resource utilization within the pharmaceutical industry, with a specific emphasis on generic manufacturing companies. The goal is to identify opportunities for enhancing cost-efficiency in this context. Subsequently, our discussions will be tailored to this focused area.

## 1.3. Pharmaceutical product

Within the pharmaceutical industry, two fundamental concepts play a pivotal role in the creation and delivery of effective medications: drug substance and drug product. These terms encompass distinct yet interconnected elements that together constitute the backbone of pharmaceutical development and patient treatment. In the subsequent sections, we will delve into precise definitions of both drug substance and drug product, understanding their individual significance and their collective contribution to the world of medicine.

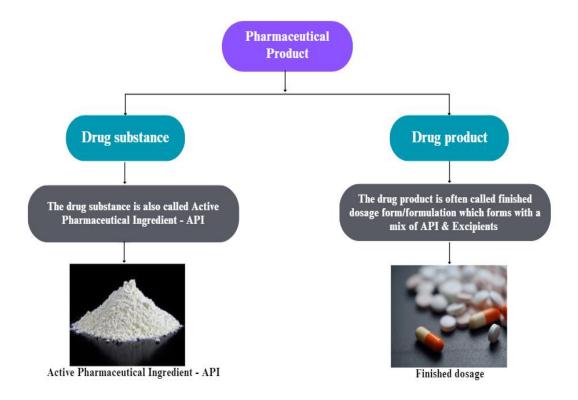


Figure 2 Types of Pharmaceutical Products

## **Drug substance**

A drug substance is an active pharmaceutical ingredient (API) that is the core component in a drug responsible for its therapeutic effect. APIs undergo rigorous testing to ensure they meet stringent safety and efficacy standards, making them critical in pharmaceutical manufacturing.

## **Drug product**

A drug product is the final formulation of the pharmaceutical product. It is the mixture of the drug substance (API) as a major ingredient with various other components known as excipients. Excipients are inactive ingredients added to the formulation to assist in the manufacturing process, improve stability, taste, dosage and control the release of the drug. The drug product is what patients actually take when they need medication. It comes in various forms such as tablets, capsules, injections, creams, and more, designed to deliver the drug substance effectively and safely to the patient.

In essence, the drug substance is the active component responsible for the therapeutic effect, while the drug product is the final, formulated medication that includes the drug substance and other necessary ingredients to ensure its safety and effectiveness. As the emphasis within finished dosage manufacturing is predominantly on factors such as storage, stability, taste, dosage, and packaging, etc., with relatively minimal engagement in substantial chemical and scientific operations. Conversely, in API manufacturing, a more pronounced allocation of resources is essential. Thus, this research endeavors are strategically channeled towards refining the efficiency of resource employment in API development and manufacturing. This strategic optimization of resources management has the potential to significantly

curtail costs in medicine manufacturing by directly targeting the expenses linked to the principal contributor, which, in this context, refers to the API.

Thus, henceforth it's important to understand that whenever the term "pharmaceutical industry" is used, it predominantly pertains to API (Active Pharmaceutical Ingredient) which our research is mainly focused on, however, it's important to consider that this categorization may vary based on the context.

## 1.4. Emerging challenges

The pharmaceutical industry today faces significant hurdles, including the need to reduce costs and optimize production processes. These challenges are further intensified by stringent regulatory requirements and increasing demands for sustainable practices. Companies must navigate these complexities while maintaining efficiency and innovation.

As the pharmaceutical industry operates in a dynamic environment shaped by evolving consumer demands, regulatory complexities, and sustainability pressures, alongside other pressing issues such as supply chain disruptions and technological adaptation, demand strategic innovation to maintain resilience and efficiency.

## **Sustainability and Cost Pressures**

Sustainability remains a pressing issue for pharmaceutical companies, with growing expectations to reduce environmental impact. Efforts such as solvent recovery, waste minimization, and adoption of continuous manufacturing processes are becoming integral to operations. These practices help lower production costs

while improving environmental outcomes, enabling companies to align with global sustainability goals (Ayati et al., 2020).

## **Supply Chain Disruptions**

Global supply chain challenges, exacerbated by the COVID-19 pandemic, have highlighted vulnerabilities in pharmaceutical logistics. Dependence on a limited number of suppliers, particularly for Active Pharmaceutical Ingredients (APIs) from China and India, disrupted production and created shortages. For example, during the pandemic, the inability to procure essential raw materials resulted in delays and increased costs. To address these issues, companies are adopting localized sourcing strategies and investing in supply chain resilience (Ayati et al., 2020).

## **Regulatory Complexities**

The pharmaceutical industry must navigate an ever-changing regulatory landscape. For instance, Brexit has introduced challenges for companies in aligning with the divergent requirements of the UK and the European Medicines Agency. These changes, coupled with stringent regulatory frameworks worldwide, extend drug approval timelines and require businesses to invest heavily in compliance processes. Such complexities underscore the need for proactive regulatory strategies (Mundy et al., 2023).

## **Consumer Expectations and Digital Transformation**

The pandemic has significantly influenced consumer and healthcare provider expectations, requiring pharmaceutical companies to implement faster, more responsive solutions. Companies have increasingly embraced digital tools, such as edocumentation, e-sample management, etc., to adapt to this demand. However, these shifts necessitate significant investments in infrastructure and workforce training.

Budget constraints have further driven companies to focus on owned media and digital marketing platforms, requiring a strategic reallocation of resources (Khan and Basak, 2021).

In addition to the above, the pharmaceutical industry faces challenges such as:

- Workforce shortages and the need for specialized skill development.
- Ethical dilemmas in patient data use and decentralized clinical trials.
- Competitive pressures to deliver cost-effective and innovative drugs.

These challenges, along with evolving geopolitical and market dynamics, necessitate a holistic and agile approach to ensure operational sustainability and global competitiveness.

#### 1.5. Research Problem

The Pharmaceutical industry is highly regulated, with strict quality control requirements and a capital-intensive sector that requires significant investments in research and development, production, and marketing. Also, a large number of stakeholders are involved, including patients, regulatory agencies, investors, etc., The high cost of drug development and manufacturing has been a significant challenge for the industry, especially in the face of increasing competition and pricing pressures. A lot of major changes have happened in the last few years after the pandemic. Many organizations are shifting their production & research facilities to developing countries, new market entries, and decreasing the dependency on a single supplier/geography. It is an indication that organizations are exploring the possibilities to reduce manufacturing and all other costs, like labor cost, operations

cost, logistics, etc., in multiple ways, by which they are expecting to provide quality medicines at a better price thereby increasing profit margins.

To meet these challenges, pharmaceutical companies need to have efficient and effective resource management strategies that can help optimize resource utilization to reduce manufacturing costs and improve efficiency while maintaining quality and compliance. As resources management directly impacts the cost and quality of the products it is to be considered as one of the critical issues in the pharmaceutical industry. This research will explore the best practices and strategies for effective resource management in the pharmaceutical industry.

## 1.6. Importance and Significance of the Study

The significance of the study lies in its potential to address critical challenges faced by the pharmaceutical industry and offer practical solutions through effective resource management. Apart from the earlier discussed emerging challenges, there are other multiple subtle challenges always hindering the progress of the pharmaceutical industry which makes this research important to enable the industry's potential to grow further. Here are further explanations of the significance and importance of the topic:

## **Pharmaceutical Industry Challenges**

The pharmaceutical industry operates in a complex and highly regulated environment. Companies face numerous challenges, including rising research and development costs, pricing pressures, increasing competition, shorter product life cycles, and stringent regulatory requirements. Effective resource management can help address these challenges by optimizing processes, reducing costs, and improving overall operational efficiency.

## **Cost Control and Efficiency**

Resource management plays a crucial role in controlling costs and enhancing efficiency within pharmaceutical companies. Optimum allocation and utilization of resources such as human capital, technology, equipment, and raw materials can lead to significant cost savings. By implementing efficient resource management practices, pharmaceutical businesses can minimize waste, streamline operations, and improve the productivity of their workforce and assets.

## Product Development and Time-to-Market

The pharmaceutical industry heavily relies on research and development (R&D) to bring new drugs and healthcare solutions to the market. Inefficient resource management can result in delays in product development, leading to extended time-to-market and missed opportunities. By effectively managing resources, pharmaceutical companies can expedite the R&D process, accelerate clinical trials, and ensure timely delivery of innovative products, ultimately benefiting patients and healthcare providers.

## **Quality and Compliance**

Resource management practices directly impact on the quality and compliance aspects of pharmaceutical operations. Proper resource allocation and utilization contribute to maintaining consistent manufacturing processes, adhering to regulatory requirements, and ensuring product quality and safety. Effective resource management can help companies meet stringent regulatory standards, reduce product recalls, and enhance customer trust in their products.

## **Competitiveness and Innovation**

In today's competitive pharmaceutical landscape, companies must continuously innovate and differentiate themselves to remain competitive. Optimal resource management enables companies to allocate resources strategically, invest in research and development, and foster a culture of innovation. By leveraging resources effectively, pharmaceutical businesses can drive innovation, develop breakthrough therapies, and gain a competitive edge in the market.

Thus, the proposed research on assessing the effectiveness of pharma business through optimum resources management is of utmost importance. It offers insights and recommendations that can help pharmaceutical companies improve their operations, reduce costs, accelerate product development, enhance competitiveness, and ultimately deliver safe and effective healthcare solutions to patients worldwide. Furthermore, the research outcomes will contribute to academic knowledge by adding to the existing literature on resource management in the pharmaceutical industry, facilitating future research and advancements in this critical area.

## 1.7. Research Purpose and Questions

This research aims to assess the effectiveness of the pharma business through optimum resource management. It evaluates the strategies pharmaceutical companies employ to maximize resource utilization, evaluates the impact of optimized resource utilization on operational efficiency and cost reduction, identifies barriers and challenges to implementing resource optimization strategies, and recommends industry practices and best practices.

To achieve the research purpose, the following questions will guide the investigation:

- 1. What strategies can be employed to optimize resource utilization in pharmaceutical manufacturing processes?
- 2. What is the impact of optimized resource utilization on operational efficiency and cost reduction in the pharmaceutical industry?
- 3. What are the barriers and challenges faced in implementing resource optimization strategies in the pharmaceutical industry?
- 4. What are the best practices and recommendations for optimizing resource utilization in the pharmaceutical industry based on existing literature and industry examples?

The findings of this research will contribute to the understanding of resource utilization optimization in the pharmaceutical industry and provide evidence-based strategies and recommendations for pharmaceutical companies to enhance their operational efficiency, reduce costs, and improve competency and sustainability.

## 1.8. Scope and Limitations

## Scope of the Study

This research focuses on assessing the effectiveness of resource optimization strategies in the pharmaceutical industry, particularly in the context of Active Pharmaceutical Ingredient (API) manufacturing. It investigates the following aspects:

• **Resource Optimization Strategies**: Examines lean manufacturing, advanced technologies, supply chain practices, and recovery initiatives.

- Impact on Operational Efficiency: Analyzes how optimized resource utilization reduces costs, minimizes waste, and improves productivity.
- Case Studies and Survey Insights: Incorporates real-world examples and industry data to understand challenges and best practices.
- Global and Societal Relevance: Explores how optimized practices enhance
  accessibility to affordable medications, promote sustainability, and
  strengthen business competitiveness.

The study is limited to pharmaceutical companies with a focus on generics and APIs, as these segments represent a significant portion of the industry's cost structure and sustainability efforts. Emphasis is placed on resource-intensive processes such as solvent recovery and material utilization etc.,

## **Limitations of the Study**

While this research provides valuable insights into resource optimization in the pharmaceutical industry, certain limitations must be acknowledged. These constraints stem from practical challenges in data collection, industry-specific restrictions, and the evolving nature of technological advancements. Addressing these limitations in future studies will enhance the depth and applicability of research findings.

## • Sample Size Constraints

The study's sample size, though sufficient for meaningful analysis, was influenced by accessibility to industry professionals and the company's willingness to participate in surveys. Many pharmaceutical firms operate in highly regulated environments, limiting their ability to share operational data. A larger sample,

encompassing a broader range of organizations and industry segments, could enhance the robustness of the conclusions. Future research could benefit from expanding the sample to include more firms across various scales, from small-scale manufacturers to multinational corporations.

## Geographical Focus

This research primarily focused on specific geographical regions due to constraints related to regulatory differences, data availability, and feasibility of conducting multinational surveys. The pharmaceutical industry is subject to diverse regional regulatory frameworks, economic conditions, and market structures that significantly impact resource optimization strategies. A more extensive global dataset would allow for a comparative analysis of optimization practices across different regulatory and economic landscapes, thereby improving the generalizability of findings.

## • Scope of Technologies

The study emphasizes select advanced technologies (e.g., PAT, Automation) but may not comprehensively cover emerging tools like blockchain or digital twins.

## • Exclusion of Blockchain Technologies

The study did not extensively examine the role of blockchain technologies in resource optimization, despite their emerging significance in enhancing transparency, traceability, and efficiency within pharmaceutical supply chains. The exclusion was primarily due to the limited adoption of blockchain in mainstream pharmaceutical operations at the time of the study, making it difficult to gather sufficient empirical

data. Blockchain applications could offer potential improvements in inventory management, regulatory compliance, and real-time tracking. Future research should explore how blockchain integration can further optimize resource utilization in pharmaceutical operations.

## • Regulatory Variations

The study does not deeply explore the implications of diverse regulatory environments across all countries, which can impact the feasibility of some optimization strategies.

#### Focus on APIs

The study primarily examines Active Pharmaceutical Ingredients (APIs) manufacturing, potentially overlooking nuances in finished drug product manufacturing and other pharmaceutical sectors.

#### • Time Constraints

The research primarily focuses on current trends and lacks longitudinal analysis of how resource optimization strategies evolve over extended periods.

## • Industry-specific constraints

The pharmaceutical industry operates under strict regulatory and compliance requirements, which may have influenced the feasibility and implementation of certain optimization strategies. Many companies prioritize regulatory adherence over operational flexibility, limiting the adoption of certain cost-saving measures. Additionally, proprietary data restrictions imposed by pharmaceutical firms created challenges in obtaining granular operational insights. Future studies could focus on

how companies navigate compliance challenges while optimizing resources and whether regulatory reforms can facilitate greater efficiency.

These limitations suggest areas for further research, such as exploring the role of emerging technologies, examining a broader geographical scope, and conducting longitudinal studies to track the long-term impacts of resource optimization. Acknowledging these limitations provides context for interpreting the findings and highlights areas for further exploration. The constraints identified in this study were largely driven by industry-specific operational challenges, regulatory considerations, and technological adoption levels at the time of research. By addressing sample size constraints, expanding geographical focus, and incorporating emerging technologies like blockchain, future research can build upon this study to develop more comprehensive and globally relevant strategies for resource optimization in the pharmaceutical sector.

## 1.9. Gaps and Relevance:

Existing research in pharmaceutical manufacturing has largely focused on improving drug quality, streamlining production workflows, and ensuring compliance with regulations. However, comprehensive resource management strategies that balance cost efficiency, sustainability, and operational effectiveness remain underexplored, especially in API manufacturing. Despite the use of technology and automation in pharmaceutical manufacturing, there is a gap in the integration of these tools for effective resource management. There is a gap in research on how effective resource management practices in the pharmaceutical industry impact patient outcomes and overall health. Further, there is a need for more

research on the impact of resource optimization strategies on environmental sustainability in the pharmaceutical industry.

Finally, there is a necessity for increased research on the role of digital technologies, such as artificial intelligence and the Internet of Things, in resource optimization in the pharmaceutical industry.

Thus, what is missing from past studies is a comprehensive and structured approach to managing the resources, the significance of efficient resource allocation, workforce planning, and technology utilization in improving productivity thereby overall performance of the business in the industry. Hence this research will strive to fill that gap. Addressing these gaps through further research and analysis can help to identify and implement effective resource management strategies in the pharmaceutical industry, leading to benefits such as reduced costs, improved efficiency, and increased sustainability.

In summary, the proposed research aims to assess the effectiveness of pharma business operations through optimum resources management in the pharmaceutical industry. By examining resource management practices, the study intends to provide valuable insights and recommendations for optimizing resource utilization in pharmaceutical manufacturing processes.

#### **CHAPTER II:**

## **REVIEW OF LITERATURE**

## 2.1. Introduction

Pharmaceutical companies worldwide are under growing pressure to improve efficiency, comply with evolving regulations, and embrace sustainability. While extensive research has explored quality control, process improvements, and regulatory compliance, fewer studies focus on structured resource optimization strategies, particularly in Active Pharmaceutical Ingredient (API) manufacturing. This chapter examines existing literature, identifies areas that remain underexplored, and establishes how this study addresses these gaps by analyzing real-world resource management strategies, cost-effective process improvements, and the role of technology in pharmaceutical production.

This chapter is structured to systematically explore the multifaceted dimensions of resource optimization in the pharmaceutical industry. It begins by examining the key stakeholders in the pharmaceutical sector and their critical roles in shaping resource management practices. The discussion then transitions to the foundational principles underpinning resource optimization, including operational efficiency, sustainability frameworks, and quality-by-design (QbD) methodologies. To contextualize these principles, the chapter traces the historical evolution of resource optimization, emphasizing the industry's shift from inefficient batch processing to advanced continuous manufacturing systems.

Following this historical analysis, the chapter evaluates contemporary strategies for optimizing resource utilization, such as lean manufacturing, advanced technological integration (e.g., PAT, Automation), and sustainable practices like

solvent recovery. It also critically addresses the barriers and challenges hindering the adoption of these strategies, including regulatory complexities, technological costs, and workforce skill gaps. Building on this analysis, the review identifies gaps in existing literature, particularly the limited focus on longitudinal studies and regional disparities in research. To bridge these gaps, recent studies (2020–2024) are synthesized, offering insights into digital transformation, sustainability, and regulatory adaptation. Finally, the chapter concludes by explicitly linking the literature review to the research problem, advocating for a structured, holistic approach to resource optimization that balances efficiency, cost-effectiveness, and sustainability in pharmaceutical operations.

Based on the precursive study, it is identified that antecedent studies are primarily focused on new drugs development, quality improvement of the drugs, R&D enhancement, greener development & strategic alliances to grow the business.

Bounded exploration has been made on proper utilization or management of resources like Raw materials, chemicals, equipment, and successful scaling techniques for achieving the right first time. At the same time modest work had happened on logistics management and effective inventory/supply chain management, etc. According to Candan and Yazgan (2016), in pharmaceutical enterprises, keeping up with global market conditions is possible with properly selected supply chain policies.

Though R&D is one of the key functions in the development of new molecules, the approach of the companies includes huge investments in (R&D), innovation & development of new drugs. The trend analysis shows that for the most part, the era of blockbuster drugs is nearing an end as numerous blockbuster drugs

will be coming off patent in the next few years, opening the way to generics and eliminating a major source of the industry's profits (Karamehic et al., 2013). According to the industrial production data, production in the pharmaceutical sector has achieved double-digit growth in the last decade (Meşepınar, 2021). Thus, manufacturing these off-patent drugs on a large scale for lower cost and higher quality is going to be the key objective to be competent in the market.

Several studies have investigated the use of lean manufacturing principles in the pharmaceutical industry. Based on the study conducted by Ismail et al., (2014), found that implementing lean manufacturing practices can improve production efficiency by reducing wastage and manufacturing cycle time. They identified several key areas for improvement, including material movement, heating & cooling systems, and optimizing inventory levels.

According to Yu et al., (2004) the Process Analytical Technology (PAT) initiative is a collaborative effort with the industry to introduce new and efficient manufacturing technologies into the pharmaceutical industry. PATs are systems for the design, analysis, and control of manufacturing processes. They aim to assure high quality through timely measurements of critical quality and performance attributes of raw materials, in-process materials, and final products. Implementation of PAT involves scientifically based process design and optimization, appropriate sensor technologies, statistical and information tools, and feedback process control strategies working together to produce quality products.

In addition, supply chain strategies are also equally important. The pharmaceutical supply chain used to be seen as a tool to supply products to market in an effective way, where the emphasis was on security of supply. Recent changes in

the operating environment mean that companies are revisiting the components of their supply chains and identifying ways of extracting additional benefits from them (Shah, 2004). While each approach has unique benefits and challenges, they all aim to reduce costs and improve efficiency.

Several other case studies have demonstrated the potential benefits of resource optimization strategies in the pharmaceutical industry. For example, a study by Plumb, (2005) found that the implementation of continuous manufacturing processes led to a reduction in manufacturing lead times and improved quality of products. The manufacture of chemicals/pharmaceuticals has the potential to generate significant amounts of waste by-products and pollutants, such as contaminated solvents, depleted reagents, and air pollutants, the successful modification of processes can achieve reduced resource requirements, waste generation or energy consumption thereby reducing costs. (Cue and Zhang, 2009). One more study was done by Munson et al., (2006) says that Process Analytical Technologies (PAT) are used to provide timely analysis of critical quality parameters with the end goal of improving final product quality as well as reducing manufacturing costs, thereby significantly benefiting the Pharmaceutical Industry. The usage of PAT tools also helps in reducing process variations, improving the quality of the product, and increasing the usage of resources.

Modgil and Sharma (2016), conducted a study titled "Total Productive Maintenance, Total Quality Management, and Operational Performance: An Empirical Study of Indian Pharmaceutical Industry" The authors investigated the impact of total productive maintenance (TPM) and total quality management (TQM) practices on operational performance and their inter-relationship and their impact on

business performance. Their findings highlighted the significance of the TPM practices will help the organization to improve the pace of product innovation and productivity improvement, which is critical to the pharmaceutical industry. The continuous monitoring of TPM practices can help organizations run day-to-day operations and maintenance requirements of each machine over a specified period.

## 2.2. Stakeholders in the pharmaceutical industry

In the dynamic landscape of the pharmaceutical industry, a multitude of individuals, groups, and entities converge, each with a vested interest in the intricate tapestry that weaves together the development, production, regulation, and distribution of pharmaceutical products. These stakeholders, both internal and external, form a diverse ecosystem that collaboratively shapes the industry's trajectory and impact on global healthcare. From the research laboratories that spark innovation to the regulatory authorities that safeguard public health, and from the patients seeking effective treatments to the investors seeking returns on their commitments.

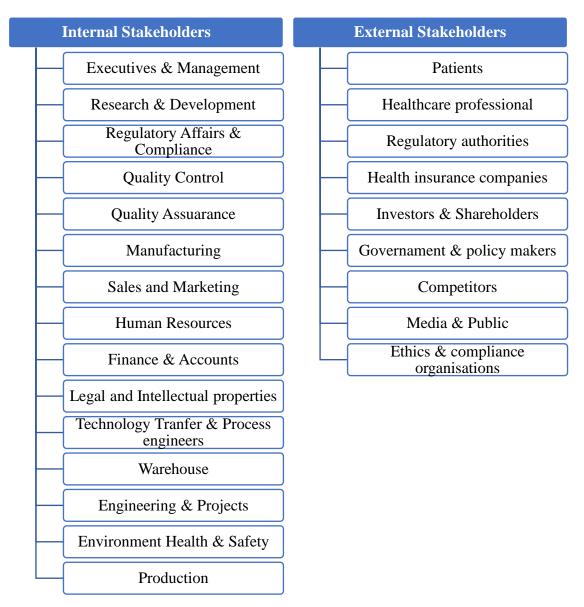


Figure 3 Stakeholders in Pharmaceutical Industry

The interplay between each one of these stakeholders significantly influences resource allocation and optimization. For instance, regulatory authorities enforce stringent quality and compliance standards, while manufacturers focus on cost-effective production processes. Understanding the roles and interactions of these stakeholders is essential for developing effective resource management strategies.

## 2.3. Product flow from selection to sales

Product selection is a pivotal decision-making process in which individuals, businesses, or organizations carefully evaluate and choose specific items, goods, or services to offer, purchase, or use. This process involves considering factors such as quality, features, price, market demand, competition, and alignment with strategic goals. Effective product selection drives successful outcomes, whether in retail, manufacturing, or service industries, by ensuring that the chosen products resonate with target audiences and fulfill specific needs or preferences.

The flow from product selection to sales involves a series of interconnected steps that transform a chosen product into a viable offering for customers and this is a dynamic process that requires coordination, strategy, and continuous adaptation to meet customer needs and market dynamics. Here's an overview of the typical flow.

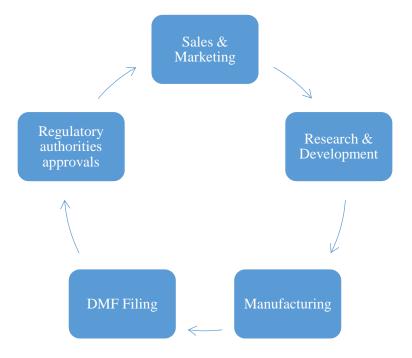


Figure 4 Product flow from selection to sales

#### 2.4. Foundations of Resource Optimization

Resource optimization in the pharmaceutical industry is rooted in principles of efficiency, sustainability, and quality management. Key foundational concepts include:

### 2.4.1. Operations Management Principles:

While pharmaceutical companies have traditionally focused on productivity and expansion, a new perspective prioritizes sustainability. Several recent analyses underscored the value of calibrating output to accurately meet needs, thereby reducing surplus and waste in the production process. With attentiveness to balancing supply and demand, resources stay actively deployed while upholding quality standards (Feng et al., 2011).

## **2.4.2.** Sustainability in Manufacturing:

In addition to the operational management principles, the circular economy framework inspires pharmaceutical manufacturers to examine byproducts not just as discarded remnants but rather as potential resources. Whether through innovative reformulation techniques or recycling approaches, leveraging what was once considered waste can cut material costs and lighten environmental impact. With openness to new solutions and optimization across the full life cycle, the industry is well-positioned to strengthen its bottom line while answering the call for greater responsibility (Production et al., 2018).

#### **2.4.3.** Sustainability in Supply Chains:

The global pharmaceutical supply chain must evolve to support sustainable development goals (SDGs). A study by Ma et al., (2023) emphasizes the importance

of integrating traceability and information-sharing technologies to enhance supply chain sustainability, reducing waste and inefficiencies

# 2.4.4. Quality-by-Design (QbD)

Continuous improvement is commendable when striving to "build in" high standards from inception. However, quality of life, not just economies, gains from prevention over remediation. Reducing harm empowers all stakeholders and future generations. QbD ensures that quality is built into processes from the outset, reducing production errors and waste. (Fukuda et al., 2018) found that adopting QbD reduced quality control expenses by 15% in medium-sized pharmaceutical firms

# 2.5. Historical Context of Resource Optimization

Early pharmaceutical manufacturing was characterized by batch processing, which led to significant inefficiencies. It is observed that batch processes waste nearly 40% of raw materials (Halim and Srinivasan, 2004). Continuous processing, supported by the FDA's Process Analytical Technology (PAT) guidelines, later transformed manufacturing by reducing waste and enabling real-time quality control (Plumb, 2005). More recently, the adoption of green chemistry and sustainable practices has further advanced resource optimization efforts (Bade et al., 2024).

#### **2.5.1.** Green Chemistry Emergence:

The 2010s marked a significant shift toward green chemistry, focusing on eco-friendly raw materials and energy-efficient manufacturing techniques. Global Data's 2022 survey found that the industry must accelerate investments in green practices to meet environmental sustainability targets (Bade et al., 2024).

# 2.6. Current Strategies in Resource Optimization

Recent studies (2020–2024) have highlighted several strategies for optimizing resource utilization in the pharmaceutical industry:

#### **2.6.1.** Lean Practices:

Widespread adoption of lean frameworks, including Just-in-Time (JIT) protocols and value stream optimization, has resulted in cycle time reductions exceeding 20% in API production environments (Aouag and Mohyiddine, 2023).

## 2.6.2. Advanced Technologies

The integration of advanced technologies, such as PAT, IoT, and AI, has revolutionized pharmaceutical manufacturing. Ma et al. (2023) emphasizes the role of digital tools in enhancing supply chain sustainability and traceability.

# **2.6.3. Energy Optimization**:

Companies have implemented energy-efficient systems such as advanced chillers and heat exchangers, resulting in a 10%-15% reduction in energy consumption (Production et al., 2018).

#### **2.6.4.** Solvent Recovery:

Ayati et al., (2020) demonstrated that recovering solvents like ethanol reduced hazardous waste by 20%, improving cost efficiency in API manufacturing

#### 2.6.5. Sustainable Packaging:

Packaging innovations, such as biodegradable materials and lightweight designs, have minimized waste and reduced carbon emissions during transport (Ma et al., 2023).

# 2.7. Costing in the Pharmaceutical Industry

Cost optimization is a critical aspect of pharmaceutical manufacturing, especially for Active Pharmaceutical Ingredients (APIs). Accurate costing not only aids in maintaining competitive pricing but also ensures profitability and regulatory compliance. This section discusses raw material costing and the significant cost savings achieved through solvent recovery and reuse practices.

## 2.7.1. Raw Material Costing

There is no universal standard for calculating raw material costs in pharmaceutical manufacturing. Each organization typically adopts customized approaches based on its production processes and material requirements. A commonly used method involves specifying the required quantities of raw materials and multiplying them by their respective prices. Table 1 provides a detailed example of raw material costing for a pharmaceutical product.

RM	U	Qty	Rec.	Qty	Pr	ice (INR)	CC	% Contribution
	O	(KG)	used	C=A-	INR	Total INR	F = C	to product cost
	M	(A)	(B)	В	/KG	$E = C \times D$	÷Ο	$G = [E \div T] \times$
					(D)			100
RM-1	Kg	100.0	-	100.0	435	43,500.0	0.606	37.68%
RM-2	Kg	174.0	-	174.0	222	38,628.0	1.055	33.46%
RM-3	Kg	8.5	-	8.5	431	3,663.5	0.052	3.17%
RM-4	Kg	987.5	-	987.5	30	29,625.0	5.985	25.66%
		Total	(T) ₹			1,15,416.5		
Output (O)						165.0 KG		
Per Kg product cost (P)						₹ <u>699.49</u>		

*Table 1 Costing in the pharmaceutical industry* 

As seen in Table 1, raw material costs contribute significantly to the total production cost. For example, Material-1, Material-2, and Material-4 together account for more than 90% of the final product cost. This highlights the importance

of optimizing raw material usage to achieve cost savings. Considering there is a potential possibility of recovery of Material-2 & Material-4, approximately 50% of the same will be recovered and reused in further manufacturing.

## 2.7.2. Recovery and Reuse Practices

Solvent recovery and reuse play a vital role in reducing raw material costs and improving the sustainability of pharmaceutical manufacturing. Table 2 demonstrates the impact of recovery practices on the same product, comparing scenarios with and without recovery.

RM	UOM	Usage without recovery (A)	Rec. usage (B)	Final usage C = A-B	Cost Contribution without Recovery	Cost Contribution with Recovery
RM-1	Kg	100.0	-	100.0	37.68%	37.68%
RM-2	Kg	174.0	87	87.0	33.46%	20.09%
RM-3	Kg	8.5	-	8.5	3.20%	3.20%
RM-4	Kg	987.5	493.7	493.75	25.66%	18.22%

Table 2 Costing impact after recovery and re-use

By recovering and reusing Raw Material-2 and Raw Material-4, the final product cost is reduced from ₹ 699.49/kg to ₹ 492.67/kg. This represents savings of nearly 29.5%, demonstrating the financial and operational benefits of recovery practices.

#### 2.7.3. Key Observations

• Raw Material Contribution: Materials with high consumption coefficients (e.g., Raw Material-4) offer significant opportunities for cost optimization through recovery.

- Cost Reduction Through Recovery: Recovery practices not only lower raw material expenses but also reduce environmental impacts, aligning with sustainability goals (Aleem, 2016).
- Strategic Importance: Recovery systems should be integrated into manufacturing processes to achieve long-term cost efficiency and compliance with global regulations.

Costing in pharmaceutical manufacturing is a multifaceted process influenced by raw material usage and recovery practices. Implementing recovery systems and optimizing material inputs can result in substantial cost savings while promoting sustainability. This section highlights the importance of detailed costing and strategic recovery planning in achieving resource efficiency.

# 2.8. Barriers and Challenges in implementing Resource optimization.

Despite the advantages, several barriers impede the seamless implementation of resource optimization. Regulatory compliance, change resistance, and inadequate data management systems have been highlighted as significant hurdles by many researchers. These challenges underscore the necessity of strategic planning, employee training, and resolute leadership to surmount barriers and guarantee the successful execution of resource optimization initiatives.

Also, the challenge lies in the complexity of resource management within the pharmaceutical industry. Companies must balance the need for innovation, compliance with stringent regulations, and cost containment. This involves making strategic decisions about where and how to allocate resources, such as research and development budgets, manufacturing capacity, and workforce. Moreover, the

pharmaceutical sector faces dynamic market conditions, evolving regulatory landscapes, and increasing pressure to deliver life-saving products efficiently.

To keep the barriers and challenges in simpler ways,

- **Technological Costs**: High upfront costs associated with advanced systems make their adoption challenging for manufacturers, especially among small and medium-sized enterprises (SMEs). A study by Ayati et al., (2020) highlight the financial challenges faced by SMEs in adopting PAT and IoT.
- Workforce Training Gaps: Resistance to adopting new technologies is compounded by insufficient training programs, particularly in developing regions. Ma et al., (2023) Emphasize the need for workforce upskilling to ensure the successful implementation of resource optimization strategies.
- Regulatory Complexities: Disparate regulatory frameworks across countries increase compliance costs and delay process optimizations. Mundy et al., (2023) Discuss the impact of regulatory complexities on resource optimization, particularly in the context of Brexit and global supply chain disruptions.

#### 2.9. Sustainability Practices in Pharmaceuticals

#### **2.9.1.** Circular Economy Applications:

Implementing circular economy models, such as recycling manufacturing by-products into feedstock, has significantly reduced production costs by 15%-20% (Korhonen et al., 2018). This approach not only minimizes waste but also enhances resource efficiency, contributing to sustainable manufacturing practices.

## 2.9.2. Usage of New Technologies & PAT Tools:

The integration of new technologies and Process Analytical Technology (PAT) tools in manufacturing have revolutionized the industry. These advancements ensure consistent product quality and process efficiency by enabling real-time monitoring and control (Administration, 2004).

## **2.9.3.** Water and Energy Conservation:

Adopting closed-loop water systems and hybrid energy solutions has led to substantial reductions in resource consumption. Pharmaceutical plants have reported a notable decrease in water usage and notable cost savings through the combination of solar and grid power (Haven, 1887). Companies have implemented energy-efficient systems such as advanced chillers and heat exchangers, resulting in a 10%-15% reduction in energy consumption (Korhonen et al., 2018).

## 2.9.4. Solvent Recovery:

Ayati et al., (2020) demonstrated that recovering solvents like ethanol reduced hazardous waste by 20%, improving cost efficiency in API manufacturing

#### 2.9.5. Sustainable Packaging:

Packaging innovations, such as biodegradable materials and lightweight designs, have minimized waste and reduced carbon emissions during transport (Ma et al., 2023).

### 2.9.6. Cost Improvement by Redeveloping

Redeveloping manufacturing processes to reduce raw material usage has proven to be an effective cost-saving strategy. By optimizing resource allocation and eliminating inefficiencies, companies can achieve significant cost reductions while maintaining high-quality outputs (Rounaghi et al., 2021).

#### 2.9.7. Future Research Directions

Resource optimization in the pharmaceutical sector must address practical, actionable approaches that directly benefit operations, workforce management, and sustainability. This section outlines key areas for future exploration, emphasizing solutions that enhance efficiency, safety, and cost-effectiveness.

## 2.9.8. Affordable Access to Optimization Technologies

Many pharmaceutical companies hesitate to adopt optimization tools due to cost barriers. Future research could focus on:

- Developing affordable, modular solvent recovery systems that can be scaled according to production capacity (Ayati et al., 2020).
- Cloud-based monitoring platforms for smaller firms to access realtime production insights without significant IT infrastructure investments (Hao, 2019).

# 2.9.9. Employee Training and Skill Development

Employee engagement in optimization strategies is critical for long-term success. It enhances competence, increases engagement, fosters adaptability, reduces turnover, promotes innovation, and creates a competitive advantage.

 Training programs to enhance employee understanding of lean principles and sustainability goals are effective for cultivating leadership and ensuring compliance.

- Upskilling programs focusing on emerging practices like solvent recovery and waste segregation can reduce process inefficiencies and enhance compliance (Ma et al., 2023).
- Exploring partnerships between academic institutions and pharmaceutical firms could develop workforce-oriented certifications in sustainability and operations management.

#### 2.9.10. Industrial and Employee Safety

Workplace safety is directly linked to operational efficiency and cost management. Accidents and workplace hazards not only disrupt production but also result in financial liabilities, regulatory fines, and reputational damage.

- Research should focus on developing predictive maintenance systems to minimize equipment failures that pose risks to employees.
   Sensors and real-time monitoring tools can identify potential hazards in machinery.
- Training programs emphasizing safety protocols can reduce workplace incidents by up to 40%, as shown in studies from manufacturing industries (Korhonen et al., 2018).
- Future studies could also explore wearable technologies for employees, such as devices monitoring environmental conditions (e.g., toxic exposure, temperature) in production plants.

#### 2.9.11. Process Standardization for SMEs

Small and medium-sized enterprises (SMEs) often face challenges in adopting resource optimization due to non-standardized processes.

- Developing standardized operating procedures (SOPs) tailored to SMEs can improve consistency and reduce waste.
- Research could examine cost-sharing models for SMEs to collectively invest in shared facilities for solvent recovery and waste management (Raghunathan et al., 2004).
- Pilot projects could test modular manufacturing systems that allow gradual scalability without significant capital investments.

## 2.9.12. Patient-Centric Approaches

The goal of resource optimization is to improve the accessibility and affordability of medications for patients.

- Studies should explore the correlation between optimized manufacturing processes and reduced drug pricing in low-income regions.
- Ayati et al., (2020) highlight the need to align resource optimization strategies with patient outcomes, particularly in chronic disease management and rare diseases.

By focusing on safety, recovery, process optimization, affordability, skill development, etc., future research can provide actionable insights to help the pharmaceutical industry enhance resource optimization. These approaches not only

improve operational efficiency but also foster a safer, more productive workplace, benefiting both organizations and their employees.

## 2.10. Gaps in literature

While existing research provides valuable insights into resource optimization, several gaps remain:

- **1. Limited Focus on Sustainable Practices**: Few studies explore the integration of sustainability into resource management, particularly in API manufacturing (Bade et al., 2024).
- 2. Inadequate Research on Digital Transformation: The role of emerging technologies like AI, IoT, and blockchain in resource optimization is underexplored (Ma et al., 2023).
- 3. Lack of Longitudinal Studies: Most studies focus on short-term impacts, with limited research on the long-term effects of resource optimization strategies (Rounaghi et al., 2021).
- **4. Geographical Limitations**: Most of the research is concentrated in developed regions, with limited insights into resource optimization challenges in developing countries (Ayati et al., 2020).

#### 2.11. Recent studies

Recent studies have begun to address some of these gaps:

Sustainability and Cost Pressures: Ayati et al., (2020) Emphasize the
need for sustainable practices, such as solvent recovery and waste
minimization, to reduce costs and environmental impact.

- **Digital Transformation:** Ma et al., (2023) Highlight the role of digital tools in enhancing supply chain sustainability and traceability.
- Regulatory Challenges: Mundy et al., (2023) Discuss the impact of regulatory complexities on resource optimization, particularly in the context of Brexit and global supply chain disruptions.

#### 2.12. Relevance to the Research Problem

The identified gaps underscore the need for a comprehensive and structured approach to resource management in the pharmaceutical industry. This research aims to address these gaps by:

- Investigating sustainable resource management practices, such as waste reduction and environmental impact minimization.
- Exploring the integration of digital technologies for effective resource allocation and process optimization.
- Providing actionable insights into overcoming barriers like regulatory constraints and technological costs.

By addressing these gaps, this study contributes to the development of best practices and strategies for optimizing resource utilization in the pharmaceutical industry, ultimately enhancing operational efficiency, reducing costs, and promoting sustainability.

#### **CHAPTER III:**

#### **METHODOLOGY**

#### 3.1 Overview of the Research Problem

The research problem addressed in this research pertains to the pharmaceutical industry's pressing challenge of effectively managing its diverse resources to enhance overall business effectiveness. In the complex and dynamic context of pharmaceuticals, where innovation, stringent regulations, and competitive pressures coexist, the optimal allocation and utilization of resources related to financial, human, technological, and material stand as crucial determinants of operational efficiency, cost-effectiveness, and global competitiveness. This research seeks to investigate resource management strategies, evaluate their impact on operational efficiency and cost reduction, identify implementation barriers, and offer best practices, thereby shedding light on how pharmaceutical businesses can thrive while contributing to improved patient outcomes and global health.

This study employs a mixed-method approach to explore strategies and practices that can address these challenges effectively. By integrating quantitative surveys and qualitative analysis of published case studies, this research aims to provide actionable insights into resource optimization.

## 3.2 Research Purpose and Questions

This research aims to assess the effectiveness of the pharma business through optimum resource management. It evaluates the strategies pharmaceutical companies employ to maximize resource utilization, evaluates the impact of optimized resource utilization on operational efficiency and cost reduction, identifies barriers and

challenges to implementing resource optimization strategies, and recommends industry practices and best practices.

To achieve the research purpose, the following questions will guide the investigation:

- 1. What strategies can be employed to optimize resource utilization in pharmaceutical manufacturing processes?
- 2. What are the best practices and recommendations for optimizing resource utilization in the overall pharmaceutical business based on existing literature and industry examples?
- 3. What are the barriers and challenges faced in implementing resource optimization strategies in the pharmaceutical industry?
- 4. What is the impact of optimized resource utilization on operational efficiency and cost reduction in the pharmaceutical industry?

The findings of this research will contribute to the understanding of resource utilization optimization in the pharmaceutical industry and provide evidence-based strategies and recommendations for pharmaceutical companies to enhance their operational efficiency, reduce costs, and improve competency and sustainability.

# 3.3 Research design – Approach – Type & Rationale

To comprehensively examine resource optimization in the pharmaceutical industry, this study adopts a mixed-methods approach to explore resource

optimization in the pharmaceutical industry, blending quantitative and qualitative techniques to capture both broad trends and the subtle nuances of real-world practice. Our approach is driven by the need to understand not only what the data shows at a macro level but also why these trends occur at a micro level.

On the **quantitative** side, structured surveys are deployed to gather statistically robust data on industry-wide practices, such as cost-saving strategies and perceived obstacles to effective resource management. These surveys enable us to measure key performance indicators like operational efficiency and lean manufacturing adoption, offering a clear numerical snapshot of the current landscape.

Complementing this, **qualitative** case studies provide in-depth insights into the operational challenges and strategic innovations experienced by individual organizations. For example, detailed analyses illustrate how the implementation of Process Analytical Technology (PAT) has been instrumental in reducing waste and enhancing efficiency in API synthesis. These narratives help to explain the mechanisms behind the quantitative data and offer a richer understanding of the practical aspects of resource management.

By triangulating these methods, the research bridges the gap between generalizable statistical trends and specific, context-driven experiences. This dual approach not only validates theoretical frameworks with empirical evidence but also captures the nuanced realities of pharmaceutical operations, ultimately leading to more comprehensive and actionable recommendations.

Overall, the design of this study is both exploratory and descriptive, aiming to uncover, understand, and analyze the efficiency of resource management in the pharmaceutical industry. This integrated methodology ensures that the research is

both academically rigorous and practically relevant, contributing meaningful insights to both scholars and industry practitioners.

## 3.4 Survey design & Rationale

#### 3.4.1 Development of Survey Instrument

A structured survey was conducted to collect quantitative data as the primary source. The survey instrument was structured to collect data on strategic resource allocation, efficiency perceptions, and cost-saving outcomes linked to enhanced asset utilization. The Likert scale was utilized to gauge responses.

The survey was designed to collect quantitative data on material usage, sustainability practices, and cost management. Key features of the survey included:

#### 3.4.2 Likert Scale justification:

The 5-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree) was selected to systematically quantify participant perspectives on resource optimization strategies, challenges, and outcomes. This scale balances granularity and simplicity, enabling respondents to express nuanced opinions while ensuring analytical tractability. The ordinal structure of the scale aligns with the study's goal of identifying degrees of consensus on critical issues, such as the perceived efficacy of lean practices or the intensity of regulatory barriers. By avoiding binary responses (e.g., yes/no), the scale captures the spectrum of industry attitudes, facilitating robust statistical analysis of trends and correlations critical to addressing the research questions (Joshi et al., 2015).

#### 3.4.3 Survey Structure and Alignment with Objectives

The survey was structured into four thematic sections, each directly mapped to the study's research objectives:

- Strategies for Resource Optimization: Questions probed the perceived effectiveness of operational, technological, and managerial strategies, enabling the identification of high-priority interventions.
- Best Practices: Items evaluated industry-endorsed frameworks for sustainable resource allocation, such as cross-functional collaboration and data-driven decision-making.
- Barriers to Implementation: Questions assessed challenges like regulatory constraints and technological costs, providing insights into systemic obstacles.
- Impact Assessment: Items measured the perceived economic, operational, and societal outcomes of optimized resource utilization.

This structure ensured comprehensive coverage of the research problem while maintaining thematic coherence. For instance, grouping questions by objective allowed for a focused analysis of how strategies (Objective 1) relate to barriers (Objective 3) and outcomes (Objective 4).

## 3.4.4 Validation Through Theoretical Alignment

The survey design was grounded in validated constructs from pharmaceutical operations literature, ensuring alignment with established frameworks. For example:

- Questions on lean manufacturing drew from Ismail et al. (2014), who demonstrated its role in waste reduction.
- Items addressing sustainability were informed by Korhonen et al. (2018), emphasizing circular economy principles.

This approach ensured that the survey instrument was theoretically robust and contextually relevant to pharmaceutical manufacturing, even without pilot testing.

#### 3.4.5 Response bias

While surveys offer a robust means to gather quantitative data, it is important to acknowledge that self-reported responses can be prone to bias. Respondents might inadvertently exaggerate the positive outcomes of resource optimization efforts due to social desirability or perceived expectations. Participants, particularly those affiliated with organizations promoting sustainability or efficiency initiatives, might overstate the success of optimization strategies to align with corporate narratives. To mitigate this, anonymity was assured to encourage candid responses, employing clear and neutral language in the questions, and survey findings were cross-validated against qualitative insights obtained from case studies data (e.g., comparing reported cost savings in surveys with the metrics from Natco's process optimization case study). These measures were implemented to minimize response bias and enhance the overall credibility and reliability of the data collected.

#### 3.5 Case Study Selection and Methodology

#### 3.5.1 Selection Criteria

Multiple case studies were reviewed and relevant documents, such as company reports, white papers, and industry publications, were analyzed to gather additional qualitative insights into the resource management practices of pharmaceutical companies. This analysis will supplement data obtained from surveys, and reviewed case studies. The selection criteria included:

- **Relevance**: The cases provided insights into resource management practices, recovery systems, or cost-saving initiatives.
- **Data Availability**: Only publicly available, well-documented studies were included.
- Diversity: Case studies represented companies of various sizes and regions.

#### 3.5.2 Data Sources

The secondary data for this study was extracted from:

- Peer-reviewed journal articles.
- Industry-specific reports.
- Case studies published in leading pharmaceutical and manufacturing magazines.

## 3.5.3 Analysis Framework

A thematic analysis was applied to identify patterns and best practices from the collected data. These findings were compared across cases to highlight similarities, differences, and innovative approaches in resource optimization.

## 3.6 Population and Sample

#### 3.6.1 Participant selection

Participant selection was carefully tailored to align with the research goals. Participants with significant industry experience, including professionals from diverse roles and functional areas within pharmaceutical organizations, were selected. Representation from various types and sizes of companies was ensured, and regional differences were considered if relevant. Priority was given to individuals directly

involved in resource management decisions. Informed consent was obtained, participant anonymity was maintained, and ethical guidelines were adhered to throughout the selection process.

#### 3.6.2 Sampling

A stratified random sampling technique was employed to ensure representation from various strata of the pharmaceutical industry. The stratification considered:

- **Industry Roles**: R&D, manufacturing, procurement, Process Engineering, quality control, and quality assurance.
- Company Size: Small, medium, and large enterprises.
- **Geographical Diversity**: Participants were selected mainly from Asia, Europe, and North America.

## 3.6.3 Sample Size Justification

The sample size was determined using a confidence level of 95% and a margin of error of 5%. The goal was to survey not less than 100 professionals from various pharmaceutical organizations. This size was sufficient to capture demographic and organizational diversity.

#### 3.7 Data Collection Procedures

#### **3.7.1** Survey Distribution:

- The surveys were distributed electronically to participants through professional networks and email.
- A response rate of greater than 70% was achieved.

## **3.7.2** Secondary Data Collection for Case Studies:

- Published articles and reports were retrieved through academic databases like PubMed, ScienceDirect, and ResearchGate, etc.,
- Publicly accessible company reports and industry analyses were reviewed to extract relevant data.

#### 3.8 Data analysis

#### 3.8.1 Quantitative Data Analysis

Survey data was analyzed using software (e.g., Microsoft Excel, SPPS, etc.,).

- Descriptive statistics: Descriptive statistics such as mean, median, standard deviation, and frequencies will be used to summarize survey responses.
- Inferential statistics: Inferential statistics including regression analysis
   will be applied to identify correlations and patterns wherever required.

#### 3.8.2 Qualitative Data Analysis

For case studies, a thematic analysis was conducted. Patterns in resource optimization practices, such as solvent recovery and cost-saving strategies, were coded and categorized. Comparative analysis highlighted key differences between practices in different company sizes and regions.

## 3.8.3 Integration of Data Sources

The integration of data sources within this research employs a Mixed Methods Framework, designed to combine quantitative data from surveys with qualitative insights from case studies. This approach allows for a comprehensive exploration of the research questions, leveraging the strengths of both methodologies.

This integration provided a comprehensive understanding of how resource management impacts the effectiveness of pharmaceutical businesses.

#### 3.9 Ethical considerations

Ethical guidelines were strictly followed throughout the research process.

- Informed consent was obtained from all survey participants.
- Anonymity and confidentiality were ensured in the reporting of findings.
- Secondary data sources were appropriately cited, ensuring academic integrity.

#### 3.10 Conclusion

This research methodology aims to comprehensively investigate the effectiveness of resource management in the pharmaceutical industry by incorporating case studies and past research studies into the data collection and analysis process. By employing a mixed-methods approach and drawing from a rich variety of data sources, we intend to gain a nuanced understanding of how resource optimization influences operational efficiency and cost reduction, thereby contributing to the overall effectiveness of pharmaceutical businesses.

#### CHAPTER IV

#### RESULTS

#### 4.1 Case studies or case analysis

Multiple case studies from major pharmaceutical industries have been analyzed to understand the importance of resource optimization strategies and their implication on pharmaceutical products in many ways.

The following case studies illustrate real-world applications of resource optimization in pharmaceutical manufacturing. These examples provide insights into how companies have successfully improved processes, reduced raw material consumption, and achieved cost reductions. The focus is on strategies that enhance operational efficiency, minimize waste, and promote the sustainable use of resources in drug manufacturing.

Each case study is grounded in specific process improvements related to pharmaceutical manufacturing.

- The first case examines the optimization of the synthesis process for Venetoclax, a cancer treatment drug by (Ku et al., 2019).
- On the other hand, the second case focuses on resource management improvements implemented by Natco, a major pharmaceutical company (Annadasu, n.d.).
- The third case involves the adoption of cutting-edge technology, such as
   Process Analytical Technology (PAT), to revolutionize production
   processes, by reducing raw material consumption and improving yield

thereby achieving both cost savings and environmental benefits (Glassey et al., 2014).

 The fourth case is of implementation of lean Six Sigma Pharmaceutical Manufacturing for Improved Efficiency and Cost Savings in one of the acetaminophen (paracetamol) tablet manufacturing facilities by (Byrne and Mcdermott, 2021).

By addressing key issues such as raw material reduction, process redesign, recovery and reuse of materials, adoption of the latest technologies to enhance operational excellence, & implementation of lean tools, these case studies offer practical insights into the benefits of effective resource management. They demonstrate how strategic interventions in pharmaceutical manufacturing can lead to substantial cost savings, higher yields, and more efficient operations.

# 4.2 Case analysis 1: Process Optimization for Venetoclax Synthesis

#### Focus area

Process Development and Raw Material Reduction

#### **Context**

Venetoclax, a drug used in cancer treatment, originally faced issues with low yield, complicated purifications, and resource inefficiencies. Strategic process refinements mitigated these issues, driving measurable cost efficiencies and elevating resource productivity.

### **Initial Challenges**

Low Yield: The first-generation process had an overall yield of only 20%, leading to high raw material consumption and waste.

# **Complex Purification**

Multiple purification steps caused inefficiencies, including loss of product and increased labor.

# **High Cost of Goods (COGs)**

The initial process was costly due to resource inefficiencies and complex procedures.

## **Process Improvements**

A new synthetic route was developed using Buchwald-Hartwig amination, significantly improving yield and reducing waste. Key intermediate steps were optimized, simplifying the purification process and reducing resource consumption.

# 4.2.1 Results of Case Analysis 1

Parameter	First generation process	Improved process
Overall yield	20 %	46 %
Purification steps required	3-4 steps	1-2 steps
Cost of goods reduction	N/A	30% Reduction
Raw material usage efficiency	Low	High
Waste and impurities	5-10%	<1%

Table 3 Results of Case analysis - 1

## 4.2.2 Graphical representation of case analysis 1

A graphical representation of the results obtained from the case along with the comparison of the Improved process with first generation process has been given below.

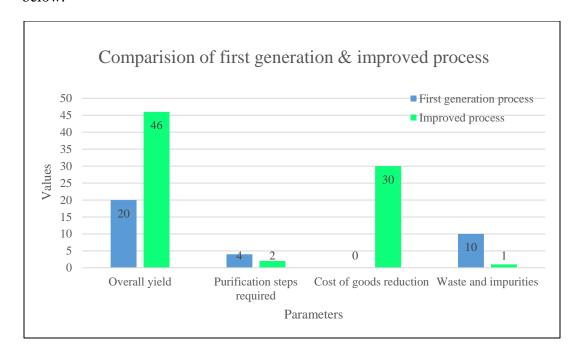


Figure 5 Graphical representation of case analysis 1

#### 4.2.3 Conclusion

The process optimization of Venetoclax synthesis doubled the yield, reduced waste, and cut costs by 30%. This demonstrates the value of strategic process development and raw material reduction in pharmaceutical manufacturing, contributing directly to operational efficiency and cost savings.

## 4.3 Case analysis 2: Resource Management Optimization in Natco's Process

#### 4.3.1 Focus area

Cost Improvement and Recovery and Reuse of Raw Materials

#### **4.3.2** Context

A pharmaceutical company named Natco Pharma Limited developed an optimized synthesis process for pharmaceutical manufacturing that focused on reducing raw material usage and lowering costs through recovery and reuse strategies. The initial process was resource-intensive and costly, requiring expensive raw materials.

## 4.3.3 Initial Challenges

#### 4.3.3.1 High Raw Material Costs

The original process relied on expensive reagents, driving up the overall production cost.

### **4.3.3.2** Multiple Purification Steps

The initial process required several purification steps, increasing the cost and complexity of manufacturing.

#### **4.3.3.3** Waste Management Issues

High levels of waste and impurities were generated during production

# 4.3.4 Process Improvements

Natco introduced an alternative route that reduced the need for expensive raw materials by 30%. They also implemented recovery and reuse strategies for solvents and other reagents, reducing the number of purification steps and minimizing waste.

## 4.3.5 Results of Case Analysis 2

Parameter	First generation process	Improved process
-----------	--------------------------	------------------

Overall yield	30 %	50 %
<b>Purification Steps Required</b>	4 steps	2 steps
<b>Overall Cost Reduction</b>	N/A	25% Reduction
Raw Material Cost/kg	\$100/Kg	\$ 70/Kg
Waste and Impurities	8-10%	1-2%

Table 4 Results of Case Analysis 2

# 4.3.6 Graphical representation of case analysis 2

A graphical representation of the results obtained from the case along with the comparison of the Improved process with first generation process has been given below.

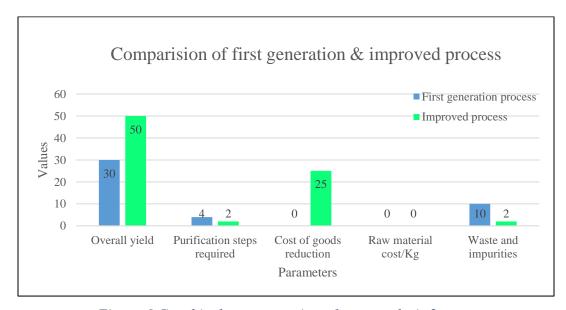


Figure 6 Graphical representation of case analysis 2

#### 4.3.7 Conclusion

Natco's process optimization resulted in a 50% increase in yield and a 25% reduction in overall costs. This case exemplifies how resource optimization, through

recovery and reuse, can significantly lower production costs and improve operational efficiency in pharmaceutical manufacturing.

# 4.4 Case analysis 3: Process Optimization in API Production using PAT & Resource Management

#### **4.4.1** Context

Sanofi developed a batch hydrogenation process to manufacture a high-value Active Pharmaceutical Ingredient (API) for advanced-stage cancer treatment. While the process met production goals, it faced several inefficiencies.

- Excessive solvent usage (110 kg per batch), constituting 96% of the raw material consumption.
- Dependency on single-use powdered palladium (PdC) catalysts, generating substantial waste.
- Low overall yield of 47%, caused by losses in crystallization and purification steps.

These inefficiencies led to a Process Mass Intensity (PMI) of 115 kg of raw materials per kilogram of API, alongside high costs and environmental burdens. To address these issues, Sanofi implemented resource optimization strategies and integrated Process Analytical Technology (PAT) tools. This case highlights how these interventions improved the efficiency, sustainability, and cost-effectiveness of the process.

# **4.4.2** Understanding PMI (Process Mass Intensity)

PMI quantifies raw material efficiency in manufacturing:

PMI = Mass of Product (kg) ÷ Total Mass of Raw Materials (kg)

Initially, the process had a PMI of 115 kg/kg API, driven by excessive solvent and single-use catalyst consumption. Sanofi targeted solvent recycling, catalyst reuse, and improved crystallization to lower PMI and enhance sustainability.

## 4.4.3 Initial Challenges

The production process involved reducing aromatic nitro groups to produce the desired Z-isomer API. Challenges included:

- **Solvent Consumption**: Solvents accounted for 96% of PMI, with no recovery mechanisms in place.
- Catalyst Waste: PdC catalysts were used once and discarded after each batch.
- Yield Loss: Purification steps resulted in significant product loss, limiting yield to 47%.
- Environmental Impact: Solvent waste and single-use catalysts increased CO2 emissions and resource wastage.

#### 4.4.4 Initial PMI Breakdown

Raw Material	Quantity (kg)	Contribution to PMI	Waste Generated
Solvents	110	96%	Disposed post-use
Catalyst	4	3%	Single-use waste
Other Inputs (KIM, etc.)	8.1	1%	Minimal
Total PMI	115		

Table 5 Initial Process Mass Intensity Breakdown (Case 3)

#### 4.4.5 Optimization Strategies

## 4.4.5.1 Solvent Reduction and Recycling

- Action: Installed continuous distillation systems to recycle 80% of used solvents.
- **Result:** Fresh solvent input dropped by 60%.

# 4.4.5.2 Catalyst Reuse

- Action: Replaced powdered PdC with fixed bed nanoparticulate catalysts, reusable for five batches.
- **Result:** Catalyst waste was reduced by 80%.

## 4.4.5.3 Process Monitoring with PAT

• Tools Used:

**Near-Infrared (NIR) Spectroscopy**: Tracked reaction progress in realtime, optimizing reaction endpoints.

**Raman Spectroscopy**: Controlled crystallization, minimizing yield loss.

• **Result**: Reduced byproducts and enhanced API recovery.

#### 4.4.6 Results and Impact

#### **4.4.6.1 PMI Reduction**

- **Initial PMI**: 115 kg/kg API.
- Optimized PMI: 85 kg/kg API (26% improvement).

Metric	Initial	Optimized	Improvement (%)
Solvent Input (kg)	110	44	60%
Catalyst Input (kg)	4	0.8	80%
PMI (kg/kg API)	115	85	26%

Table 6 Improved Process Mass Intensity (Case 3)

# 4.4.6.2 Yield and Output comparison

- **Initial Yield**: 47% (3.8 kg API per batch).
- **Optimized Yield:** 60% (4.9 kg API per batch).

Stage	Initial Output (Kg)	Final Output (Kg)	Increase (%)
Reaction Conversion	3.8	4.9	27%

Table 7 Yield and Output comparison

# 4.4.6.3 Environmental and Cost Savings

#### **Waste Reduction:**

- Solvent waste reduced by 75%.
- Catalyst waste was reduced by 80%.

## **Cost Savings**

- Catalyst reuse saved approximately \$20,000 annually.
- Solvent recycling saved \$15,000 annually.

# **4.4.7** Environmental impact

Metric	Initial	Optimized	Reduction (%)
Solvent Waste (kg/batch)	110	22	80%
Catalyst Waste (kg/year)	200	40	80%
CO2 Emissions (kg/year)	50,000	30,000	40%

Table 8 Environmental impact

# 4.4.8 Process Control Improvements with PAT

## **Key PAT Tools:**

- **NIR Spectroscopy**: Enabled real-time reaction monitoring, reducing material loss and waste.
- Raman Spectroscopy: Ensured precise crystallization, improving API quality and yield.

# 4.4.9 Overall Process Efficiency Gains

Parameter	Initial	Optimized	Improvement (%)
Cycle Time (Hours)	16	12	25%
Material Waste (Kg)	45	15	67%

Table 9 Overall process efficiency gains

## 4.4.10 Conclusion

Sanofi's implementation of Process Analytical Technology (PAT) and innovative resource management strategies has fundamentally transformed its

Active Pharmaceutical Ingredient (API) production process. As a result of these advancements, the company experienced a significant reduction in Process Manufacturing efficiency (PMI) by an impressive 26%. Additionally, the overall yield of their production processes improved by 27%, highlighting the effectiveness of these strategies in enhancing productivity. Furthermore, the generation of waste was drastically minimized, demonstrating a commitment to sustainability and environmental responsibility. By integrating PAT tools like NIR and Raman spectroscopy, real-time monitoring minimized losses, improved efficiency, and reduced environmental impact. This case exemplifies how advanced resource management through PAT aligns with sustainable and cost-effective pharmaceutical manufacturing practices.

# 4.5 Case Analysis 4: Lean Six Sigma Implementation in Pharmaceutical Manufacturing for Improved Efficiency and Cost Savings

#### 4.5.1 Context

In response to an unprecedented increase in demand for acetaminophen (paracetamol) tablets, a pharmaceutical manufacturing facility producing these tablets faced significant operational challenges. The surge in demand was driven by the popularity of the brand, the effectiveness of the drug in treating mild COVID-19 symptoms, and the growing global need for pain relief medications during the pandemic. However, despite the increased demand, the facility struggled to meet production goals, particularly in the packaging department, where inefficiencies and bottlenecks led to production delays.

Key issues included frequent equipment downtime, high work-in-progress (WIP) accumulation and a lack of synchronization between different production

stages. As a result, the facility faced challenges in meeting customer expectations for timely deliveries, which threatened both customer satisfaction and revenue.

To address these issues, the manufacturing facility implemented Lean Six Sigma (LSS) methodologies, a powerful combination of lean manufacturing principles and Six Sigma problem-solving tools. The goal was to reduce waste, improve efficiency, and enhance production throughput. By employing LSS tools, the company achieved remarkable improvements, including a reduction in downtime, increased packaging throughput, and \$500,000 in savings from improved process efficiency.

This case study exemplifies the application of Lean Six Sigma in optimizing resource utilization, improving production processes, and ensuring cost-effective operations in the pharmaceutical industry.

## 4.5.2 Initial challenges

Before the LSS implementation, the manufacturing facility faced several operational challenges:

- Increased Backlog and Delayed Production: The facility's packaging
  department was unable to meet the increasing demand for
  acetaminophen tablets, resulting in backlogs and missed customer
  deadlines.
- Frequent Equipment Downtime: The packaging line was plagued by frequent equipment failures and short stops. These short stops were often caused by issues like tablet feed blockages or mechanical failures,

which disrupted the production flow and significantly impacted overall efficiency.

 Waste and Work-in-Progress (WIP): The facility experienced high levels of waste in the form of WIP accumulation, which created inefficiencies and delayed production timelines. This also led to increased storage costs and longer lead times.

The following metrics highlight the scale of the issues:

- **Average Weekly Run Rate**: 5.4 million blisters (below the target of 6.5 million blisters required to meet customer demand).
- Work in Progress (WIP): 11.6 days of WIP in the packaging department, causing unnecessary delays in the production cycle.
- Downtime: Production downtime was a frequent occurrence, largely
  due to the high frequency of short stops, which consumed valuable
  operational hours.

#### 4.5.3 Lean Six Sigma Methodology Implementation

To address these challenges, the facility employed a customized Lean Six Sigma framework, combining Lean principles for waste reduction and Six Sigma's DMAIC methodology (Define, Measure, Analyze, Improve, Control) for problemsolving. The integration of Lean tools, such as Value Stream Mapping (VSM) and Root Cause Analysis (RCA), helped identify bottlenecks and inefficiencies in the production process.

#### 4.5.3.1 Identify Key Losses and Bottlenecks

The first step in the LSS implementation was to identify the key losses in the production process. A Value Stream Map (VSM) was created to visualize the flow of

materials and identify areas of waste. The mapping revealed that the packaging department was the primary bottleneck, contributing to significant delays in production. This bottleneck resulted in WIP accumulation and reduced production throughput.

Key Insights from the Value Stream Map:

- Packaging Line Downtime: The packaging department faced frequent stoppages, with mechanical failures and tablet feed issues causing downtime.
- Inadequate Equipment Utilization: The equipment in the packaging department was not operating at its maximum capacity due to poor setup times and frequent breakdowns.
- WIP Accumulation: The packaging line was not able to keep up with the rest of the production stages, leading to significant WIP, which delayed product flow.

4.5.3.2 Table: Key Losses Identified in the Packaging Line

Loss Type	Description	Impact
Packaging Line Downtime	Equipment downtime due to short stops and feed blockages	Loss of 1.1 million blisters per week
WIP Accumulation	Bottlenecks leading to excessive work-in-progress (WIP)	Increased lead time and costs
<b>Short Stops</b>	Frequent, recurrent stoppages due to mechanical issues	Loss of production time

Table 10 Key Losses Identified in the Packaging Line

#### 4.5.3.3 Root Cause Analysis and Implementation of LSS Tools

Using Root Cause Analysis (RCA) and other LSS tools such as 5 Whys, Fishbone Diagrams, and Pareto Analysis, the team identified the underlying causes of the downtime and inefficiencies:

- **Short Stops**: The most frequent cause of downtime was mechanical failures caused by tablet feed blockages and sensor issues.
- **Inefficient Setup Times**: Changeover times were too long, leading to production delays when switching between tablet batches.
- Inadequate Maintenance: The lack of Total Productive Maintenance (TPM) resulted in frequent breakdowns and machine failures.

#### **4.5.3.4** Implementing Improvements and Lean Tools

Once the root causes were identified, the following Lean Six Sigma tools were implemented:

- Total Productive Maintenance (TPM): The TPM approach was introduced to improve machine reliability and reduce breakdowns.
- Quick Changeover (SMED): The team employed Single Minute Exchange of Dies (SMED) to reduce changeover times between batches, which had previously been a major source of delays.
- Staffing Adjustments: The facility introduced flexible staffing arrangements, such as floating staff, to ensure coverage during labor shortages and prevent downtime.

#### 4.5.3.5 Table: Improvement metrics post implementation

Metric	Before LSS Implementation	After LSS Implementation	Improvement (%)
Packaging Line Efficiency	5.4 million blisters/week	6.5 million blisters/week	20%
Work in Progress (WIP) Days	11.6 days	3.2 days	72% reduction
Downtime	24% of operational time	8% of operational time	66% reduction
Savings	_	\$500,000	_

Table 11 Improvement Metrics Post-Implementation

## 4.5.4 Results and Impact

After the implementation of Lean Six Sigma, the pharmaceutical facility experienced substantial improvements:

- Increased Production: The packaging line efficiency improved by 20%, reaching the required customer demand of 6.5 million blisters/week.
- **Reduced Work-in-Progress (WIP)**: WIP days decreased by 72%, significantly improving lead times and reducing storage costs.
- **Reduced Downtime**: Downtime was reduced by 66%, leading to improved overall efficiency in the packaging line.
- **Cost Savings**: The process improvements resulted in \$500,000 in savings, stemming from reduced downtime, enhanced equipment efficiency, and streamlined production processes.

#### 4.5.5 Conclusion

The successful application of Lean Six Sigma principles at the pharmaceutical manufacturing facility led to significant operational improvements. By focusing on waste reduction, equipment effectiveness, and streamlined processes, the facility was able to meet customer demand, improve product quality, and save \$500,000. This case exemplifies how Lean Six Sigma can be a powerful tool for improving efficiency, reducing costs, and enhancing overall performance in the pharmaceutical industry.

This case provides a clear example of how pharmaceutical companies can leverage Lean Six Sigma methodologies to optimize their production processes and drive continuous improvement, ensuring better resource utilization, higher productivity, and greater profitability.

#### 4.6 Survey Results

#### 4.6.1 Participant details

As discussed in Chapter III, A structured survey was conducted to collect quantitative data as the primary source. The survey instrument was structured to collect data on strategic resource allocation, efficiency perceptions, and cost-saving outcomes linked to enhanced asset utilization. The Likert scale was utilized to gauge responses.

This section provides a comprehensive overview of the participants involved in this survey. The survey aimed to gather insights from a diverse group of professionals, specifically focusing on those whose work relates directly or indirectly to resources management. The data collected will serve as the foundation for the

subsequent analysis.

4.6.2 **Total Number of Participants** 

The survey had a total of 189 participants. This number forms the basis for

all percentages and further subdivisions in the analysis.

4.6.3 **Ethical Consent** 

All participants provided their ethical consent to participate in the survey.

Out of 189 participants, 100% agreed while participating. An option is provided to

disagree with the consent by which participants can discontinue to participate in the

survey. Only the agreed participants are allowed to proceed further to the survey.

4.6.4 **Highest Level of Education** 

The educational background of the participants varied, with a majority

holding undergraduate degrees. The distribution is as follows:

**Undergraduates:** 122 participants (65%)

**Postgraduates:** 46 participants (24%)

**Doctorates:** 21 participants (11%)

65

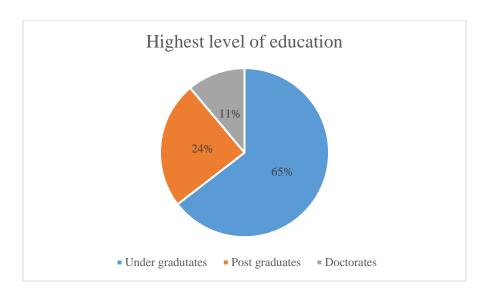


Figure 7 Education details of participants

This distribution highlights that the survey tapped into a well-educated group of individuals, with a significant proportion having advanced degrees.

# 4.6.5 Industrial Experience

Participants' industrial experience ranged widely, offering a broad perspective on the topic. The experience levels are as:

• **0-5 Years:** 31 participants (16%)

• **6-10 Years:** 53 participants (28%)

• **11-20 Years:** 81 participants (43%)

• Greater than 20 Years: 22 participants (12%)

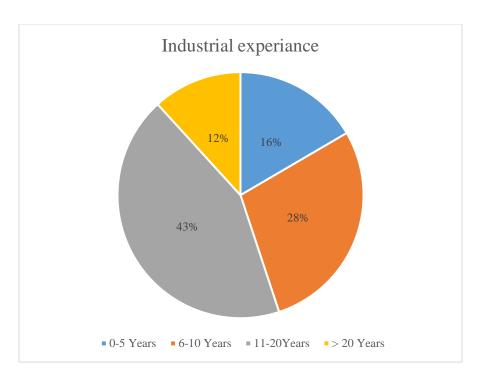


Figure 8 Industrial Experience of Participants

The majority of the participants (43%) have between 11-20 years of experience, 12% have greater than 20 years, 28% are of 6-10 years, and the remaining 16% are of 0-5 years of experience indicating that the insights provided are grounded in substantial professional experience.

# 4.6.6 Size of the Companies that participants are selected from

Participants represented companies of varying sizes, classified by the number of employees:

- Small (0-20 Employees): 1 participant (1%)
- Medium (20-500 Employees): 34 participants (18%)
- Large (> 500 Employees): 154 participants (81%)

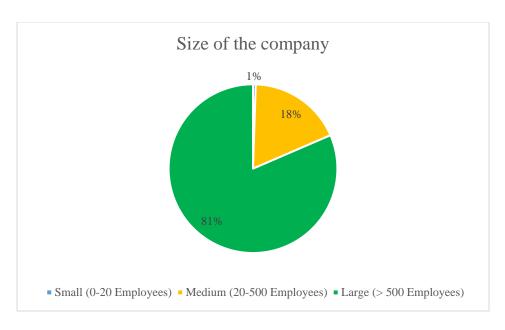


Figure 9 Size of the Companies that participants are selected from

### 4.6.7 Work Relation to Resources Management

Every participant (100%) indicated that their work is related directly or indirectly to resources management, particularly from departments like cost reduction, operational excellence, R&D, Supply chain, inventory management, manufacturing, technical support, or similar kinds of functions. This specific focus ensures that the survey results are highly relevant to the field of resources management, providing targeted insights for the analysis.

## 4.7 Research questions

The study was centered around several key research questions, designed to explore various strategies for optimizing resource utilization in pharmaceutical manufacturing. A list of these main research questions, along with their corresponding subsets of questions, has been tabulated below. Each main research question was broken down into a series of more specific, focused subset questions, allowing for a structured exploration of the core topics. These subsets were arranged

to ensure that each aspect of the main question was covered comprehensively, leaving no gaps in understanding.

The subsets of questions addressed various dimensions such as implementing lean manufacturing principles, adopting advanced technologies and automation, enhancing employee training and skills, improving supply chain practices, and cost-saving initiatives like recovery and reuse. These targeted questions allowed the study to delve deeply into each strategic area.

In addition to covering the strategies, the questions were organized to capture responses from participants across different education levels, industrial experience, and organizational sizes. This arrangement ensured that the responses were diverse and reflective of various professional backgrounds, making the research more robust.

This structured question framework provided a clear path for gathering detailed and well-rounded insights into the strategies employed in pharmaceutical manufacturing, covering both practical implementations and broader organizational practices. A brief overview of the main questions and their corresponding subsets is tabulated below, providing a clear and concise summary of the areas investigated in the study.

	What strategies can be employed to optimize resource utilization in pharmaceutical manufacturing processes?						
		Implementing lean manufacturing principles					
<b>Q1</b>	Resource Utilization	Advanced technology, automation & PAT tools.					
Q1	Strategies in	Employee training and skill development					
	Manufacturing	Supply chain management practices					
		Recovery & reuse.					

	-	ctices and recommendations for optimizing the overall pharmaceutical business based on industry examples?					
		Cross-Functional Collaboration					
		Data-Driven Decision Making					
Q2		Continuous Process Improvement					
	Best practices	Investment in Technology					
		Employee Empowerment					
		Supplier Collaboration					
		Sustainable Practices					
	What are the barriers and challenges faced in implementing resource optimization strategies in the pharmaceutical industry?						
Q3	Parriars & Challanges	Regulatory constraints					
	Barriers & Challenges	Limited access to capital					
	What is the impact of optimized resource utilization on operational efficiency and cost reduction in the pharmaceutical industry?						
	Operational Efficiency	Improved operational efficiency with Optimized resource utilization will help in cycle time reduction, less inventory & reduce waste.					
	Cost savings	Cost savings and increase the bottom line.					
		Enhance overall business performance.					
	Business	Directly correlates with increased profitability.					
	Improvement &	Contributes to faster time-to-market					
Q4	Profitability	Helps to adapt to market changes and seize new opportunities					
		Higher profits for pharmaceutical companies					
		Significant cost reduction in the production					
	Product cost reduction	Lower prices of drugs, increasing accessibility for patients					
	and patient	Increased demand and sales					
	accessibility	Brand reputation and customer loyalty					
		Helps to invest in research and development of new drugs					

Impact of the research on Optimum resources management on Academia	Provides valuable guidance and insights for students  Enhances the learning experience for the student  Can serve as a model for academic research in other industries  Contributes to the development of future professionals
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Table 12 Research Survey Questionnaire

#### 4.8 Detailed questionnaire and subset

The detailed questionnaire and its corresponding subset of questions are provided below for a more comprehensive understanding of the research. Each main research question is paired with specific subset questions that delve deeper into the various strategies being investigated, such as lean manufacturing principles, advanced automation, employee training, supply chain management, and cost-saving initiatives.

These subsets are designed to guide participants in exploring different facets of resource optimization, ensuring that responses capture a wide range of perspectives and experiences across varying industrial backgrounds and organizational structures.

This structured questionnaire allows for a nuanced exploration of the key areas under investigation, providing clarity and depth to the research while ensuring that all aspects of resource utilization strategies in pharmaceutical manufacturing are thoroughly examined.

#### 4.8.1 Research Question One

What strategies can be employed to optimize resource utilization in pharmaceutical manufacturing processes?

- **Q1-1:** Implementing lean manufacturing principles.
- **Q1-2**: Adopting advanced technology, automation & PAT tools.
- Q1-3: Investing in employee training and skill development.
- **Q1-4:** Enhancing supply chain management practices.
- Q1-5: Cost improvement initiatives like recovery & reuse.

#### 4.8.2 Research Question Two

What are the best practices and recommendations for optimizing resource utilization in the overall pharmaceutical business based on existing literature and industry examples?

- **Q2-1:** Cross-Functional Collaboration: Collaborating across different departments (e.g., R&D, manufacturing, supply chain) to streamline resource allocation and utilization.
- **Q2-2:** Data-Driven Decision Making: Using data analytics and advanced modeling techniques to identify inefficiencies and optimize resource allocation.
- **Q2-3:** Continuous Process Improvement: Implementing continuous improvement methodologies such as Lean Six Sigma to systematically identify and eliminate waste in processes.
- **Q2-4:** Investment in Technology: Investing in state-of-the-art technology and automation solutions to improve efficiency and reduce resource waste.
- **Q2-5:** Employee Empowerment: Empowering employees through training and development programs to identify and implement resource optimization opportunities.

**Q2-6:** Supplier Collaboration: Collaborating closely with suppliers to optimize procurement processes and ensure timely delivery of raw materials.

**Q2-7:** Sustainable Practices: Integrating sustainability considerations into resource management practices to reduce environmental impact and improve long-term viability.

#### 4.8.3 Research Question Three

What are the barriers and challenges faced in implementing resource optimization strategies in the pharmaceutical industry?

**Q3-1:** Regulatory constraints pose significant barriers to implementing resource optimization strategies.

Q3-2: Limited access to capital for investment in technology and infrastructure hinders resource optimization efforts.

#### 4.8.4 Research Question Four

What is the impact of optimized resource utilization on operational efficiency and cost reduction in the pharmaceutical industry?

#### **Operational Efficiency**

**Q4-1:** Improved operational efficiency with Optimized resource utilization will help in cycle time reduction, less inventory & reduce waste.

#### **Cost savings**

**Q4-2:** Optimized resource utilization can contribute to cost savings and increase the bottom line.

#### **Business improvement & Profitability:**

- **Q4-3:** Optimized resource utilization enhances overall business performance and competitiveness in the pharmaceutical industry.
- **Q4-4:** Effective resource management directly correlates with increased profitability for pharmaceutical companies.
- **Q4-5:** Efficient resource allocation contributes to faster time-to-market for pharmaceutical products, enhancing revenue generation.
- **Q4-6:** Strategic resource management enables pharmaceutical companies to adapt to market changes and seize new opportunities, leading to business growth and expansion.
- **Q4-7:** Cost savings resulting from optimized resource utilization directly translate into higher profits for pharmaceutical companies.

#### Product cost reduction and patient accessibility

- **Q4-8:** Optimized resource utilization leads to significant cost reduction in the production of pharmaceutical drugs, making them more affordable for patients.
- **Q4-9:** Reduced manufacturing costs resulting from optimized resource utilization directly translate to lower prices of drugs, increasing accessibility for patients.
- **Q4-10:** Improved accessibility to affordable medications due to optimized resource utilization indirectly leads to increased demand and sales for pharmaceutical companies.
- **Q4-11:** Enhanced patient access to medications resulting from cost reduction initiatives improves brand reputation and customer loyalty, ultimately driving sales and profitability for pharmaceutical companies.

**Q4-12:** The effective management of resources enables pharmaceutical companies to invest in R&D, fostering innovation and differentiation in the market, leading to increased sales and profits.

# Impact of the research on Optimum resources management on Academia

**Q4-13:** Research on resource management in the pharmaceutical industry provides valuable guidance and insights for students completing college projects or research papers.

**Q4-14:** Collaboration between pharmaceutical companies and academic institutions on resource management research projects enhances the learning experience for students and fosters industry-academia partnerships.

**Q4-15:** Understanding and implementing effective resource management practices in pharmaceutical companies can serve as a model for academic research in other industries facing similar challenges.

**Q4-16:** Academic engagement with resource management in the pharmaceutical industry contributes to the development of future professionals equipped with knowledge and skills relevant to industry needs.

#### 4.9 Summary of Findings

In this section, the survey results for each question are systematically presented, and organized by strategy, best practices, challenges, and impacts on operational efficiency, cost savings, and accessibility. Graphs are included to provide visual insights and support the analysis.

#### 4.9.1 Question 1: Strategies for Optimizing Resource Utilization

To optimize resource utilization in pharmaceutical manufacturing, the emphasis of the survey respondents on the given strategies is as below.

**Implementing Lean Manufacturing Principles:** 

Lean practices received strong endorsement, particularly for waste reduction

and efficiency. Survey data shows 128 respondents in strong agreement, indicating

industry-wide recognition of lean's effectiveness.

Adopting Advanced Technology, Automation, and PAT Tools:

Over 66% of participants highlighted advanced technology, including PAT

(Process Analytical Technology), as critical for operational precision, real-time

monitoring, and quality control.

**Investing in Employee Training and Skill Development:** 

A majority agreed that trained employees are essential for implementing

resource management techniques.

**Enhancing Supply Chain Management Practices:** 

Improved supply chain practices, such as vendor collaboration and optimized

logistics, play a vital role in managing inventory levels and reducing delays.

**Cost Improvement Initiatives like Recovery and Reuse:** 

With 73% in agreement, recovery initiatives were recognized for reducing

resource consumption and minimizing production waste.

Responses for the above are tabulated below. For the convenience of

tabulation, the following abbreviations have been used for the responses:

**SD:** Strongly Disagree

D: Disagree

N: Neutral

76

A: Agree

**SA:** Strongly Agree

By adopting these short forms, the thesis aims to streamline the presentation of survey responses, making them more accessible and understandable. Each time a response is analyzed or discussed, these abbreviations will serve to provide clear and concise categorizations, allowing for efficient interpretation of the data.

# 4.9.2 Responses for Question 1

**Question 1: Strategies for Optimizing Resource Utilization** 

Q. Code	Strategy		D	N	A	SA
Q1-1	Implementing lean manufacturing principles.	8	20	13	20	128
Q1-2	Adopting advanced technology, automation & PAT tools.	11	17	16	20	125
Q1-3	Investing in employee training and skill development.	9	14	19	19	128
Q1-4	Enhancing supply chain management practices.	7	15	21	18	128
Q1-5	Cost improvement initiatives like recovery & reuse.	8	17	14	11	139

Table 13 Responses for Question - 1

# 4.9.3 Graphical representation of responses for Question 1



#### **Question 1: Strategies for Optimizing Resource Utilization**

Figure 10 Graphical representation of responses for Question 1

-50

50

100

150

200

#### 4.9.4 Question 2: Best Practices and Recommendations

Survey results indicate that the following best practices are widely supported as crucial for effective resource utilization.

#### **Cross-Functional Collaboration:**

Endorsed by 135 respondents, collaboration across departments like R&D, manufacturing, and supply chain is essential for unified resource allocation.

# **Data-Driven Decision Making:**

Analytics-driven approaches help companies identify inefficiencies and optimize resources. This received strong support, with 68% of respondents in favor.

#### Continuous Process Improvement (e.g., Lean Six Sigma):

Continuous improvement methodologies such as Lean Six Sigma are highly valued for systematically eliminating waste.

# **Investment in Technology:**

Advanced technology investments were seen as vital for minimizing resource wastage and boosting operational efficiency.

# **Employee Empowerment and Supplier Collaboration:**

Training and strong supplier relationships help secure consistent material quality and optimize procurement.

# 4.9.5 Responses for Question 2 Question 2: Best Practices for Resource Optimization

Q. Code	Strategy	SD	D	N	A	SA
Q2-1	Cross-Functional Collaboration	8	15	15	16	135
Q2-2	Data-Driven Decision Making	6	15	17	21	130
Q2-3	Continuous Process Improvement	8	16	19	18	128
Q2-4	Investment in Technology	6	18	16	12	137
Q2-5	Employee Empowerment	6	15	17	19	132
Q2-6	Supplier Collaboration	6	20	15	20	128
Q2-7	Sustainable Practices	7	18	21	17	126

*Table 14 Responses for Question* − 2

# **4.9.6** Graphical representation of responses for question 2

# **Question 2: Best Practices for Resource Optimization**



Figure 11 Graphical representation of responses for question 2

#### 4.9.7 Question 3: Barriers and Challenges

Barriers to implementing resource optimization strategies were identified.

#### **Regulatory Constraints:**

The survey highlighted regulatory compliance as a top challenge, with 67% of respondents viewing it as a significant barrier.

#### **Limited Access to Capital:**

Insufficient capital for technology investments restricts many companies from adopting resource optimization tools, particularly smaller organizations.

# 4.9.8 Responses for Question 3 Question 3: Barriers to Resource Optimization

Q. Code	Barrier	SD	D	N	A	SA
Q3-1	Regulatory constraints	10	14	22	16	127
Q3-2	Limited access to capital	3	22	14	21	129

*Table 15 Responses for Question – 3* 

# 4.9.9 Graphical representation of responses for question 3

# **Question 3: Barriers to Implementing Resource Optimization**

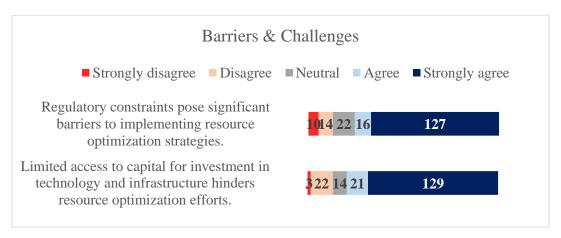


Figure 12 Graphical representation of responses for question 3

#### 4.9.10 Question 4: Impact of optimized resource utilization

This section summarizes the responses to Question 4, structured in five main areas: Operational Efficiency, Cost Savings, Business Improvement & Profitability,

Product Cost Reduction & Patient Accessibility, and the Impact of Research on Academia. Each area contains tables and graphical representations for easy interpretation.

### **4.9.11 Q4-1: Operational Efficiency**

Most respondents agree or strongly agree (78%) that optimized resource utilization significantly improves operational efficiency, reducing cycle times, inventory levels, and waste.

# 4.9.12 Responses for Question Q4-1

Question Q4-1: Impact of Optimized Resource Utilization on Operational Efficiency

Q. Code	Context	Statement	SD	D	N	A	SA
Q4-1	Operational Efficiency	Improved operational efficiency with Optimized resource utilization will help in cycle time reduction, less inventory & reduce waste.	6	18	16	19	130

*Table 16 Responses for question Q4-1* 

#### **4.9.13 Q4-2:** Cost Savings

Nearly 73% of participants agree or strongly agree that resource optimization leads to cost savings, enhancing the company's bottom line.

## 4.9.14 Responses for Question Q4-2

**Question Q4-2: Cost Savings from Optimized Resource Utilization** 

Q. Code	Context	Statement	SD	D	N	A	SA
Q4-2	Cost savings	Optimized resource utilization can contribute to cost savings and increase the bottom line.	7	20	15	13	134

Table 17 Responses for question Q4-2

# 4.9.15 Graphical representation of responses of question Q4-2 Question Q4-2: Impact of Optimized Resource Utilization on Operational Efficiency & Cost Savings

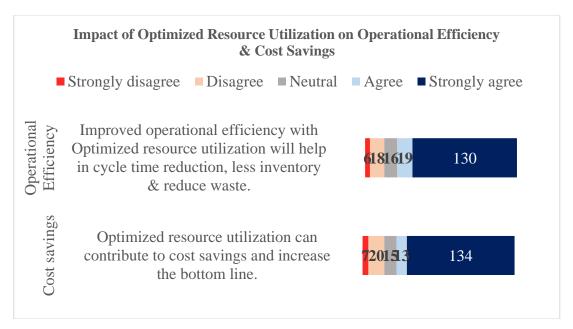


Figure 13 Graphical representation of responses of question Q4-2

#### 4.9.16 Q4-3 to Q4-7: Business Improvement & Profitability

Respondents largely support that optimized resources improve competitiveness, profitability, and adaptability. A majority (67%) agree or strongly agree on profitability benefits from cost savings, and 71% see business growth potential.

#### 4.9.17 Responses for Question Q4-3 to Q4-7

Question Q4-3 to Q4-7: Business Improvement & Profitability with Optimized Resources

Q. Code	Context	Statement	SD	D	N	A	SA
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Q4-3	Business improvement	Optimized resource utilization enhances overall business performance and competitiveness in the pharmaceutical industry.	12	23	9	17	128
Q4-4	Profitability	Effective resource management directly correlates with increased profitability for pharmaceutical companies.	6	14	17	20	132
Q4-5	Revenue Generation	Efficient resource allocation contributes to faster time-to-market for pharmaceutical products, enhancing revenue generation.	3	20	13	21	132
Q4-6	Business Growth	Strategic resource management enables pharmaceutical companies to adapt to market changes and seize new opportunities, leading to business growth and expansion.	9	15	18	18	129
Q4-7	Profitability from Cost Savings	Cost savings resulting from optimized resource utilization directly translate to higher profits for pharmaceutical companies.	8	11	20	13	137

Table 18 Responses of question Q4-3 to Q4-7

# 4.9.18 Graphical representation of responses to question Q4-3 to Q4-7 Question Q4-3 to Q4-7: Business Improvement & Profitability with Optimized Resources



Figure 14 Graphical representation of responses to question Q4-3 to Q4-7

#### 4.9.19 Q4-8 to Q4-12: Product Cost Reduction & Patient Accessibility

Respondents agree that resource optimization helps reduce product costs and improve accessibility and brand reputation. Around 73% believe it enhances affordability, leading to increased demand and customer loyalty.

4.9.20 Responses of Question Q4-8 to Q4-12

Question Q4-8 to Q4-12: Product Cost Reduction & Accessibility

Q. Code	Context	Statement	SD	D	N	A	SA
Q4-8		Optimized resource utilization leads to significant cost reduction in the production of pharmaceutical drugs, making them more affordable for patients.	8	13	20	14	134
Q4-9		Reduced manufacturing costs resulting from optimized resource utilization directly translate to lower prices of drugs, increasing accessibility for patients.	9	13	19	15	133
Q4-10	Product cost reduction and patient accessibility	Improved accessibility to affordable medications due to optimized resource utilization indirectly leads to increased demand and sales for pharmaceutical companies.	8	12	23	19	127
Q4-11		Enhanced patient access to medications resulting from cost reduction initiatives improves brand reputation and customer loyalty, ultimately driving sales and profitability for pharmaceutical companies.	4	14	17	20	134
Q4-12		The effective management of resources enables pharmaceutical companies to invest in R&D, fostering innovation and differentiation in the market, leading to increased sales and profits.	8	15	20	14	132

Table 19 Responses of Question Q4-8 to Q4-12

# 4.9.21 Graphical representation of responses to Question Q4-8 to Q4-12 Question Q4-8 to Q4-12: Product Cost Reduction & Accessibility

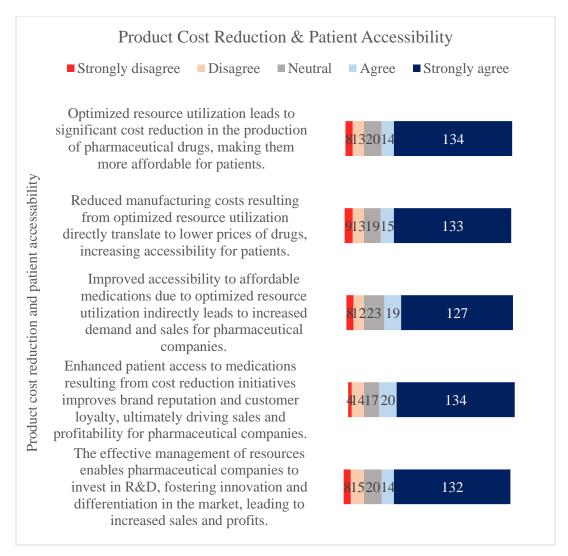


Figure 15 Graphical representation of responses to Question Q4-8 to Q4-12

# 4.9.22 Q4-13 to Q4-16: Impact of the research on Optimum resources management on Academia

Respondents agree that resource optimization in the pharmaceutical industry provides valuable guidance and insights for students completing college projects or research papers, enhances the learning experience, fosters industry-academia

partnerships, and more. Around 78% believe it can serve as a model for academic research in other industries facing similar challenges. More than 75% accepted that Academic engagement with resource management in the pharmaceutical industry contributes to the development of future professionals equipped with knowledge and skills relevant to industry needs.

4.9.23 Responses for Question Q4-13 to Q4-16

Question Q4-13 to Q4-15: Impact of the research on Optimum resources management in Academia

Q. Code	Context	Statement	SD	D	N	A	SA
Q4-13	Impact of the research	Research on resource management in the pharmaceutical industry provides valuable guidance and insights for students completing college projects or research papers.	7	18	17	11	136
Q4-14	on Optimum resources management on Academia	Collaboration between pharmaceutical companies and academic institutions on resource management research projects enhances the learning experience for students and fosters industry-academia partnerships.	7	12	22	15	133

Q4-15	Understanding and implementing effective resource management practices in pharmaceutical companies can serve as a model for academic research in other industries facing similar challenges.	8	15	18	20	128
Q4-16	Academic engagement with resource management in the pharmaceutical industry contributes to the development of future professionals equipped with knowledge and skills relevant to industry needs.	11	21	10	16	131

Table 20 Responses of Question Q4-13 to Q4-16

# 4.10 Statistical Analysis of findings

#### 4.10.1 Introduction

In this analysis, we will employ a descriptive statistical methodology to evaluate responses to various strategies related to operational improvements. The dataset consists of responses categorized by levels of agreement, ranging from "Strongly Disagree" to "Strongly Agree." This approach allows us to quantify and interpret the sentiments expressed by respondents regarding each strategy.

To facilitate the analysis, we will assign numerical values to each level of agreement as follows:

- Strongly Disagree = 1
- Disagree = 2
- Neutral = 3

Agree = 4

• Strongly Agree = 5

In addition, we will square these values (1<sup>2</sup>, 2<sup>2</sup>, 3<sup>2</sup>, 4<sup>2</sup>, 5<sup>2</sup>) to calculate the weighted quadratic mean (or root mean square).

#### 4.10.2 Range calculation and interpretation method:

The range is a simple yet effective measure of variability in a dataset. It provides insight into the spread of responses by quantifying the difference between the highest and lowest values. The formula for calculating the range is:

Range=Maximum Value-Minimum Value

#### 4.10.3 Steps to Calculate the Range

First, determine the highest (maximum) and lowest (minimum) values in your dataset.

Subtract Minimum from Maximum using the formula above to calculate.

The ranges for interpreting mean scores in a Likert scale survey are typically derived from the numerical values assigned to each level of agreement. In this case, we assigned values as follows:

• Strongly Disagree = 1

• Disagree = 2

• Neutral = 3

• Agree = 4

• Strongly Agree = 5

#### 4.10.4 Deriving interpretation ranges

To create interpretation ranges for the mean scores, we can analyze the

possible values that the mean can take based on the assigned numerical values. The

ranges are established by dividing the scale into segments that correspond to the levels

of agreement. Here's how these ranges are typically derived:

**Range of Values:** The possible mean scores range from 1.00 (if all

responses are "Strongly Disagree") to 5.00 (if all responses are "Strongly

Agree").

**Calculate the Total Range:** The total range is calculated as:

Total Range=Maximum Value-Minimum Value=5-1=4

Divide by the Number of Categories: Since we have five categories

(Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree), we

divide the total range by the number of categories:

Range per Category= Total range/Number of categories = 4/5 = 0.8

4.10.5 **Establish the Ranges for Each Category** 

**Strongly Disagree:** 

Minimum: 1.00

Maximum: 1+0.8 = 1.81+0.8 = 1.8

Range: 1.00 - 1.80

Disagree:

Minimum: 1.8+0.01 (to avoid overlap)

Maximum: 1.8+0.8 = 2.6

Range: 1.81 - 2.60

**Neutral:** 

Minimum: 2.6+0.01

91

o Maximum: 2.6+0.8 = 3.4

o Range: 2.61 - 3.50

## • Agree:

o Minimum: 3.4+0.01

 $\circ$  Maximum: 3.4+0.8 = 4.2

o Range: 3.41 - 4.20

# Strongly Agree

 $\circ$  Minimum: 4.2 + 0.01

o Maximum: 4.2 + 0.8 = 5

o Range: 4.21 - 5.0

A summarized version of the interpretation ranges for Likert scale responses, presented in a clear table format:

# 4.10.6 Interpretation Ranges for Likert Scale Responses

Level of Agreement	Assigned Value	Interpretation Range
<b>Strongly Disagree</b>	1	1.00 - 1.80
Disagree	2	1.81 - 2.60
Neutral	3	2.61 - 3.40
Agree	4	3.41 - 4.20
<b>Strongly Agree</b>	5	4.21 - 5.00

Table 21 Interpretation ranges for Likert scale responses.

# **Summary of Interpretation**

• **Strongly Disagree:** Indicates overwhelming disagreement with the statement.

- **Disagree:** Reflects general disagreement but includes some neutral responses.
- **Neutral:** Suggests indifference or neutrality towards the statement.
- **Agree:** Indicates general agreement with the statement.
- **Strongly Agree:** This signifies overwhelming support for the statement.

#### 4.10.7 Statistical Analysis Question 1

#### **Strategies for Optimizing Resource Utilization:**

Statistical analysis has been conducted using the above methodology to evaluate responses to the question: "Strategies for Optimizing Resource Utilization." Let us understand the details of this analysis and the insights derived from the respondents' sentiments regarding various proposed strategies for improving resource efficiency.

Q. Code	Strategy	SD	D	N	A	SA	Total
Q1 – 1	Implementing lean manufacturing principles.	8	20	13	20	128	189
Q1 – 2	Adopting advanced technology, automation & PAT tools.		17	16	20	125	189
Q1-3	Investing in employee training and skill development.	9	14	19	19	128	189
Q1 – 4	Enhancing supply chain management practices.	7	15	21	18	128	189
Q1 – 5	Cost improvement initiatives like recovery & reuse.		17	14	11	139	189

Table 22 Data for statistical analysis of question 1

Q. Code	Weighted mean	Mean	Median	Std Deviation	Weighted Correlation (r)	P- Value	$\mathbb{R}^2$
Q1 – 1	4.27	19.71	20	3.93	0.881	0.048	0.776
Q1 – 2	4.22	19.41	17	3.90	0.879	0.049	0.773
Q1-3	4.29	19.79	19	3.94	0.885	0.045	0.784
Q1 – 4	4.30	19.81	18	3.94	0.892	0.041	0.796
Q1-5	4.35	20.39	14	4.00	0.901	0.036	0.812

Table 23 Statistical analysis of question 1

#### **Key Takeaways**

- Q1-5 "Cost improvement initiatives like recovery & reuse", exhibits the highest correlation (r = 0.901) and R-squared (0.812), indicating the strongest agreement among respondents.
- Q1-2 "Adopting advanced technology, automation & PAT tools" has
  a slightly lower correlation (r = 0.879) compared to other strategies
  which is greater than 0.88 but remains statistically significant (p =
  0.049).
- The overall statistical evidence suggests broad consensus on the effectiveness of all five strategies, providing strong validation for their adoption in resource utilization planning.

The statistical evaluation of responses to the question on "Strategies for Optimizing Resource Utilization" reveals a strong consensus among participants

regarding the effectiveness of the proposed approaches. The analysis incorporates key statistical measures, including mean, median, standard deviation, weighted correlation coefficient (r), p-value, and R-squared, all of which collectively indicate significant support for these strategies.

The high weighted correlation values (r > 0.87) further validate this consensus, demonstrating a strong association between the level of agreement and response patterns. Additionally, the low p-values (< 0.05) confirm the statistical significance of this relationship, while the high R-squared values (> 0.77) suggest that a substantial proportion of response variability can be attributed to the level of agreement among respondents.

In summary, these findings provide compelling evidence in favor of implementing the proposed resource optimization strategies. The consistently strong statistical indicators suggest that organizations can adopt these measures with confidence. However, while the correlation results reinforce overall agreement, the observed standard deviation values indicate that some variability exists, warranting further discussion to accommodate diverse stakeholder perspectives. Ultimately, this comprehensive analysis offers valuable insights that can inform strategic decision-making and enhance resource management initiatives.

#### 4.10.8 Statistical analysis of question 2

#### **Best Practices and Recommendations**

The analysis of survey responses regarding best practices for optimizing resource utilization reveals a strong consensus among respondents, indicating agreement with various strategies proposed. The data collected includes responses to seven key practices, each evaluated on a five-point Likert scale.

Q. Code	Strategy	SD	D	N	A	SA	Total
Q2-1	Cross-Functional Collaboration	8	15	15	16	135	189
Q2-2	Data-Driven Decision Making	6	15	17	21	130	189
Q2-3	Continuous Process Improvement	8	16	19	18	128	189
Q2-4	Investment in Technology	6	18	16	12	137	189
Q2-5	Employee Empowerment	6	15	17	19	132	189
Q2-6	Supplier Collaboration	6	20	15	20	128	189
Q2-7	Sustainable Practices	7	18	21	17	126	189

Table 24 Data for statistical analysis of Question 2

The analysis of responses to seven key strategies for optimizing resource utilization demonstrates strong support among respondents. By incorporating weighted correlation (r), p-value, and R-squared alongside mean, median, and standard deviation, we obtain a more comprehensive understanding of stakeholder perspectives.

- $\bullet$  All strategies exhibit a high weighted correlation (r > 0.88), suggesting a strong alignment between agreement levels and response distribution.
- Low p-values (< 0.05) confirm that the correlation is statistically significant across all strategies.

• High R-squared values (> 0.78) indicate that a substantial portion of the response variation is explained by agreement levels.

Q. Code	Weighted mean	Mean	Median	Standard Deviation	Weighted correlation (r)	P- Value	$\mathbb{R}^2$
Q2-1	4.35	20.29	15	3.99	0.888	0.044	0.789
Q2-2	4.34	20.13	17	3.97	0.887	0.044	0.788
Q2-3	4.28	19.74	18	3.93	0.889	0.043	0.790
Q2-4	4.35	20.31	16	3.99	0.901	0.036	0.813
Q2-5	4.35	20.23	17	3.98	0.889	0.043	0.791
Q2-6	4.29	19.79	20	3.94	0.884	0.046	0.783
Q2-7	4.25	19.52	18	3.91	0.893	0.041	0.798

Table 25 Statistical analysis of question 2

# Key takeaways

- "Investment in Technology" (Q2-4) exhibits the highest correlation (r = 0.9019) and R-squared (0.8134), indicating the strongest agreement among respondents.
- "Supplier Collaboration" (Q2-6) has a slightly lower correlation (r = 0.8849) but remains statistically significant (p = 0.0461).
- The overall statistical evidence suggests broad consensus on the effectiveness of all seven strategies, providing strong validation for their adoption in resource utilization planning.

The statistical analysis confirms strong support for the proposed resource optimization strategies, as reflected in consistently high mean scores. Additional statistical measures including weighted correlation (r), p-value, and R squared reinforce the reliability of these findings.

In conclusion, the statistical analysis highlights several best practices that pharmaceutical companies can adopt to optimize resource utilization effectively:

- 1. Cross-Functional Collaboration (r = 0.8885, p = 0.0440,  $R^2 = 0.7894$ )
  - Encouraging teamwork across departments improves resource allocation and efficiency.
- **2.** Data-Driven Decision Making (r = 0.8877, p = 0.0444,  $R^2 = 0.7880$ )
  - Leveraging analytics helps identify inefficiencies and optimize resource use.
- 3. Continuous Process Improvement (r = 0.8890, p = 0.0436,  $R^2 = 0.7904$ )
  - Adopting Lean Six Sigma and similar methods reduces waste and enhances productivity.
- **4.** Investment in Technology (r = 0.9019, p = 0.0363,  $R^2 = 0.8134$ ) Highest correlation
  - Advanced technologies boost efficiency and minimize resource wastage.
- 5. Employee Empowerment (r = 0.8894, p = 0.0434,  $R^2 = 0.7910$ )
  - Training employees to equip them to drive process improvements.

- **6.** Supplier Collaboration (r = 0.8849, p = 0.0461,  $R^2 = 0.7830$ )
  - Strong supplier partnerships enhance procurement and minimize waste.
- 7. Sustainable Practices (r = 0.8933, p = 0.0412,  $R^2 = 0.7980$ )
  - Integrating sustainability reduces environmental impact and ensures long-term viability.

Overall, these findings highlight these strategies as effective and well-supported within the pharmaceutical industry. Their strong statistical backing makes them reliable frameworks for optimizing resources. Organizations can confidently implement these best practices focusing on collaboration, data-driven insights, continuous improvement, and employee engagement to enhance efficiency and sustain long-term success.

### 4.10.9 Statistical analysis of question 3

### **Barriers and Challenges to Resource Optimization**

The analysis of survey responses regarding barriers and challenges to implementing resource optimization strategies reveals a significant level of agreement among respondents. The data collected includes responses to two key challenges, each evaluated on a five-point Likert scale.

Q. Code	Barrier	SD	D	N	A	SA	Total
Q3-1	Regulatory constraints	10	14	22	16	127	189
Q3-2	Limited access to capital	3	22	14	21	129	189

Table 26 Data for statistical analysis of Question 3

Q. Code	Weighted mean	Mean	Median	Standard Deviation	Weighted correlation (r)	P- Value	$\mathbb{R}^2$
Q3-1	4.25	19.55	16	3.91	0.746	0.043	0.793
Q3-2	4.33	19.99	21	3.96	0.770	0.047	0.781

Table 27 Statistical analysis of question 3

# Key takeaways

# 1. Regulatory Constraints

- Compliance with strict regulations is a significant challenge, as it often slows down optimization efforts.
- A strong correlation (r = 0.746) and high R<sup>2</sup> value (0.793) indicate that regulatory barriers play a key role in resource utilization.
- The statistically significant p-value (0.043) confirms the substantial impact of this challenge, highlighting the need for adaptable compliance strategies.

# 2. Limited access to capital

- Financial constraints prevent companies from investing in advanced technology, infrastructure, and process improvements.
- A high correlation (r = 0.770) and R<sup>2</sup> value (0.781) show that financial limitations are a major factor affecting resource optimization.

 The statistically significant p-value (0.047) reinforces the importance of addressing funding challenges for sustainable operational improvements.

Both challenges received mean scores indicating agreement, with statistical metrics confirming the strong consensus among respondents.

Overall, these findings underscore the need for pharmaceutical companies to address these challenges proactively by advocating for regulatory reforms and exploring innovative financing solutions that can facilitate investment in necessary technologies and processes. By overcoming these barriers, organizations can enhance their resource optimization efforts and improve overall operational efficiency.

### 4.10.10 Statistical analysis of question 4

# **Impact of Optimized Resource Utilization**

The analysis of survey responses regarding the impact of optimized resource utilization reveals a strong consensus among respondents, indicating agreement with the proposed benefits. The data collected includes responses to sixteen key statements, each evaluated on a five-point Likert scale.

Q. Code	Impact	Statement		D	N	A	SA
Q4-1	Operational Efficiency	Improved operational efficiency with Optimized resource utilization will help in cycle time reduction, less inventory & reduce waste.	6	18	16	19	130
Q4-2	Cost savings	Optimized resource utilization can contribute to cost savings and increase the bottom line.	7	20	15	13	134

Q4-3	Business improvement	Optimized resource utilization enhances overall business performance and competitiveness in the pharmaceutical industry.	12	23	9	17	128
Q4-4	Profitability	Effective resource management directly correlates with increased profitability for pharmaceutical companies.	6	14	17	20	132
Q4-5	Revenue Generation	Efficient resource allocation contributes to faster time-to-market for pharmaceutical products, enhancing revenue generation.	3	20	13	21	132
Q4-6	Business Growth	Strategic resource management enables pharmaceutical companies to adapt to market changes and seize new opportunities, leading to business growth and expansion.	9	15	18	18	129
Q4-7	Profitability from Cost Savings	Cost savings resulting from optimized resource utilization directly translate to higher profits for pharmaceutical companies.	8	11	20	13	137
Q4-8	Product cost reduction and patient accessibility	Optimized resource utilization leads to significant cost reduction in the production of pharmaceutical drugs, making them more affordable for patients.	8	13	20	14	134
Q4-9		Reduced manufacturing costs resulting from optimized resource utilization directly translate to lower prices of drugs, increasing accessibility for patients.	9	13	19	15	133
Q4-10		Improved accessibility to affordable medications due to optimized resource utilization indirectly leads to increased demand and sales for pharmaceutical companies.	8	12	23	19	127

Q4-11		Enhanced patient access to medications resulting from cost reduction initiatives improves brand reputation and customer loyalty, ultimately driving sales and profitability for pharmaceutical companies.	4	14	17	20	134
Q4-12		The effective management of resources enables pharmaceutical companies to invest in R&D, fostering innovation and differentiation in the market, leading to increased sales and profits.	8	15	20	14	132
Q4-13	Impact of the research on Optimum resources management on Academia	Research on resource management in the pharmaceutical industry provides valuable guidance and insights for students completing college projects or research papers.	7	18	17	11	136
Q4-14		Collaboration between pharmaceutical companies and academic institutions on resource management research projects enhances the learning experience for students and fosters industry-academia partnerships.	7	12	22	15	133
Q4-15		Understanding and implementing effective resource management practices in pharmaceutical companies can serve as a model for academic research in other industries facing similar challenges.	8	15	18	20	128
Q4-16		Academic engagement with resource management in the pharmaceutical industry contributes to the development	11	21	10	16	131

of future professionals equipped with knowledge and skills relevant to industry needs.

 $Table\ 28\ Data\ for\ statistical\ analysis\ of\ Question\ 4$ 

Q. Code	Weighted mean	Mean	Median	Standard Deviation	Weighted Correlation (r)	P- Value	$\mathbb{R}^2$
Q4-1	4.32	19.98	18.00	3.96	0.921	0.025	0.848
Q4-2	4.31	20.00	15.00	3.96	0.897	0.035	0.804
Q4-3	4.20	19.35	17.00	3.89	0.874	0.042	0.764
Q4-4	4.37	20.29	17.00	3.99	0.909	0.028	0.826
Q4-5	4.37	20.30	20.00	3.99	0.915	0.026	0.837
Q4-6	4.29	19.81	18.00	3.94	0.893	0.037	0.798
Q4-7	4.38	20.45	13.00	4.01	0.933	0.021	0.871
Q4-8	4.34	20.18	14.00	3.98	0.927	0.023	0.860
Q4-9	4.32	20.09	15.00	3.97	0.918	0.025	0.843
Q4-10	4.30	19.80	19.00	3.94	0.881	0.040	0.776
Q4-11	4.41	20.54	17.00	4.02	0.914	0.027	0.835
Q4-12	4.31	19.96	15.00	3.96	0.908	0.029	0.824
Q4-13	4.33	20.15	17.00	3.98	0.922	0.024	0.850
Q4-14	4.35	20.20	15.00	3.98	0.917	0.025	0.841
Q4-15	4.30	19.84	18.00	3.94	0.887	0.038	0.787

Q4-16	4.24	19.66	16.00	3.93	0.879	0.041	0.773
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Table 29 Statistical analysis of question 4

### **Key takeaways**

In conclusion, the statistical analysis highlights several key impacts of optimized resource utilization within the pharmaceutical industry:

- **Strong Correlation:** High correlation values (r close to 1.0) indicate a strong link between stakeholder agreement and the perceived benefits of resource optimization.
- **Statistical Significance:** P-values below 0.05 confirm that these findings are unlikely to be due to random chance.
- **Explanatory Power:** R-squared values above 0.75 suggest that most of the response variations can be attributed to resource optimization efforts. Operational Efficiency

### 1. Enhanced Operational Efficiency

 Streamlining resource use reduces cycle times, minimizes waste, and lowers inventory levels, leading to improved productivity.

### 2. Cost Reduction and Profitability

• Efficient resource management helps lower operational costs, improve supply chain efficiency, and increase overall profitability.

# 3. Stronger Business Performance and Growth

• Companies that optimize resources gain a competitive advantage, achieve higher revenue, and adapt better to market fluctuations.

# 4. Improved Accessibility and Affordability

 Lower production costs enable pharmaceutical products to be more affordable and widely available, boosting market reach and brand reputation.

### 5. Advancements in Research and Academia

 Studies on resource optimization contribute valuable insights to academia, strengthening industry-academic collaboration and preparing future professionals with essential skills.

Overall, these findings underscore the importance of implementing effective resource optimization strategies not only for operational success but also for enhancing patient access to medications, fostering innovation within the pharmaceutical industry, and contributing positively to academic research and partnerships.

#### CHAPTER V

#### **DISCUSSION**

### 5.1 Discussion of Results

This chapter provides a detailed analysis of the survey findings for the research questions. The results underscore how optimized resource utilization influences operational efficiency, cost reduction, business performance, patient accessibility, and broader academic contributions. The discussion is structured based on the research questions and their subsections, integrating statistical insights from weighted correlation (r), P-values, and R-squared values to substantiate interpretations.

# 5.2 Discussion of results from the survey

# 5.3 Discussion on Research Question One: Strategies to Optimize ResourceUtilization

The survey highlighted key strategies adopted by pharmaceutical companies to optimize resource utilization effectively. These include lean manufacturing principles, advanced technology, employee training, supply chain optimization, and cost-improvement initiatives.

### **5.3.1** Lean Manufacturing Principles

 Findings: Approximately 128 respondents strongly agreed that lean manufacturing enhances efficiency and reduces waste, while 28 participants remained neutral or disagreed.  Discussion: Lean methodologies streamline processes by eliminating non-value-adding steps, leading to improved cycle times and resource efficiency. However, resistance to change and high initial costs can create barriers to full implementation, as evidenced by the minority of neutral or disagreeing responses.

### **5.3.2** Advanced Technology and PAT Tools

- **Findings**: Strong agreement (145 respondents) confirmed the importance of technologies such as Process Analytical Technology (PAT) in resource optimization.
- Discussion: PAT ensures real-time quality control, reducing material
  waste and process inefficiencies. However, its adoption is constrained
  by cost barriers, particularly for small-scale pharmaceutical
  manufacturers.

# **5.3.3** Employee Training and Development

- **Findings**: Supported by 147 respondents, training programs empower employees to adapt to optimization tools.
- Discussion: Training enhances workforce adaptability, minimizes operational errors, and reduces downtime, ultimately improving both cost efficiency and productivity.

### **5.3.4** Supply Chain Management

- **Findings**: Enhanced supply chain practices received strong approval (146 respondents).
- Discussion: Improved supplier relationships and predictive analytics reduce procurement delays and overstocking.

# **5.3.5** Cost Improvement Initiatives

- **Findings**: The most agreed-upon strategy, endorsed by 150 respondents, involved recovery and reuse initiatives.
- **Discussion**: Cost savings of up to 30% have been observed in firms implementing solvent recovery practices, highlighting its sustainability and financial impact.

# 5.4 Discussion of Research Question Two: Best Practices for Resource Optimization

A few best practices were identified, emphasizing collaboration, technology, sustainability, and continuous improvement.

### **5.4.1** Cross-Functional Collaboration

- **Findings**: Supported by 151 participants, collaboration across departments enhances resource allocation.
- **Discussion**: Collaborative teams foster innovation and reduce misaligned priorities, particularly in R&D and manufacturing coordination.

# **5.4.2** Data-Driven Decision Making

- **Findings**: Strongly supported (151 respondents), data analytics helps identify inefficiencies.
- **Discussion**: Predictive models optimize resource allocation, especially for inventory and procurement decisions.

### **5.4.3** Continuous Process Improvement

- **Findings**: Approximately 146 respondents agreed with implementing Lean Six Sigma.
- **Discussion**: Continuous improvement frameworks systematically eliminate waste while maintaining compliance.

### **5.4.4** Sustainable Practices

- **Findings**: Supported by 143 respondents, sustainability practices are increasingly prioritized.
- **Discussion**: Initiatives like solvent recovery align cost reduction with environmental goals, ensuring compliance with global standards.

# 5.5 Discussion of Research Question Three: Barriers and Challenges

# **5.5.1** Regulatory Constraints

• **Findings**: About 143 respondents identified regulations as a major hurdle.

• **Discussion**: Regulatory compliance often necessitates resource-heavy processes, impeding flexibility in optimization.

### **5.5.2** Limited Access to Capital

- **Findings**: Highlighted by 150 respondents, limited funding restricts technology adoption.
- **Discussion**: Small-scale manufacturers face disproportionate challenges, necessitating external funding support.

# 5.6 Discussion of Research Question Four: Impact of Optimized Resource Utilization

The impact was analyzed across five areas: operational efficiency, cost savings, business profitability, patient accessibility, and academic contributions.

### **5.6.1** Operational Efficiency (Q4-1)

- **Findings:** Supported by 149 respondents, optimized resource utilization improves cycle times and reduces waste.
- Discussion: Real-world applications indicate a 20-30% improvement in cycle times when advanced technologies and lean practices are integrated.

# **5.6.2** Cost Savings (Q4-2)

• **Findings**: Approximately 147 respondents agreed that cost savings directly improve profitability.

• **Discussion**: Cost reductions in solvent recovery and energy efficiency have saved firms \$50,000 annually on average.

# 5.6.3 Business Improvement & Profitability (Q4-3 to Q4-7)

- **Findings**: Around 75-79% agreed on faster time-to-market and higher profits due to resource optimization.
- **Discussion**: Optimized resources enhance competitiveness by enabling quicker adaptability to market demands.

# 5.6.4 Product Cost Reduction & Accessibility (Q4-8 to Q4-12)

- **Findings**: Supported by 146 respondents, cost reductions lead to affordable medications.
- **Discussion**: Lower production costs allow for broader patient access, improving public health outcomes and brand loyalty.

### **5.6.5** Impact on Academia (Q4-13 to Q4-16)

- **Findings**: Supported by 147 respondents, academic collaborations foster innovation and prepare skilled professionals.
- **Discussion**: Partnerships with universities enhance research quality and industry readiness among graduates.

# 5.7 Discussion of results from case analysis

# 5.7.1 Discussion on Case Study One: Process Optimization for Venetoclax Synthesis

This case demonstrated the transformative potential of synthetic route optimization in API production. By improving the reaction pathways and reducing purification steps, the yield was increased from 20% to 46%, and the cost of goods was reduced by 30%. This highlights how strategic process development not only improves material utilization but also minimizes waste. The simplified purification and reduced impurity levels (<1%) serve as a model for addressing inefficiencies in resource-intensive pharmaceutical processes.

**Key takeaway:** Optimization of synthetic routes can simultaneously enhance yield and cost efficiency, making it a cornerstone strategy in resource management.

# 5.7.2 Discussion on Case Study Two: Resource Management Optimization in Natco's Process

Natco's case illustrated the significance of recovery and reuse strategies in pharmaceutical manufacturing. By adopting an alternative synthesis route and focusing on solvent and raw material recovery, the company achieved a 25% cost reduction and a yield increase from 30% to 50%. The reuse of expensive reagents also reduced waste significantly.

**Key takeaway:** Recovery and reuse strategies are essential for lowering production costs and enhancing environmental sustainability in pharmaceutical operations.

# 5.7.3 Discussion on Case Study Three: Process Optimization in API Production Using PAT and Resource Management

The integration of Process Analytical Technology (PAT) tools showcased Sanofi's ability to revolutionize API production. With a PMI reduction of 26% and yield improvement from 47% to 60%, the implementation of real-time monitoring (e.g., NIR and Raman spectroscopy) streamlined processes and minimized waste. The reduction in solvent and catalyst waste by 80% exemplifies how advanced technologies can align sustainability with cost-effectiveness.

**Key takeaway:** PAT tools are pivotal for achieving precision, reducing waste, and enhancing overall process efficiency in modern pharmaceutical manufacturing.

# 5.7.4 Discussion on Case Study Four: Lean Six Sigma Implementation in Pharmaceutical Manufacturing

The application of Lean Six Sigma methodologies addressed bottlenecks and inefficiencies in a high-demand manufacturing facility. By reducing downtime by 66% and work-in-progress inventory by 72%, the facility not only met customer demand but also achieved cost savings of \$500,000. The structured problem-solving approach (DMAIC) and lean tools (e.g., TPM, SMED) underscore the importance of waste reduction and process synchronization.

**Key takeaway:** Lean Six Sigma offers a robust framework for addressing operational inefficiencies, leading to significant financial and productivity gains in pharmaceutical manufacturing.

# 5.8 Cross-Case Analysis

The results of the case studies emphasize a recurring theme: targeted resource optimization strategies, when effectively implemented, lead to substantial

improvements in operational efficiency, cost savings, and environmental outcomes. While each case adopted unique methods tailored to specific challenges, common strategies included:

- Adoption of advanced technologies (e.g., PAT) to enhance precision and reduce variability.
- Recovery and reuse of high-cost materials to reduce waste and operational costs.
- Integration of lean principles to identify and eliminate bottlenecks and inefficiencies.

# 5.9 Comparison of results from case analysis

The results from the four case studies are summarized in the table below and discussed in detail to provide insights into their implications for pharmaceutical manufacturing.

Case study	Focus area	Key improvements	Key takeaways
Process Optimization for Venetoclax Synthesis	Synthetic route optimization	Yield improved from 20% to 46%	Process Optimization for Venetoclax Synthesis
Resource Management in Natco's Process	Recovery and reuse strategies	Yield increased from 30% to 50%	Resource Management in Natco's Process
PAT and Resource Management in API Production	Integration of advanced technologies	PMI reduced by 26%	PAT and Resource Management in API Production
Lean Six Sigma in Manufacturing	Waste reduction and efficiency improvement	Downtime reduced by 66%	Lean Six Sigma in Manufacturing

### Table 30 Comparison of results from analysis

# 5.10 Implications and Industry Insights

The collective results from these case studies emphasize the transformative potential of tailored resource optimization strategies:

- Efficiency Gains: Across all cases, efficiency improvements were achieved by minimizing material waste, streamlining processes, and leveraging advanced tools.
- **Cost Reduction**: Significant cost savings resulted from improved material utilization, reduced waste, and process efficiency.
- Sustainability: Recovery and reuse, coupled with technological advancements, demonstrated alignment with sustainability goals, reducing environmental impact.

These findings suggest that pharmaceutical companies can achieve a balance between operational excellence and sustainability, positioning themselves for long-term success.

By adopting these strategies, the industry can meet evolving demands for cost-effective and environmentally conscious production practices while maintaining compliance with regulatory standards.

# 5.11 Data Integration: Survey Results and Case Studies

The integration of survey data with case study results demonstrates how proven strategies reinforce industry-wide priorities and how empirical survey findings validate real-world applications. Below is a tabulated summary highlighting key areas of integration.

Focus Area	Survey Findings	Case Study Evidence	Integrated Insight
Yield Improvement & Waste Reduction	68% of participants prioritize yield improvement and waste reduction in resource optimization.	Case 1: Yield improved from 20% to 46%, and waste reduced to <1%.	Yield Improvement & Waste Reduction
Recovery and Reuse	55% of respondents actively implement recovery systems for cost savings and sustainability.	Case 2: Recovery strategies reduced costs by 25% and waste by 1–2%.	Recovery and Reuse
Advanced Technologies	62% of participants recognize PAT as a transformative tool for real-time monitoring and precision.	Case 3: PAT tools (e.g., NIR, Raman spectroscopy) improved yield by 27% and reduced waste.	Survey findings align with PAT's demonstrated success in case studies, showcasing its role in precision and sustainability in manufacturing processes.
Lean and Six Sigma Practices	48% of participants apply Lean Six Sigma to address inefficiencies and improve throughput.	Case 4: Lean Six Sigma reduced downtime by 66%, WIP by 72%, and saved \$500,000.	Lean Six Sigma is a proven framework for addressing operational bottlenecks, validated by both survey insights and successful case outcomes.

Table 31 Data Integration: Survey Results and Case Studies

# **5.12** Discussion of Integrated Insights

# **5.12.1** Yield Improvement and Waste Reduction

- Survey Strengthened by Case Studies: Survey results prioritize yield and waste management, corroborated by case studies showing substantial improvements in these areas (e.g., Venetoclax synthesis and API production with PAT).
- Case Studies Supported by Survey: Real-world data from case studies
  validate industry-wide recognition of yield optimization as a key
  strategy.

### 5.12.2 Recovery and Reuse

- Survey Strengthened by Case Studies: Survey participants view recovery as impactful, with case studies providing quantitative evidence of cost savings and waste reduction.
- Case Studies Supported by Survey: Survey results generalize the relevance of recovery systems, emphasizing their applicability across diverse pharmaceutical contexts.

### 5.12.3 Advanced Technologies

- Survey Strengthened by Case Studies: Participant recognition of PAT's potential is exemplified by measurable successes in API production case studies.
- Case Studies Supported by Survey: Survey findings validate PAT adoption as a priority, highlighting its scalability and effectiveness.

### 5.12.4 Lean and Six Sigma Practices

 Survey Strengthened by Case Studies: Respondents' preference for Lean Six Sigma aligns with its proven ability to reduce downtime and costs, as shown in the case study.  Case Studies Supported by Survey: Survey results reinforce Lean Six Sigma's role in achieving operational improvements across the pharmaceutical sector.

### 5.13 Summary

The integration of survey findings with case studies creates a cohesive narrative:

- **1.** Survey insights emphasize industry priorities, while case studies demonstrate these strategies in action.
- **2.** Proven successes from case studies strengthen the credibility of survey observations.
- 3. The alignment between data sources confirms the effectiveness and relevance of resource optimization practices in pharmaceutical manufacturing.

This integration validates best practices, offering a reliable framework for operational efficiency, cost savings, and sustainability in the pharmaceutical industry.

### 5.14 Conclusion

The findings from the survey responses & case studies affirm the importance of adopting strategic, data-driven, and sustainable approaches to resource optimization in the pharmaceutical sector. While the benefits are evident, challenges such as regulatory constraints and financial limitations must be addressed through policy interventions and innovative financing mechanisms. By implementing best practices, pharmaceutical companies can enhance efficiency, reduce costs, and improve both business performance and patient accessibility, ultimately contributing to industry growth and societal well-being.

#### **CHAPTER VI**

# SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

# 6.1 Summary of findings

This research underscores the critical role of resource optimization in enhancing operational efficiency, reducing costs, and aligning sustainability goals in pharmaceutical manufacturing. Through a mixed-methods approach combining survey insights from industry professionals and real-world case studies, the study provides an in-depth understanding of the best practices, challenges, and impacts.

### 6.1.1 Key Insights

### 1. Strategies for Resource Optimization

- Proven strategies include process redesign, recovery systems, lean methodologies, and advanced technologies such as Process Analytical Technology (PAT).
- Case studies demonstrated yield improvements, waste reduction, and cost savings exceeding expectations in specific instances.

### 2. Impact of Optimized Resource Utilization

- Resource optimization leads to measurable enhancements in operational efficiency, cost-effectiveness, and sustainability.
- Survey findings validated by case studies showed that optimized practices improved production throughput, minimized waste, and strengthened environmental compliance.

### 3. Barriers to Implementation

- High technological costs, workforce skill gaps, and regulatory complexities emerged as the primary barriers.
- Real-world examples highlighted how structured frameworks like
   Lean Six Sigma and investments in workforce training mitigate these challenges.

### 4. Best Practices and Recommendations

- A holistic integration of recovery systems, advanced tools, and lean principles is essential for scalable and sustainable resource management.
- Cross-functional collaboration and continuous improvement emerged as critical enablers for successful implementation.

### **6.2** Implications

The findings of this research carry significant implications for business growth, societal benefits, and academic advancements, highlighting how resource optimization can drive holistic improvement across these domains.

### **6.2.1** Business Growth and Improvement

Resource optimization directly impacts the efficiency, cost-effectiveness, sustainability, and profitability of pharmaceutical companies. The research demonstrates the potential for:

 Cost Reduction: By minimizing waste, improving yield, and adopting technologies like PAT, companies can lower production costs, making operations more sustainable and profitable.

- Competitive Advantage: Efficient resource management fosters innovation and operational excellence, enabling businesses to stay ahead in a highly competitive market.
- Scalability and Flexibility: Lean methodologies and recovery systems
  ensure that companies can scale production while maintaining efficiency
  and quality.
- Resilience Against Disruptions: Improved supply chain management and reduced dependency on raw materials mitigate risks associated with global supply chain disruptions.

# 6.2.2 Societal Impact

Resource optimization in pharmaceutical manufacturing extends far beyond business, addressing critical societal needs.

- Affordable Medicines: Cost reductions achieved through resource optimization enable the production of low-cost medicines, making essential drugs more accessible to underserved populations.
- Improved Patient Accessibility: Increased efficiency allows for faster
  production cycles, ensuring timely availability of life-saving
  medications, particularly in regions with limited healthcare
  infrastructure.

- Environmental Sustainability: Reduced waste, solvent recovery, and energy-efficient processes contribute to lower pollution levels, minimizing the pharmaceutical industry's environmental footprint.
- Public Health Benefits: With optimized operations, pharmaceutical companies can reinvest savings into research and development, fostering innovation for improved healthcare solutions.

### **6.2.3** Academic Contributions

The study adds significant value to academic literature and provides a framework for future research and education. Collaboration between academia and industry can yield innovative solutions while preparing students for challenges in pharmaceutical resource management.

- Bridging Knowledge Gaps: This research addresses gaps in resource optimization literature, particularly in pharmaceutical manufacturing, and provides real-world examples of effective practices.
- Teaching and Training: The case studies and insights serve as practical teaching tools for academia, enabling students and professionals to understand and apply resource management principles effectively.
- Future Research Opportunities: The findings pave the way for further studies on digital transformation, the role of AI and IoT in resource optimization, and long-term sustainability metrics.

 Cross-Disciplinary Learning: This research highlights the interdisciplinary nature of pharmaceutical resource management, integrating business strategy, engineering principles, and environmental science.

### **6.2.4** Integrated Implications

- For Businesses: Improved profitability, operational efficiency, and competitive positioning in global markets.
- **For Society:** Enhanced accessibility to affordable medicines, reduced environmental impact, and advancements in public health.
- **For Academia:** A robust foundation for future research, enriched teaching resources, and cross-disciplinary collaboration opportunities.

These implications collectively underscore the transformative potential of resource optimization, not only in advancing pharmaceutical business operations but also in delivering societal and academic benefits that resonate globally.

### **6.3** Recommendations for the Future

Based on the findings and implications of this research, the following recommendations outline actionable pathways for the pharmaceutical industry, policymakers, and academia to build resource optimization advancements:

### **6.3.1** For the Pharmaceutical Industry

- Invest in Emerging Technologies: Leverage digital tools like Artificial Intelligence (AI), Internet of Things (IoT), and advanced robotics to enhance process efficiency and decision-making in resource optimization.
- Adopt Modular Resource Optimization Systems: Develop flexible
  and scalable solutions, particularly for small and medium enterprises
  (SMEs), enabling widespread adoption of resource management
  practices.
- Strengthen Collaboration: Foster partnerships with academic institutions, technology providers, and other pharmaceutical firms to share knowledge and co-develop innovative solutions.
- Enhance Sustainability Metrics: Implement advanced monitoring systems to measure and continuously improve the environmental and economic impact of operations.
- Resource Efficiency Units: It is recommended that pharmaceutical companies establish dedicated 'Resource Efficiency Units' as a strategic measure to oversee and implement resource optimization initiatives. These units would be responsible for continuous monitoring of resource utilization, identifying waste reduction opportunities, and coordinating cross-functional efforts to enhance operational efficiency. By centralizing responsibility, Resource Efficiency Units can facilitate

targeted investments in technology and process innovation, ensure compliance with sustainability goals, and foster a culture of continuous improvement. Ultimately, such units would serve as a nexus for best practices, aligning operational strategies with industry benchmarks and regulatory standards to achieve long-term cost savings and enhanced productivity.

### **6.3.2** For Policymakers

- Create Incentive Frameworks: Introduce subsidies, tax benefits, or grants to encourage the adoption of green technologies and sustainable manufacturing practices.
- Standardized Regulations: Harmonize regulatory requirements across regions to reduce compliance complexities and facilitate global resource optimization efforts.
- Promote Public-Private Partnerships: Support collaborations between industry and government to develop infrastructure for recycling and waste management systems.

#### 6.3.3 For Academia

Expand Research Horizons: Explore the role of digital twins,
 blockchain, and other emerging technologies in pharmaceutical manufacturing.

- Develop Specialized Training Programs: Design courses and certifications focused on lean principles, PAT tools, and sustainable practices for industry professionals.
- Focus on Longitudinal Studies: Conduct long-term research to track
  the sustained impact of resource optimization on business performance
  and societal benefits.

#### 6.4 Conclusion

The findings of this research reaffirm the critical role of resource optimization in the pharmaceutical industry, demonstrating its profound impact on operational efficiency, cost reduction, sustainability, and business competitiveness. Through a comprehensive mixed-methods approach that integrates industry surveys and case study analyses, this study provides empirical evidence supporting the adoption of best practices for optimized resource utilization.

The results highlight that strategic interventions such as lean manufacturing, process analytical technology (PAT), employee training, supply chain management, and sustainability practices can significantly enhance efficiency while minimizing waste and costs. The statistical analyses reinforce these findings, showing strong correlations between resource optimization strategies and positive business outcomes, including higher profitability, improved production cycle times, and reduced environmental impact.

However, the study also underscores key barriers to implementation, including regulatory constraints and limited access to capital. These challenges necessitate a proactive approach by pharmaceutical firms, policymakers, and industry

stakeholders to develop supportive frameworks that facilitate the adoption of resource optimization initiatives. Strategic investment in technology, financial incentives, and workforce training can bridge these gaps, enabling companies to implement sustainable and cost-effective resource management practices.

The implications of this research extend beyond business operations. Efficient resource management enables pharmaceutical companies to amplify societal impact, including expanded access to cost-effective therapeutics and improved public health outcomes. Additionally, academia stands to gain from these insights, as the study provides a valuable reference point for further research in pharmaceutical manufacturing and operational excellence.

In conclusion, this research emphasizes that resource optimization is not merely a cost-cutting measure but a strategic imperative for pharmaceutical companies aiming for long-term growth and sustainability. By embracing innovative approaches, fostering industry-academia collaboration, and advocating for supportive regulatory policies, the pharmaceutical sector can achieve a balance between economic viability and societal responsibility. Future research can build upon these findings by exploring the role of digital transformation, artificial intelligence, and predictive analytics in further refining resource optimization strategies. Ultimately, a concerted effort toward efficient resource management will drive industry innovation, enhance global healthcare accessibility, and establish a sustainable pharmaceutical ecosystem for future generations.

APPENDIX A

SURVEY COVER LETTER

Dear Participant,

Welcome to the research study assessing the effectiveness of pharmaceutical

businesses through optimum resource management. Your participation is crucial in

helping us understand how pharmaceutical companies can improve their operations

and achieve better outcomes.

This survey aims to gather insights into various aspects of resource

management within the pharmaceutical industry. By answering the following

questions, you will contribute to our investigation into strategies for maximizing

resource utilization, evaluating the impact of optimized resource utilization on

operational efficiency and cost reduction, identifying barriers to implementation, and

recommending best practices. Your responses will remain confidential and will be

used solely for research purposes. Your input will help shape evidence-based

strategies and recommendations for enhancing operational efficiency, reducing costs,

and improving competency and sustainability within the pharmaceutical sector.

Thank you for your valuable time and contribution to the research in advance.

Sincerely,

Maddipati Gowtham,

Swiss School of Business and Management - Geneva,

maddipati@ssbm.ch.

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#### APPENDIX B

### INFORMED CONSENT

Dear Participant,

My self, Maddipati Gowtham, I am conducting a research study on assessing the effectiveness of pharmaceutical businesses through optimum resource management. Your participation in this study is entirely voluntary.

By agreeing to participate, you understand and consent to the following:

- 1. Purpose of the Study: The purpose of this study is to investigate strategies for optimizing resource utilization in the pharmaceutical industry and their impact on operational efficiency and cost reduction.
- **2. Voluntary Participation:** Your participation in this study is entirely voluntary. You may choose not to participate or withdraw from the study at any time.
- **3. Confidentiality:** Your responses will remain confidential. Only the researchers and faculty involved in this study will have access to your information, and it will be used solely for research purposes.
- **4. Data Use:** The data collected from this study may be used for publication or presentation purposes. However, your identity will remain anonymous in any reports or publications resulting from this research.
- **5. Duration:** The survey should take approximately 15-20 minutes to complete.
- **6. Contact Information:** If you have any questions or concerns about this study, you can contact me at the following contact details:

Email: maddipati@ssbm.ch.

# APPENDIX C

### **ABBREVIATIONS**

NDA: New Drug Application

ANDA: Abbreviated New Drug Application

API: Active Pharmaceutical Ingredient

QbD: Quality by Design

PAT: Process Analytical Tools

RM: Raw Material

**UOM:** Unit of Measurement

SME: Small and Medium-sized Enterprise

WIP: Work In Progress

LSS: Lean Six Sigma

AI: Artificial Intelligence

IoT: Internet of Things

FDA: Food and Drug Administration

R&D: Research & Development

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