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RESEARCH ARTICLE

DEVELOPING A FRAMEWORK FOR THE INDIA PHARMACEUTICAL SUPPLY CHAIN - RISKS ASSESSMENT THROUGH A FMEA APPROACH

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ABSTRACT

In recent years, specifically post COVID-19, pharmaceutical industry has gained a significant place in the healthcare domain. Pharmaceutical companies are important players in the supply chain of drugs. With increasing competition, growing population and changing complexities of type of diseases, the need of pharmaceutical products has swelled over time, making the sector prone to supply chain risks.

The purpose of this paper is to identify and access various risks in the pharmaceutical supply chain in the context of India. To attend this objective, a case of a major pharmaceutical company had been considered. Failure Mode and Effect Analysis (FMEA) has been used to identify and further prioritize these risks. Further Pareto analysis, also called as 80/20 rule, is conducted to identify the risks that are vital. The "80/20" rule suggested prioritizing 17 from 35 potential causes. Second level Pareto analysis identified 6 risk elements out of these 17 elements as most critical. Root cause assessment on these six risks is done through Five Why technique.

The results of this study exhibited that Inventory Planning Issues, Labour Issues, Insufficient Storage Space, Raw Material Availability Issues, Inappropriate Forecasting, Communication Issues were the most critical issues in the pharmaceutical supply chain. The major cause to the eruption of these risks is improper Sales and Operations Planning (S&OP).

This study suggests that the managers of the pharmaceutical supply chain should first understand the various risks in the supply chain that can disrupt the function. Further through prioritization of risks, the losses or the delays in the supply chain can be reduced.

KEYWORDS

Failure Mode and Effect Analysis (FMEA), pharmaceutical supply chain, inventory management, capacity planning, production planning, supply management, communication.

INTRODUCTION

Pharmaceutical products have been significant for ages to treat diseases. The pharmaceutical industry has grown through a long and complex journey from herbal remedies to laboratory made compounds. Over decades, many companies have come up bringing innovations and life-saving medicines. Today this industry has become a multi-billion-dollar global industry. The success of this industry lies not only in creating right medicine but ensuring that it is channelled to the ultimate patient on time. This process includes sourcing of raw material, production, inventory, distribution and delivering the medicines to the patients. This is referred to as the pharmaceutical supply chain. This

supply chain poses challenges and risks. It becomes imperative for the researchers to study these risks and create models that may support supply chain decision makers to design a risk-free supply chain. A supply chain is a network between an organization and its suppliers involved in supplying and distributing a particular product to the ultimate consumer. This network includes completely different activities, people, entities, information, and resources [1]. The supply chain also represents the steps to urge the merchandise or service from its original state to the customer. The measures incorporate moving and reworking raw materials into finished products, transporting them, and distributing them to the end-user. The entities concerned are producers, vendors, storage locations, warehouses, logistics companies, retailers, and distribution centres or outlets [1]. Firms develop supply chains to scale back their prices and stay competitive within the business landscape.

AN OVERVIEW OF THE GLOBAL PHARMACEUTICAL INDUSTRY

The global pharmaceutical market is projected to grow at 5.8% to $1170 billion in FY 2021. The factors such as policies laid down by the government and insurance companies, the attitude of customers, affordability of drugs, and prevalence of diseases affect the size of the pharmaceutical markets [2].

Advancements in medical infrastructure and rising incomes have led to a levelled–up growth trajectory for pharmaceutical companies. Reduction in the prices of drugs and low taxes in the US, regulatory entry barriers being lowered for the new drugs in the US, over 6 % growth in the GDP of India and China, an increase in the chronic disease prevalence due to sedentary lifestyle and widespread population aging are the some of the political, economic, social, technological, legal and environmental factors boosting the pharmaceutical market [2].

The restraints faced by the pharmaceutical industry in the launch of significant new products that are high priced are due to high failure rates, the massive cost of development of the new product, and diminishing returns on investments [2].

THE INDIAN PHARMACEUTICAL INDUSTRY

India's pharmaceutical industry is the third-largest producer (by volume) of drugs in the world and manufactures 60% of vaccines globally [3]. India has emerged out to become a global provider when it comes to generic drugs. India exports its pharmaceutical products to over 200 countries worldwide, including developed countries like the US, Western Europe, Japan, and Australia. These countries especially have a very highly regulated market [3]. The Indian pharmaceutical sector supplies fulfil fifty percent of global demands for various vaccines. Twenty-five percent of all the medical requirements in the UK and 40 percent of the market for generic drugs is met by the Indian pharmaceutical sector supplies [4]. The US $ 100 billion is the expected mark up to which the Indian pharmaceutical sector would grow, while the US $ 25 billion is the expected mark up to which the Indian medical device market would grow by 2025. From the US $ 19.14 billion in FY 2019, pharmaceutical exports from India have risen to the US $ 13.69 billion in FY 2020 (Jan 2020). Thirty percent of the US $ 70 – India captures 80 billion Market of US generics by volume, which accounts for approximately 10 percent by value. India enjoys the luxury of exporting drug formulations, intermediates, bulk drugs, biologicals, surgical, and Ayush & herbal products [4]. Because of the availability of a workforce that is highly professional and technological developments, India has a solid manufacturing base. And because of communication and network development, the marketing and distribution system is also robust [3].

The domestic turnover, however, has increased 9.8% from Rs. 129015 crores in 2018 to Rs. 1.4 lakh crores in 2019. The projected growth over the next five years is 9 – 12% for medicine spending, which would lead India to the list of top 10 countries in medical expenditures. To reduce costs and healthcare expenses, the Indian government has taken many steps. The primary focus is the rapid introduction of generic drugs in the market [4].

CURRENT STATE AND THE CHALLENGES IN THE PHARMACEUTICAL SUPPLY CHAIN & LOGISTICS

A few generic challenges that a pharmaceutical industry faces are product line expansion to beat generic and non – brand manufacturers, smaller spans for new product development, and their approval. Further launching new innovative pharmaceutical products, continual quality improvements, and maintaining a global supply network for a more significant number of manufacturing plants, distribution and sales channels [5]. The liberalized FDI limits are being implemented with minimal attention given to the investments in research and development within the country. . The link between academics and the industry is weak. The expenditure on healthcare by the Indian households is puny. A significant threat to the

pharmaceutical industry is posed by manufacturing fake medicines or low–quality medicines. Apart from this, the undue pressure exercised by the government over pharmaceutical manufacturing companies to regulate price as per the Drug Price Control Order hamper the profitability of the companies. Small business companies face a threat from the new MRP-based excise duty regime [3].

The industry lacks a stable pricing and policy environment. The domestic pricing policy in India changes frequently and unexpectedly. Hence there are many uncertainties in the background for investments and innovations. To build a more robust platform for pharmaceutical companies, Indian regulators and the industry stakeholders should improve communications [6].

The Indian pharmaceutical market, though, depicts some unique characteristics.

- Essentially, it is the branded generics that reign the markets.
- Because of their early investments in the market and formulation development capabilities, many local players enjoy dominating positions over the market.
- Due to intense competition, the prices are low [7].

Since not much attention is paid to the supply chain by the pharmaceutical companies, the visibility is relatively low. The continual improvement concepts are not practiced in the industry. There is much of an acceptance of the current service levels when it comes to the logistic services.

Companies usually turn towards logistics service providers to overcome the negligence in collaborations between warehouse managing systems and Information Technology (IT) integration capability.

The pharmaceutical supply chain can get a lot more complex and need to be highly standardized and regulated. Increased competitive pressure, integration of IT, cost containment, managing regulatory changes, improving quality of service, and supply chain visibility are some of the biggest challenges posed in the pharmaceutical supply chains in the years to come. Investments by the pharmaceutical companies in new and advanced technologies would bring about greater flexibility, ensure the quality of products is maintained, and increase customer satisfaction. Above all, the production lead time would be reduced, increasing the overall responsiveness [8].

The challenges faced by pharmaceutical companies are collaboration concerns, making the supply chains proactive, controlling temperature, maintaining standards, and imparting flexibility to the supply chain [9]. The effective alterations (increase or decrease) within the aggregate production or the ability to make rapid switches in the output of a particular product to another, as a result of response to the changes in customer demand, reflects the flexibility or agility in a supply chain.

Managers need to make their decisions by balancing the trade-offs between forecasts, stock levels, planning, procuring, financing, and marketing strategies to achieve their goals. Inaccurate forward forecasts, increased lead times, and reduction in optimum target inventory result in unnecessary increments in supply chain costs that need to be addressed within a pharmaceutical supply chain. Developing collaborative partnerships with various stakeholders, investing in advanced technology and IT could provide relief. These can help provide comprehensive insights which would lead to effective decision-making.

This research work is directed to study this supply chain and further identify the risks in the supply chain. With this as the core, the research questions that this study aims to answer are as follows:

Research question 1: What are the various risks that impact and disrupt the pharmaceutical supply chain?
Research question 2: From the pharmaceutical supply chain identified, which are those risks that are the most critical in the system and what are the root causes to the risks identified?

LITERATURE REVIEW

Pharmaceutical companies face risk mainly from supply and suppliers. Most of reported risks were related to supply and supplier issues. Further financial risks, regulatory issues are other risks that disrupt the supply chain in this sector [10]. A study presented the SWOT analysis of the Indian pharmaceutical industry where varying regulatory requirements across domestic and export markets, Increased competition, Poor supplier service and

Uncertainty in demand are identified as the major threats [11].

The pharmaceutical industry consists of enormous research and development-based MNCs mainly focusing on branded products. Their focus is generic manufacturers, producing over the counter as well as out–of–patent ethical commodities, local manufacturers, which make the branded products under contracts/licenses as well as generic products, along with biotech and drug discovery companies and new emergent institutes which do not have manufacturing capability [12].

The planning and management of all the tasks that come under sourcing, procurement, conversion, and logistics are defined as supply chain management by The Council of Supply Chain Management Professionals [13]. The supply chain is that link that connects the market to the development of a new product. Supply chains are required to be continuously improved to improve their operational efficiencies and reduce costs.

Supply Chain Management incorporates processes like managing customer service, demand, the flow of material, and distribution to improve the Production of a good or service. It is a combination and coordination of business activities that control the flow of material and information from supplier to customer and back again [14].

Systematically and strategically coordinated business functions have tactical interdependence within the organization itself and with all its business partners to achieve improvements in the organization's performance. Material handling, storage, warehousing, picking and packaging, inventory management, transportation, logistics, and distribution are typical management system [5]. Earlier, pharmaceutical companies did not pay much attention to supply chain management, but now, they have altered their way of conducting business due to competitive advantage. A pharmaceutical supply chain comprises primary manufacturers, secondary manufacturers, distribution centres or warehouses, wholesalers, retailers, or hospitals [15].

A FUNCTIONAL LAYOUT OF A PHARMACEUTICAL SUPPLY CHAIN

A functional view of a supply chain consists of three levels: execution, planning, network, and execution. Planning is of inventory planning and forecasting of pharmaceutical requirements. Network-level has connections between suppliers, manufacturers, distributors, and customers. Transportation and order processing are part of the execution phase [16].

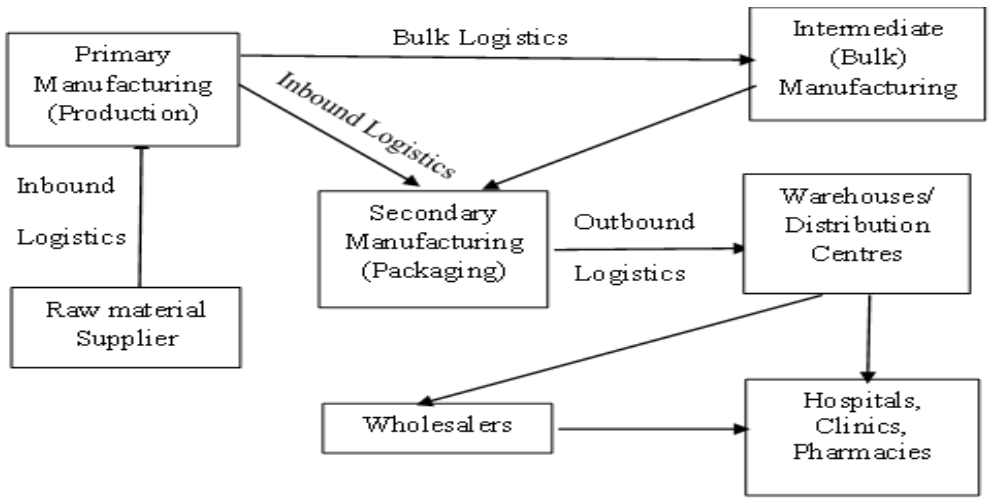
The materials that constitute chemicals that construct the molecules are manufactured by primary manufacturers [15].

Primary manufacturers formulate and manufacture active pharmaceutical ingredients (API) and other inactive materials in the standard dosage forms. These APIs are then converted, filled and packed, by secondary manufacturers, in different Stock Keeping Unit (SKU) configurations. In other words, secondary manufacturers do further process on these primary constituents and, ultimately, their packaging. Finished pharmaceutical SKUs are then moved from manufactures' stores further [8].

The pharmaceutical supply chain also incorporates other secondary drug manufacturing centres, the primary and specific other local distribution centres, the customer contact zones, including hospitals, clinics, and pharmacies, and transhipment of these drugs between the regional distribution centers as shown in Figure 1 [15].

Supply Chain Management is mainly responsible for maintaining consistency, reliability, and continuous improvement within the workflows in any organization [5].

FIGURE 1 PHARMACEUTICAL SUPPLY CHAIN SOURCE: [17]



The operational decisions in the pharmaceutical industry are usually based on product strategy rather than market strategy. These operational decisions could be enlisted as Production of a derivative product at one facility, centralization of Production or reduction in the production facilities, identification of distribution centres, designing an optimal distribution network, etc. [18]. The tactical decisions include the decisions on the extent of optimization of the material flows and the time frame. The motive behind these decisions is minimizing the total costs and fulfilling the demand [19]. The typical business process adopted by various companies of this sector begins with demand management, inventory management, distribution requirement planning, secondary production planning, and scheduling, primary manufacturing campaign planning.

Demand management – based on historical data, market or customer intelligence, and trend analysis, forward forecasts are developed (typically 3 – 24 months).

Inventory management and distribution requirement planning – is the forward forecasted demand is imposed over the appropriate distribution centres or warehouses. The inventory of finished products available is assessed, and upstream orders are placed to the secondary production facilities if required.

Secondary production planning and scheduling – orders received are first planned using Manufacturing Resource Planning tools such as strategic business plan, sales & operation plan (S&OP), master production scheduling, Materials requirement planning, etc., and then scheduled in detail.

Primary manufacturing campaign planning – The final inventory management and production planning is carried out at this stage according to which product manufacturing takes place at the manufacturing facility [20].

PHARMACEUTICAL SUPPLY CHAIN RISKS

A risk can be said to be a disruption, vulnerability, uncertainty, disaster, peril, or a hazard, and any event which causes or has a potential to cause trouble, thus affecting the efficient management of the supply chain network can be broadly termed as a Supply Chain risk [21]. Supply chain risks can be broadly classified as organizational, network, and other environmental risks about natural and artificial disasters [22].
They can also arise due to physical, economic, social, political, or legal environment and affect the supply chain outcome variables. It is not very easy to predict these with certainty [22].

Supply chain risks can also be categorized as macro-level risks, Demand management risks, Supply management risks, Product/service management risks, and Information management risks.

Here, the **Macro level risks** arise due to natural disasters, epidemics, political unrest, terror activities, government impositions, lack of human resources.

Product/service management risks involve costs incurred due to either inventory holding or underutilizing the existing capacities.

Information management risks occur when demand forecasts are erroneous, or information sharing and IT systems fail or get distorted [23].

A pharmaceutical product manufacturing company converts the raw materials it procures into final products. In this process it encompasses designing of their product, selecting the raw materials for conversion to products and sequencing the unit operations and procedures that the raw materials undergo to form the product.

The demand in the market needs to be catered to effectively and efficiently by a manufacturing company. Thus, a manufacturing company needs to pay significant attention to the lead times.

The first risk encountered by pharmaceutical companies is a raw material shortage. So, to reduce the lead times, the causes of raw material shortages and their consequences need to be taken care of in the first place [24].

Pharmaceutical supply chain risks are primarily associated with discontinuity of product or shortages in the product supplies, poor performance, errors in dispensing of products, technological errors, etc.

If the risks are not mitigated timely, they can destroy public health confidence, impact the health and safety of a patient, the company's reputation, and thereby a decrease in profit margin and shareholder value [12].

Though it is impossible to do away with the supply chain risks encountered in the day–to–day operations of a pharmaceutical company, it is possible for these companies to build an environment to make their supply chain more responsive to risk mitigation [25].

The challenges in a pharmaceutical supply chain mainly arise due to adopting either a market-focused strategy or a product-focused strategy. There are innumerable decisions that help the company sustain and perform in the market as well as maintain a competitive advantage: Production of a particular derivative product at one specific facility, centralization of output in a specific manufacturing facility, reduction of manufacturing facilities, identifying the distribution centres and optimizing the distribution network [5].

The process of manufacturing has become more complex and dynamic and has increased uncertainty because of global sourcing and distribution, which has brought in international integration and interdependence. The pharmaceutical supply chains have thus become far lengthier, complex, more vulnerable, less predictable, and thereby riskier. These supply chains are, therefore, more prone to disruptions [26].

The supply chain risks encountered by the pharmaceutical companies can be divided into the following categories [26]:

- Supplier selection risks range from Supply and supplier issue, Partnership with supplier, Raw material quality, Ordering cycle time to Information systems.
- Organizational and Strategic risks range from Technology development, Flexibility in delivering, Flexible quantities, Organization & process to Mergers and acquisition.
- Financial risks range from Tax payable changes, Currency rate, Financial risks, Tariff policies changes, Cash flow to Interest rates.
- Logistic risks range from Transportation quality, Delivery reliability to Timely delivery
- Market Risks range from Market, Consumer's taste to Demand.

Environmental risks range from Natural disaster & terrorism, Political issues, Sanction to Regulations.

RESEARCH GAP

The pharmaceutical industry has grown significantly over the past few years and still is at its peak. The drivers of growth of the industry can be traced back to its investments in innovative Research & development, infrastructure development, strong manufacturing of drugs, and creating strong demand in the market.

The industry is venturing into developing more and more complex generic drugs, which form an extensive product portfolio in domestic and global markets.

It has also made substantial infrastructural development when it comes to establishing US – FDA compliant plants. The highest number of US – FDA compliant plants outside the US are owned by India.

India has by now gained expertise in the manufacturing of low–cost generic drugs, which are patented and are now moving towards the complete end–to–end manufacturing.

Several schemes have come up that increase the demand domestically by increasing domestic healthcare spending. In the current scenario, the contribution towards the growth of pharmaceutical industries is dependent on:

- Increase in healthcare financing products
- Rising demands of generics
- Increased outsourcing activities
- Increase in demand for emerging market segments

The pharmaceutical industries have been frequently studied on their issues regarding demand uncertainties for existing drugs which might be due to the competitive environment in the market, delays in the launch of new products due to new medications being in pipelines, inefficient process development, improper yield optimization, long cycle times, ineffective capacity planning, improper network designs affecting the logistic networks, wrong plant design, etc. [20].

Pharmaceutical companies are now struggling with more significant problems like quality and regulatory issues, product proliferation issues, supply chain fragmentation, and infrastructure gaps.

These factors ultimately boil down to an assessment of downstream process issues such as procurement, manufacturing, logistics, pricing regulations, vendor selection and management, centralization/ decentralization decisions, complex unequipped distribution networks, inefficient transport, storage, power infrastructure, and underdeveloped infrastructure technology.

These factors need to be studied carefully and closely. The issues cropping up in these processes lead to varied impacts on the business. They can cause disruptions, making the company extremely vulnerable, uncertain, and may result in a more significant aspect of turning into a disaster, peril, or hazard.

These risks need to be studied in depth to make a supply chain resilient. A supply chain should be such that it can stay prepared for any events that are unexpected and effectively be able to respond and recover from any such events. They should be such that they can bounce back to their original functioning quickly and grow to better levels of performance.

For this, these risks need to be identified in the first place. This should be the prime focal point. A long–term perspective should be kept in mind of making the supply chain more proactive, more prepared, and more flexible towards the potential threats.
The risks need to be systematically laid out and assessed for their impacts on the firm's business. Quantification of these risks is essential to measure their effects. Only once the risks are quantified it possible to build a mitigation strategy to eliminate or control these risk factors.

The companies need to prioritize what issues they need to cater to on an immediate basis and what problems can be dealt with later. For this, they would have to identify the criticality and the probability of the risk factors. Based on this, the company would then decide whether to avoid, accept, reduce, control, or transfer the risk.

To sum up, researchers over the globe have been focussing on working on the risks encountered by the supply chains under various industry domains, including the pharmaceutical industry. The literature for various risks posed to the supply chain operations is easily acquirable as well as easily available over various platforms. The gap lies in the redressal of these risk factors.

A detailed evaluation of the risk factors needs to be carried out in order to formulate risk mitigation strategies. This would be the area of study of this research paper.

Other significant research gaps through literature review are identified in Table 1.

TABLE 1 RESEARCH GAPS

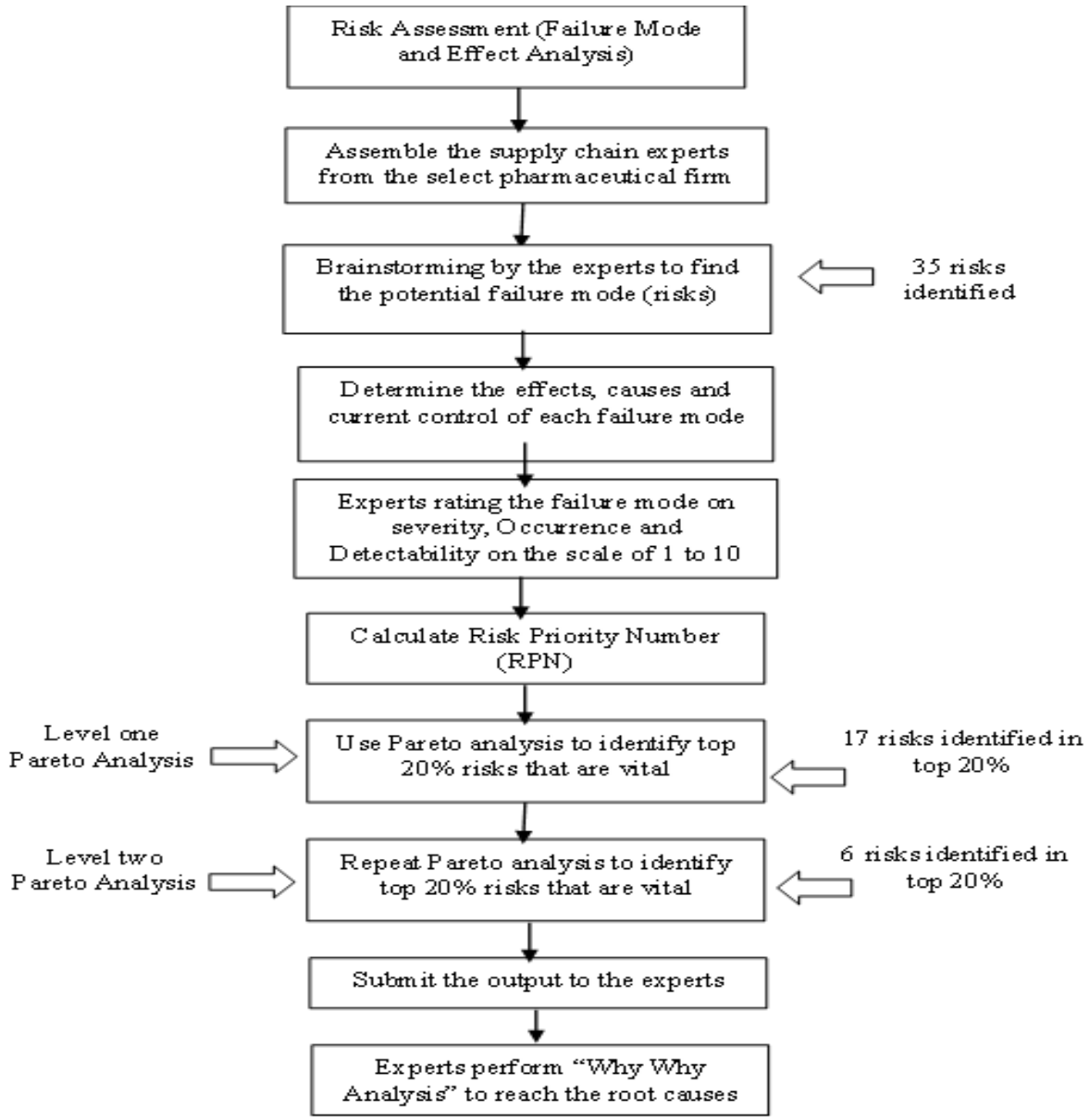
Objectives of the paper	Research gap	Authors
The paper aims at systematically reviewing the research on management in the pharmaceutical supply chain.	Authors suggest future research directions in supply chain integration in the pharmaceutical on topics of growing academic and corporate interest.	[27]

The paper aims at identifying the performance indicators of the resilient pharmaceutical supply chain and further predict the resilience level for a certain time period in the context of Bangladesh.	This research work considered only 12 indicators of the supply chain. Authors suggested more indicators should be analysed to develop the model.	[28]
The study aims to explore the downstream pharmaceutical supply chain (PSC) and provides insight to the delivery process of medicines and associated operational inefficiencies.	Since the study focussed only on the downstream domain of the pharmaceutical supply chain, it excluded those specialists operating within the upstream and central supply chain.	[29]
This study aims to access, analyse and highlight opportunities and problems of the Indian pharmaceutical sector.	The authors suggested further research interviews with experts in identifying and analysing the problems in pharmaceutical sector.	[30]

MATERIAL AND METHODS

RESEARCH FRAMEWORK:

FIGURE 2: RESEARCH FRAMEWORK



The research study carried out would give a holistic view of the risks a pharmaceutical supply chain typically encounters. These potential threats need to be minimized. In other words, these potential threats need to be prevented before they actually happen. These threats need to be identified, addressed, and monitored. The study seeks to gain an in-depth knowledge of the pharmaceutical supply chain functions and operations. The process flows within the supply chain of the pharmaceutical company are bound to have certainvulnerabilities, uncertainties, or activities, which have the potential to cause a disaster, peril or a hazard, or disruption.

These activities or events termed as risk need to be identified in order to ensure the smooth functioning of an organization. For an organization to be able to survive in a situation of crisis, keeping up its business along with gaining confidence amongst its stakeholders, mitigation of these risks is extremely necessary.

In the subsequent research work, the risk parameters with a view to quantifying these risks will be studied. This quantification would be the basis for any further analysis. The study identifies all possible failures in the design of a particular supply chain of the pharmaceutical company. These failures are assigned priority depending upon either their seriousness, their frequency, their detectability, or the consequences of these failures. The purpose is the identification of these risks in order to lay a foundation for further study on the means to either eliminate or reduce the impact of these. The severity of the risk is calculated in the subsequent stages of the research study.

This study also acts as a tool for implementing continuous improvements within the supply chain functions and operations. This research study also gives a deep insight into the performance of the sample firm. It would help to judge a company's strategic, tactical and operational decision–making capacity. The study would also address the pharmaceutical supply chain issues such as:

1. Counterfeiting issues
2. Manufacturing issues – raw material issues, quality issues, production planning issues, improper labelling, packaging
3. Transporting issues – mishandling, improper temperature controls, improper mode of shipping
4. Storage and warehousing issues - mishandling, improper temperature controlling
5. Raw material supplier issue – poor quality, high levels of an impurity, improper labelling, packaging

The company might use this data for making further alterations in their strategies or developing a new mitigation plan altogether.

DATA COLLECTION METHOD & DATA COLLECTION

For identification of supply chain risks in the supply chain, a detailed investigation of literature was done. The publications in the literature analyzed for this study range from 2010 to 2023 and are related to various subjects relevant to supply chain management, the expansion of the pharmaceutical business, and its problems, especially in the Indian context. Only studies that directly addressed issues in pharmaceutical supply chains regarding risk management and associated operation challenges were included; excluded are those that were neither relevant to the topic of study nor conducted within the set time frame. The risks identified were further validated by supply chain experts. The data collection instrument considered for this research report in the preparation of a questionnaire suitable for a case study method. An intensive investigation of the particular unit under consideration was carried out. A pharmaceutical company was selected to study the supply chain risks. Further, the selected unit is studied intensively. The respondents were the supply chain professionals from the pharmaceutical company who were interviewed in order to tap the company's data in the FMEA template and validate the risks identified through review of literature. Based on the study, a template of a questionnaire called the FMEA or Failure Mode and Effect Analysis was formulated.

The FMEA or the Failure Mode and Effect Analysis was formulated by enlisting all the risks or synonymously called potential failures. All of these come from various functions of the entire Supply Chain of the sample company and might cause serious implications as enlisted (potential failure effects). In order to quantify these risks, their Severity (S), Occurrence (O), and Detectability (D) need numerically measured on a predefined scale. Apart from this, all the probable causes of the failure and means to control these failures need to be recorded. The Risk Priority Number (RPN), which is the product of S, O, D, is thereby calculated for the risk assessment, followed by a recommendation of actions to reduce the occurrence of or prevent these failures.

Further Pareto analysis, also called as 80/20 rule, is conducted to identify the risks that are vital. Second level Pareto analysis is further conducted to prioritize the most critical elements. These risks are then subjected to Five Why technique to find the root cause of the vital risk elements.

DATA ANALYSIS & INTERPRETATION

The purpose or objective of carrying out the Failure Mode and Effect Analysis was to discover the risks in the Pharmaceutical Supply Chain of the subject company. Once the process of detection of these risks is complete, the next step is to assess these risks and prioritize them. Post the assessment and prioritization, and these risks then need to be mitigated. For this, they either need to be accepted as they are, avoided, transferred, or shared or reduced. This should then be followed by monitoring and control of these risks so that they don't turn into hazards for the smooth operation of the organization. The risk identification was made by an extensive literature review, post which the FMEA data collection sheet was formulated. This sheet then facilitated the assessment of each of the risks of the subject company by evaluating its severity, frequency of occurrence, and detectability.

The Failure Mode and Effect Analysis sheet not only tells us the severity, occurrence, and detectability of potential failures (risks) but also the current controls being employed in order to prevent or detect these failures or risks. Based on these controls being used currently, actions are recommended so as to reduce the occurrence of these failures or risks. Hence, the first step after obtaining the data is to analyze the current controls and recommend actions keeping in mind the long–term resolution of these risks

TABLE 2 FAILURE MODE AND EFFECT ANALYSIS OF THE SUPPLY CHAIN OF PHARMACEUTICAL FIRM

Process Step/ Input	Potential Failure Mode	Potential failure Effects	Severity S (1 - 10)	Potential Causes	Occurrence O (1 - 10)	Current Controls	Detectability D	RPN S*O*D	Recommended Action
PROCUREMENT/ SUPPLY SIDE	Raw material supply problems	Production disruption	6	Partnership issues with supplier	2	Engagements	2	24	VRM (Vendor Relationship Management)
				Raw material availability issues	4	Sales and Operations planning	5	120	Effective Sales and Operations planning, Safety stocks, and Norms.
				Raw material quality issues	3	Quality Parameters	1	18	Quality and R&D interventions if frequent issues.
				Inappropriate Ordering cycle time	2	Order Management	3	36	Strengthening Planning Process
				Inappropriate forecasting	4	Forecast Accuracy	5	120	Reduce Bias and improve the consensus process.
				Contract and agreement issues	2	Legal Checks	1	12	Legal Intervention
				Issues with Certificate of Good Manufacturing Practices	1	Regulatory Checks	1	6	Regulatory Intervention
				Delivery reliability issues	3	Logistics OTIF	5	90	Logistics metric review and alternate vendors
				Technological issues	1	Engagements	1	6	IT interventions
				Communication issues	4	Engagements	5	120	Strengthening Planning Process and engagements
				Processing equipment failure	2	Engagements	2	24	Manufacturing and Technology interventions
MANUFACTURING	Production failure	Inadequate product quality	8	Raw material shortage	4	Sufficiency logic	1	32	The planning process, PR>PO>Delivery
		Non - adherence to	8	Inappropriate packaging material	7	Sufficiency logic	1	56	The planning process, PR>PO>Delivery

		the production plan		Improper packaging quality	2	Quality Parameters	2	32	Quality and R&D interventions if frequent issues. Alternate Vendor.
				Inventory planning issues	5	Sufficiency logic	4	160	The planning process, PR>PO>Delivery
		Production of rejects/ Non - compliant batch	8	Insufficient storage space	6	Capacity Metric	3	144	Floor layout and Push/Pull balancing
				Technological issues	2	Reactive, Operations Halts	6	96	Predictive Maintenance Logics
				Labor issues	4	Attendance logs	5	160	Contracting and alternate vendor
DISTRIBUTION	Poor warehousing	Increased inventory carrying costs	4	Underutilization of floor & cubic space	4	Warehousing Metric	2	32	WMS implementation
				Inventory planning issues	4	Inventory Metric	2	32	Optimized Inventory Norms
		Customer loss	4	Labor productivity issues	4	Attendance logs	5	80	People Productivity metric. Log-based.
				Inappropriate material handling	2	Damage Metric	2	16	Process and SOP management
				Poor inventory turnover	5	Inventory Turns metric	2	40	Optimized Inventory Norms
		High warehousing costs	4	Prolonged order filling time	4	SLA metric	4	64	Process and SOP management
				Documentation issues	2	Order Processing Metric	4	32	Process and SOP management
				Excessive stock-outs	3	Service level Metric	1	12	Optimized Inventory Norms
				Overstocking	6	DOH and Ageing	1	24	The planning process and adherence
	Logistic failure	Increased logistics costs	6	Rate negotiation issues	2	Logistics comparisons	2	24	Reverse auctions
				Inefficient carrier evaluation and selection	4	Manual Intervention	4	96	Load optimizer and recommender
				Vehicle scheduling issues	2	call based	4	48	Integrated solutions for calls
		Customer dissatisfaction	6	Route planning issues	3	Customer SLA	4	72	Vehicle and route optimizer
				Freight consolidation issues	4	Customer SLA	4	96	Load optimizer
		Sales loss	6	Improper shipment scheduling	3	Customer SLA	4	72	TMS, E-POD, digital customer feedback
				Inappropriate material handling	1	Customer SLA	4	24	TMS, E-POD, digital customer feedback
				In-transit damage issues	2	Damage Metric	2	24	Process and SOP management

On the basis of the scores assigned to severity, frequency of occurrence, and detectability of each of the tabulated risks, a Risk Priority Number (RPN) was generated. This number further facilitated to prioritization of the risks in the Pharmaceutical Supply Chain of the subject company. In order to prioritize the potential causes that were responsible for the failure of Pharmaceutical Supply Chain functions, the Pareto Analysis method was used. For the application of this analysis tool, the Risk Priority Number (RPN) was arranged in the descending order that is the largest Risk Priority Number (RPN) was put on the top of the list while the smallest Risk Priority Number (RPN) was placed at the bottom. This was followed by the calculation of a cumulative percentage and the plotting of a graph as shown in Figure 3. The "80/20" rule suggested prioritizing 17 from 35 potential causes.

FIGURE 3 FIRST LEVEL PARETO ANALISIS

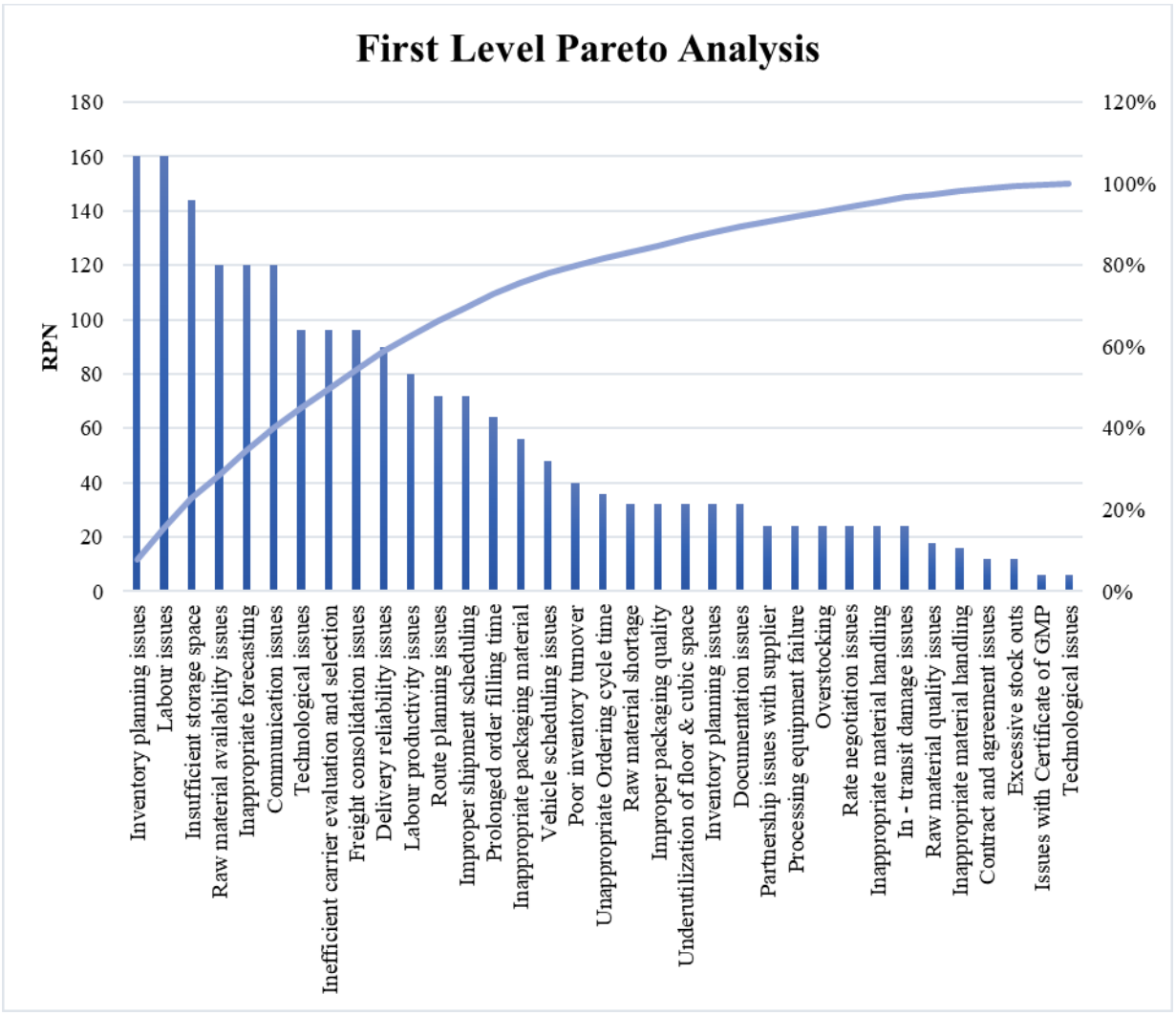
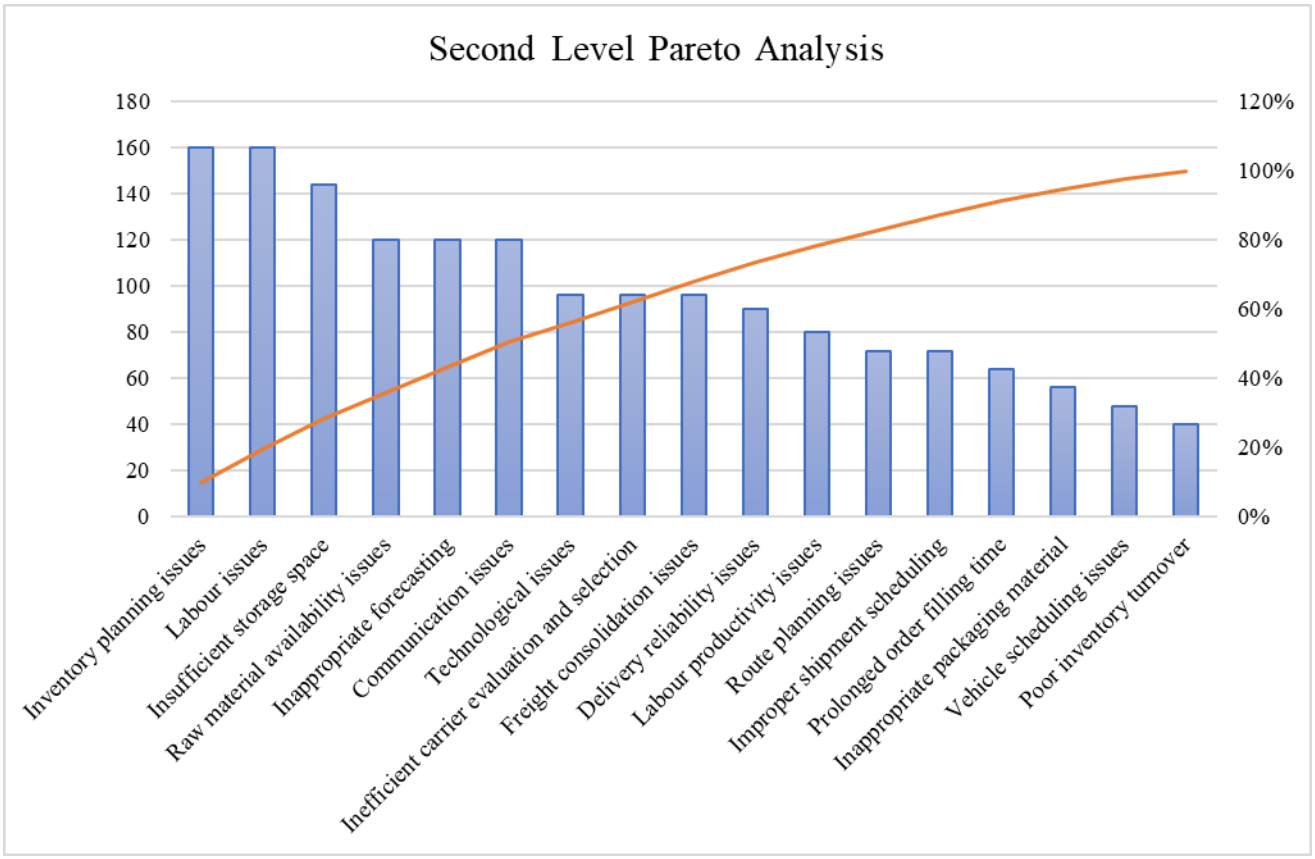


FIGURE 4 SECOND LEVEL PARETO ANALYSIS

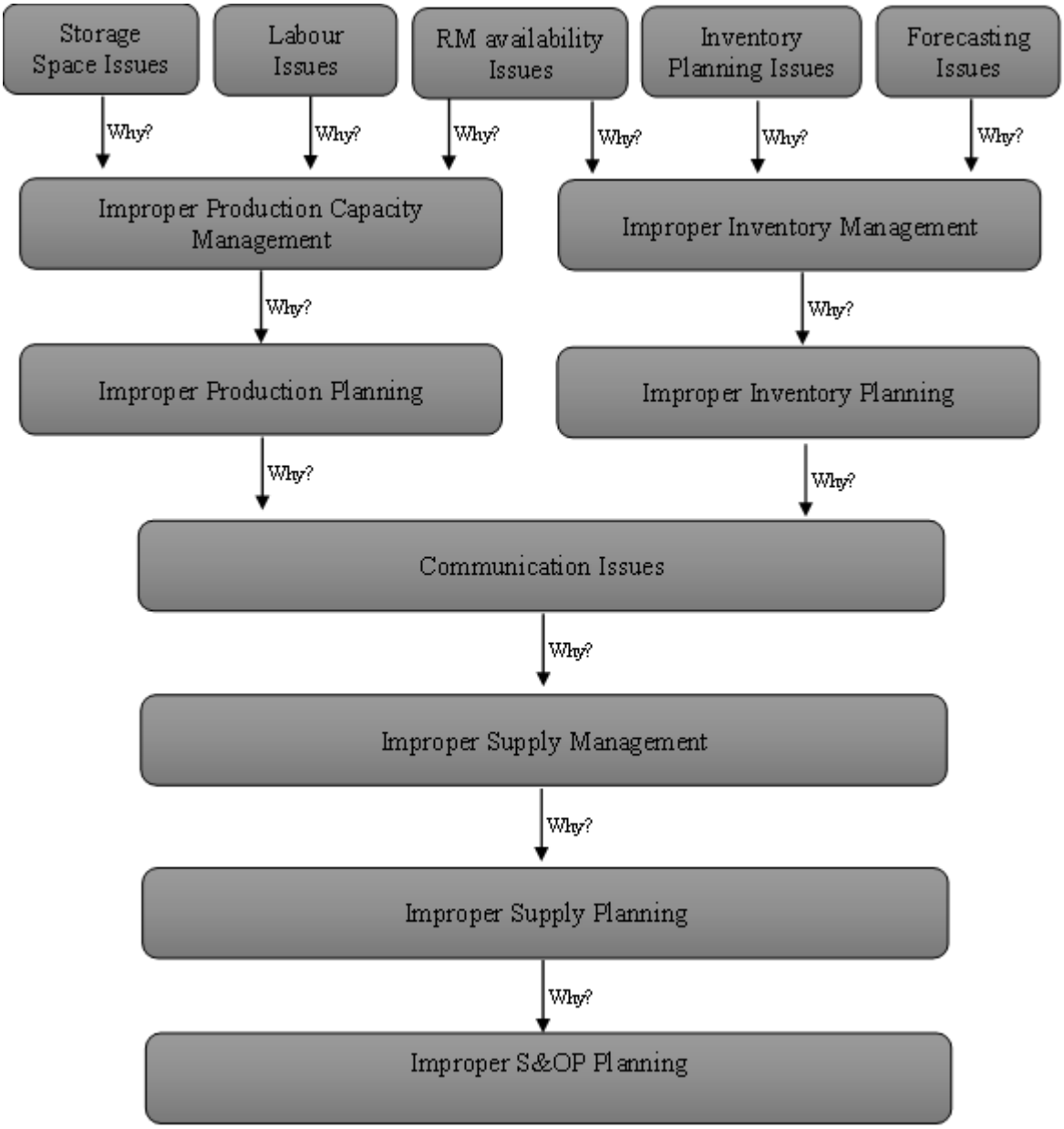


For further ease of analysis, 6 out of these 17 causes were further prioritized using the Pareto Principle as shown in Figure 4. Since the ratio may not always be 80/20, the ratio used for the second analysis is "50/50" This set of risks as prioritized in the Pareto analysis is used further by an Extended 5 Why Analysis technique to identify the root cause of the potential problems.

EXTENDED 5 WHY ANALYSIS

The Five Whys technique is a humble but influential way to troubleshoot problems by exploring cause-and-effect relationships [31]. Top six potential causes of failure of Pharmaceutical Supply Chain functions, namely – Inventory Planning Issues, Labour Issues, Insufficient Storage Space, Raw Material Availability Issues, Inappropriate Forecasting, Communication Issues, were considered for this analysis. To find a root cause of failure of Pharmaceutical Supply Chain functions, the "5 Why?" technique is used.

FIGURE 5: EXTENDED FIVE WHY ANALYSIS



RESULTS & FINDINGS

FMEA and further 5Why analysis lead to the dominant cause of disruption the supply chain. Storage space issues and labor issues arose due to improper production capacity management, while the inventor planning issues and forecasting issues arose due to improper inventory management. Nevertheless, both improper inventory management and improper production capacity management were responsible for issues related to the unavailability of RM (Although improper inventory management does not directly cause forecasting issues, the issues related to improper forecasts can be curbed using an effective and efficient inventory management system).

Improper production capacity management and improper inventory management can be traced back to being caused by improper production planning and improper inventory planning, respectively. These, in turn, arise due to the lack of healthy communication while planning.

While the paper [29] highlights financial, communication, waste and complexity issues were the major concerns, this research work has extended the findings to improper Sales and Operations Planning disrupting the pharmaceutical supply chain.

The communication issues arise out of improper supply management because of improper supply planning, which

in turn happens due to either the communication issues or improper planning during the Sales and Operations Planning (S&OP) meetings.

DISCUSSION AND CONCLUSION

It is noted that S&OP process is the root cause to other supply chain issues in the pharmaceutical firm. Hence S&OP meetings may support proper planning of the supply chain. Pre – S&OP meetings should be aimed at the identification of gaps between the demand to be fulfilled and the supply. It should provide a means for conflict resolution among the two so as to keep up to the commitments and efficiency of both marketing as well as operations/ production functions. The executive meeting mostly revolves around making decisions and courses of action as well as coming out with a feasible and reinforce able plan. The actions recommended for effective Sales & Operations Planning thus come from the above process. Supply and supplier planning need to be improved. Since supplier stands at the start of any supply chain, the proper planning and collaboration with supplier is needed.

Communication is identified as the next root cause to supply chain mismanagement. The information flow can be automated with the use of technology to avoid any misleading or incomplete information movement in the chain. The data gathered should most importantly be relevant.

- The relevant data should be clearly communicated during demand planning.
- A feasible demand plan needs to be laid out.
- This needs to be effectively communicated further for supply planning.
- Supply planning needs to consider both capacity planning as well as inventory panning.
- Based on these two factors, a feasible supply plan needs to be developed.
- It is extremely important that the inputs from the sales team in the form of the demand plan and outputs derived from the supply plan by the Operations/ Production team should be in line with no gaps. This is what needs to be ensured in a pre – S&OP meeting, while the executive meeting needs to issue a consensus plan, make decisions and review the KPIs Source [32].

LIMITATIONS AND SCOPE FOR FUTURE STUDY

This study is confined to a single pharmaceutical firm in India. Further FMEA used has an inherent limitation of subjective analysis rather than quantitative analysis. This might create acute bias from the side of the respondents. The study would help in the identification of the processes which require eliminating waste and encouraging other best practices within a supply chain. It would bring about transparency and visibility in the operability of various supply chain functions. A complex supply chain has the bane of consuming more energy and time in ensuring everything is working at a potential that is optimum. This study would simplify the risk monitoring tasks and, with continual improvements, would give leaner supply chains. The research may further be done to explore the impact of downstream members of supply chain on the pharmaceutical firms.

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