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Quality Insights on Supply Chain Risk: An Empirical Analysis

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Abstract

The present work is an attempt to investigate the implementation of quality system procedures on the supply chain risks in pharmaceutical companies. The risks inherent in the supply chain threaten the effectiveness and quality of the product. This paper presents a qualitative research method for analyzing the supply chain risks and for identifying ways of information support. Based on the review and data collected from the different pharmaceutical companies, awareness and traceability for the route of supply falls under the medium-risk class in most of the companies and is identified as a key risk factor. Results indicate that a thorough knowledge and well-defined quality system procedures on the supply chain flow and route of supply can mitigate the identified risks. The framework is validated with the case study based on semi-structured interviews and discussions. This provides a clear road map to the quality and supply chain managers to focus on the key risk areas. This paper contributes to research by proposing a complete approach, which integrates quality system perspective and supply chain process in a unique framework to understand the implications and to alleviate supply chain risks.

Keywords: Quality, Supply Chain, Risk Factors

Introduction

In today's scenario, supply chain management and a firm's operational performance always deal with the complexity and uncertainties faced. Supply chain risk analysis is an important field in operations management and logistics. Identifying the risks, assessing the probability of those risks, and understanding how those risks change if mitigation strategies are implemented contribute to a better supply chain risk management (Xue Lei et al., November 2019).

In current practice, supply chain management in the pharmaceutical industry comprises key ongoing activities such as inventory control and logistics, and meeting the defined quality deliverables for the incoming input materials.

Based on industry experience, pharmaceutical supply chain activities always carry some residual risk factors and finally fail to deliver the required results, e.g. re-scheduling/lack of inventory, product quality issues, quantity issues, delay in material supplies, and so on. Therefore, we consider it worthwhile to investigate the possible supply chain risk factors which contribute to the understanding and mitigation of the risks.

Many studies have investigated success factors for supply chain risks in general, but it has become clear that different types of studies require different approaches. So far, only few researches have been conducted pertaining to the supply chain risks insight with quality deliverables in the pharmaceutical field. This paper targets at closing this research gap by providing quality insights on supply chain risk factors while purchasing. Quality managers need to address and mitigate the identified risks in the pharmaceutical supply chain.

The paper is structured as follows: In section 2, we offer a summary of related studies based on supply chain risks with quality insights in supply chain management process. In section 3, we present our understanding on the supply chain risks and quality control measures managed by the pharmaceutical industry, related to the quality control on incoming raw materials. In section 4, we analyze the various associated supply chain risk factors involved in the pharmaceutical companies and procedural control measures in place to mitigate the risks. In section 5, we present our empirical study on the identified risk factors with quality insights in the current scenario. The results are derived based on the responses from semi-structured interviews/structured questionnaire

(sent through WebEx)/group discussion with qualified pharmaceutical professionals. Finally, section 6 provides a conclusion and discussion on the implications of risk factors, existing controls, and mitigation actions in the pharmaceutical supply chain.

Related Literature

Most of the existing studies rely on expert knowledge to evaluate supplier performance. In order to ease the pressure in the global supply chain, an intelligent supplier evaluation model is required. Supplier evaluation is an important issue in supply chain management (Yijun Cheng et al., 2020). In the current scenario, very few research is available on supply risk analysis with respect to quality insights in the pharmaceutical business. In most cases, authors show the process risk related to the supply chain area, but hardly focus on what we consider the quality insights in the supply chain risk.

Sreedevi et al. (2017) show that in emerging markets such as in India, where logistic infrastructure is poorly developed, internal capabilities alone may not be sufficient in reducing supply chain risk. The study further suggests that understanding the background of supply chain operational risks faced by firms and the conditions under which such risks are mitigated are the key areas to be focused on for better operations.

Esteban et al. (2019) focus on the recurring controversies involving supply chain-related sustainability incidents and firms with a global presence that struggle to improve environmental, social, and economic outcomes in global supply chains.

Ivanov et al. (2017) present the process flow regarding the coordination of material, information, and financial flows to transform and use the SC resources in the most rational way along the entire value chain, from raw material suppliers to customers. They provide the framework for the complete process chain on the material flow and systems.

Ali Bastas et al. (2018) suggest that a systematic review should be undertaken that includes both descriptive analysis and thematic synthesis of the state-of-the-art quality management, sustainability, and supply chain management integration literature. They conclude that integration synergies of quality and supply chain management will improve the performance of the organization with respect to quality management systems.

Manal Munir et al. (2020) provide the framework that forms an attempt to manage risk, handle unforeseen disruptions, and improve performance in ever-changing uncertain business environments. They conclude that there should be an association between supply chain integration and supply chain risk management to improve operational performance.

Merve et al. (2020) conclude that increased risk exposure levels, technological developments, and the growing information overload in supply chain networks drive organizations to embrace data-driven approaches in supply chain area.

Andri et al. (2019) suggest that in order to identify the most effective strategies of information support of supply chain, the attention should focus on the identification and management of the sources of uncertainties, risks, and cybersecurity. They conclude that identification of supply chain risk will improve the operational performance.

Xavier et al. (2017) suggest that the perception of supplier risk helps motivate the supply chain manager to enhance integration capabilities and thus achieve higher resilience. They conclude that resources, routines, and capabilities provide different results in terms of resilience, depending upon supply chain risk factors in the process flow.

Benjamin et al. (2020) conclude that efficient management of production volatility directly affects the sustainability of a company. They conclude that managing supply chain volatility is one of the core challenges of modern production networks that handle the operational process and system.

Nancy Sharma et al. (2018), reveal that an appropriate vendor managed inventory process plays a vital role in quality improvement of supply chain process.

Yaw Agyabeng-Mensah et al. (2019) conclude that supply chain quality integration is the key factor in the relationship between information technology and organizational performance.

Vishwanath Krishna Shetty (2019) indicates that the variables of supply chain practices are significantly and positively related to company output performance.

The findings of Amit Chandak et al. (2018) revealed that supply chain strategy has a positive impact on the performance of the business.

The study conducted by Kailash et al. (2017) deals with summarizing and analyzing the current challenges of internal supply chain management in the Indian manufacturing world.

Concept Update 'Quality Insight in Supply Chain Risk'

The summary of related works in section 2 shows that the common understanding of the terms 'supply chain risks' and quality insights, with respect to risks, seem to be lacking. The conclusion revealed by Sreedevi et al. (2017) indicates that the background of supply chain operational risk faced by firms and the conditions under which such risks are mitigated are very important to improve the firm's operational performance. In our point of view, quality insights in supply chain process directly helps to identify, analyze, control, and mitigate the risks for the materials. Therefore, we develop a more comprehensive explanation for the supply chain risk concept in view of quality pertaining to the pharmaceutical supply chain.

The definition proposed by Mohammed Abdel-Basset et al. (2019) focuses on the supply chain, the decision-making process which contains risks that can be influential on the company's progress, in introducing a new product, expanding in various markets, and outsourcing manufacturing operations. Ivanov et al. (2017) present the process flow regarding the coordination of material (from raw material suppliers to customers). In the pharmaceutical industry, input materials specifically include active pharmaceutical ingredients, excipients, packaging materials, and so one required for the operational process.

Xavier et al. (2017) suggest that the perception of supplier risk helps motivate the supply chain manager to enhance integration capabilities and thus achieve higher resilience. Quality/purchasing teams to mitigate the supply chain risks can pursue the basic understanding and firm's experience in the pharmaceutical industry on the quality risk management, within supply chains.

Quality Related Risk Factors in Supply Chain

In order to understand, assess, identify, analyze and mitigate the risk factors in the supply chain area, a thorough level of understanding of what is meant by the term 'risk' is required. In the pharmaceutical industry, the professionals who are responsible for mitigating the risks in the relevant process use guidance document Quality Risk Management ICH (Q9), which is available for reference. Ali Bastas et al. (2018) suggest that systematic review, which includes both descriptive analysis and thematic synthesis of state-of-the-art quality management, sustainability, and supply chain management, should be undertaken.

Using the international guidelines – ICH Q9 Quality risk management, EudraLex Volume 4 Chapter 1, Pharmaceutical Quality System guidance reference (1.10) – and industry experience, we understand the possible risk factors associated with the supply chain in view of the quality perspective. Thus, the appropriate controls on the identified risk factors may mitigate the risks for all the input materials during the supply chain process.

Sreedevi et al. (2017) study indicates that supply chain operational risk faced by firms and the conditions under which such risks can be mitigated are the key risk factors which may influence quality deliverables. The supply risk factors were studied intensively over the past decades but not specifically in the pharmaceutical supply chain under the quality point of view. So, based on the pharmaceutical supply chain knowledge, literature data, process background, and experience, the following possible risk factors are proposed:

- Knowledge of the end-to-end 'supply chain routes' for materials.
- Identify, assess, and mitigate the risks.
- Review of risks in the process.
- Quality review of the supply chain risks.
- Management focus and support.

In earlier studies, there are more factors mentioned, which can contribute in identifying the risk factors in the supply chain, but not from the quality perspective, e.g. complete supply chain risk control, quality checks, control on the expected/unexpected risks, and process controls to identify the risks.

Analysis of Risk Factors in View of Quality Perspective

In their study, Ali Bastas et al. (2018) specifically focus on the systematic review related to art quality management, sustainability, and supply chain management integration.

Sreedevi et al. (2017) show that in emerging markets such as in India, where logistic infrastructure is poorly developed, internal capabilities alone may not be sufficient in reducing supply chain risk. Our hypothesis is that apart from the results considered by Sreedevi et al. (2017) there are many hidden supply chain risk factors which affect the supply chain process and material quality. In the following sections, we will test this hypothesis using the results from semi-structured interviews/structured questionnaire and group discussions with the relevant quality professionals in the pharmaceutical companies in South India. The selected cities for the study are Chennai,

Hyderabad, and Bengaluru. The main criteria for selecting these cities is because they are pharmaceutical hubs.

Methodology of Research

Our purpose is to detect the possible supply chain risk factors in view of the quality perspective. Based on the literature on supply chain risks, study by Andri et al. (2019), and our own experience in managing supply chain risks, we developed a list of ten key risk factors mentioned in the Table 1. To discover the importance of risk factors we conducted semi-structured interviews with quality professionals in the pharmaceutical companies in India. The participants were selected based on their job role (responsible for quality function), with each participant having at least ten years of experience in the quality assurance department. Email enquiries were sent to 22 experts, inviting them to participate in the survey through a questionnaire. Twelve confirmations were received, of which ten interviews/discussions were conducted (through survey questionnaire and group discussions) between March and May 2020.

Table 1: List of Possible Risk Factors

ID	Possible Risk Factors* (*Refer Table 3 for More Specific and Elaborate Questions)
1	Accessibility knowledge on end-to-end 'supply chain routes'
2	Adequate evidence on transport validation information for the materials
3	Traceability for the actual 'route of supply – end-to-end'
4	Process controls measures to understand the changes in the supply route
5	Control points for material supplies through traders/transporters/distributors
6	Information on identification and assessment of 'supply chain risks'
7	Control measures on storage warehouses for the materials
8	Quality/supplier agreements
9	Change notification and control on the supply routes
10	Quality events on supply route issues

During the interviews, the participants were asked to rate the risk versus existing control for each of the proposed risk factors mentioned in Table 1, using the ratings 'high', 'medium' and 'low'. Moreover, the participants were asked to add any other risk factors which they felt were relevant to the study.

To derive a final score for each factor, we applied a 3-point Likert scale and assigned the values (Table 2). For each factor, the total score was the sum of the scores of the individual ratings, such that a maximum total score of 90 and a minimum of 30 was reached.

Table 2: Risk Classification, Risk Level, Rating Value and Risk Score

Risk Classification	Risk Level	Rating Value	Risk Score (Count X Risk Value)
Adequate process controls are available to handle the supply chain risk process	Low	3	30 – 50
Process controls are not adequately defined and possess medium risk in the supply chain process	Medium	6	51 – 71
No process controls and possess high risk to the supply chain process	High	9	72 – 90

Results of Survey/Interviews

It is imperative that the interviewees agree to and acknowledge that all the identified risk factors are relevant to the routine pharmaceutical supply chain operations. Discussion reveals that if the identified risk factors are handled appropriately, pharmaceutical supply chain risks may be reduced and mitigated to a large extent. Risk count from the questionnaire is used for deriving the final total risk score. However, the significance of these identified risk factors is tabulated via risk score (Table 3) for reference.

Table 3: Significance of Supply Chain Risk Factors Under Quality Insight by Risk Score

ID	Supply Chain Risk Factors (via Quality Insight)	Risk Count vs Existing Process/ Procedural Controls			Total Risk Score (Using Risk Value)
		High (9)	Medium (6)	Low (3)	
1	Quality insight in the end-to-end 'supply chain routes' for all incoming materials	1	8	1	60
2	For APIs, transport validation studies/data are available and verified for every active pharmaceutical ingredients	3	4	3	60

ID	Supply Chain Risk Factors (via Quality Insight)	Risk Count vs Existing Process/ Procedural Controls			Total Risk Score (Using Risk Value)
		High (9)	Medium (6)	Low (3)	
3	For APIs – How far the process controls ensure the actual route of supply is verified for every batch (i.e. transport validation route vs. route of supply, e.g. sea, air, road, trader, and so on) to ensure any changes in the supply route	2	6	2	60
4	For excipients/primary packaging materials – How far the process control measures available to ensure the actual route of supply is verified for every batch upon receipt to ensure any changes in the supply route (e.g. if supplied through traders/transporters/distributors, and so on)	2	5	3	57
5	Is there any written document maintained for all the incoming materials stating the 'supply chain risks' which are identified, risk assessed, and analyzed	3	3	4	57
6	How far the control measures are in place to visit/audit the storage warehouse of traders/distributors who store and distribute the materials (APIs/excipients/packaging)	3	3	4	57
7	How far the process/procedural control measures are in place to ensure/to identify any changes in supply route for the materials upon receipt	2	4	4	54
8	How aware are you about the actual 'route of supply – end-to-end' for all excipients and Primary Packaging materials (PPM) used	2	4	4	54
9	Is there any quality events reported in the past three years regarding change in the actual supply chain route other than transport validation route, e.g. deviations/incidents/change controls, and so on	2	4	4	54
10	Is the supply chain route documented in the quality/supplier agreements and purchase orders for the materials (complete traceability from start – at the manufacturing facility – to receipt at your end)	1	4	5	48

From the outcome of the survey it is more than evident that most of the analyzed supply chain risk factors (9 out of 10), in view of the quality perspective, possess medium risk in the current situation. An interesting fact that emerged from the survey shows that our proposed risk factors are very relevant and exist in the supply chain in pharmaceutical companies. Results from the study show first three high risk factors identified are related to the areas of 'transport validation studies/data, documented evidence for supply chain risk assessment, and control measures for the storage warehouse of traders/distributors'. Subsequently, many of the proposed risk factors fall under the category of medium risk, which indicates clearly that the existing process and procedures controls are not adequately defined to handle and mitigate the existing supply chain risk with respect to quality insight. It is clear that residual risk of 'medium' categories will lead to high risk in future if it still persists.

It is exciting to see that all the proposed risk factors fall under 'medium' risk in all the pharmaceutical companies. Our interpretation is that supply chain risks are evident and persists in the pharmaceutical supply chain environment. In our experience, inadequate procedural and process controls will lead to high risk, which in turn can result in untoward quality issues. Interviewers with adequate experience and managerial employees with a minimum of ten years of experience in quality assurance activities support this interpretation by pointing out the possible supply chain risk factors in the pharmaceutical business.

Conclusion

In this research paper, we attempted to identify and study the possible supply chain risk factors with quality insights. Risk factors identified are more relevant and comprehensive than other explanations found in the literature. Furthermore, we identified the ten important supply chain risk factors from the standpoint of relevant quality professionals who are responsible for identifying, analyzing the risks, and mitigating the supply chain risks in day-to-day practice in the pharmaceutical business. We found that all ten projected supply chain risk factors have an impact and a certain relevance to the quality of the incoming materials (as nine out of ten possess medium risk). The result shows that all the proposed risk factors are important and risk factors 'transport validation studies/data, documented evidence for supply chain risk assessment and control measures for the

storage warehouse of traders/distributors' were the most important to be considered. The results indicate that the existing process and procedural controls need to be re-looked at for better control and to mitigate the existing residual risk.

The study result shows implications for the pharmaceutical companies, pharmaceutical distributors involved in the complete supply chain process, and for academics pursuing research in this field.

Implications for Pharmaceutical Companies

From the analysis, we learned about possible supply chain risk factors that are more relevant to the quality of the material in the pharmaceutical business. Moreover, there were procedural gaps identified which are related to the verification of 'route of supply' upon receipt of the materials versus actual validated route of supply. We also learnt that availability of accurate information about the actual route of supply for excipients and primary is part of the identified risk factor. Furthermore, to close the gap, the quality and purchasing managers should interact on a regular basis and focus their efforts on influencing these risk success factors in an appropriate manner. This finding indicates that process and procedures controls are not adequately defined to mitigate the supply chain risk in the pharmaceutical supply chain.

Implications for Academics

Our findings from the study are in line with the findings of Sreedevi et al. (2017). However, Sreedevi et al. (2017) do not consider the risk factors pertaining to quality insight. This shows that our hypothesis was right and more relevant to the quality view on the supply chain operational risks faced by pharmaceutical firms and the conditions under which such risks can be mitigated. Moreover, this research paper provides a road map to consider while pursuing future research in this arena.

We are also aware that with ten interviewees our sample size is very limited when compared to the scope of pharmaceutical companies in South India. Therefore, our results can only be a first sign on the supply chain risk factors under quality insight. Considering this, senior management should initiate the focus on the supply chain process, and responsible quality and purchasing departments should become involved in the supply chain process risk assessment. Adequate process and procedural control measures should be articulated and put in place to mitigate the identified risks. As a direction for future research, we recommend carrying out a survey with a larger sample size in the pharmaceutical companies, and with the additional risk factors mentioned by quality managers added to the list. Moreover, it would be interesting to consider all the possible risk factors in the pharmaceutical business in various regions and different countries – for example, based on distribution network between countries, transport network, investigate the risk and control measures, warehouse network for storage and distribution of the materials, and identify the key risk areas for improvement.

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