Supply Chain Resilience in VUCA World: Towards a Holistic Approach of Quality Assurance and Risk Management

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ABSTRACT

Supply chain management is often associated with disruptions and chaos. This paper intends to explore the factors causing supply chain disruptions and develop a framework for supply chain resilience, thereby highlighting the significance of integrating quality assurance and risk management. With the help of in-depth interviews of management officials involved in the pharmaceutical supply chains in Pakistan, the study finds that a holistic approach towards quality assurance function is indispensable in the supply chain of pharmaceuticals. Drawing on the theoretical framework of chaos theory and complexity theory, the results of this study show that supply chain resilience can be achieved effectively by implementing a proper risk management system identifying the possibilities, and quantifying and mitigating the risks before they emerge. The study also highlights the differences between the supply chain resilience capability of large and small-scale pharmaceutical firms in Pakistan.

Keywords: Supply Chain Management, Supply Chain Resilience, Quality Assurance, Chaos Theory, Complexity Theory, VUCA World.

JEL Classification:

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Introduction

Today’s volatile, uncertain, complex, and ambiguous (VUCA) business environment requires organizations to establish efficient supply chain systems, from raw material to finished goods. Businesses are expanding, and so is the competition they face (Bourne, 2021; Reddy et al., 2021). Organizational processes are becoming increasingly complex, leading to more significant disruptions in the supply chains (Roberta et al., 2014; Troise et al., 2022). Any disturbance in one element of the supply chain can impact the whole system. Almost every supply chain system is characterized by uncertainty, risk, disruption, delay, and Chaos (Wilding, 1998). Supply chain disruptions include threats from an organization’s internal and external environment (Er Kara, 2020). Poor management of these threats can deteriorate the overall performance of the business. Hence, an ideal supply chain system can react and respond to uncertain conditions (Nils-ole et al., 2013). Supply chain resilience (SCR) refers to a supply chain system prepared and ready for unforeseen events and risks, uncertainties, responds to them, and counter them (Ribeiro & Barbosa-Povoa, 2018). SCR professes that the supply chain must have the ability to transform itself to
reduce or counter the level of risk or disruptions and recover from the interruptions. Efficient response and capability to rescue are inevitable to reduce the risks and achieve resilience (Ponomarov & Holcomb, 2009).

Because of the lack of empirical evidence in this field, the pharmaceutical sector in developing countries contributes little to the international supply chain debates (Singh et al., 2016). Following globalization trends, it has become necessary to assure quality beyond the firm’s boundaries to the overall supply chain; integrating the quality and supply chain management can be an effective way for supply chain partners to improve their overall performance (Zhong et al., 2016). Mitigating impacts arising from any disruptions, supply chain resilience aims to help companies cope with the different kinds of trouble rapidly, enabling operations to be restored to the previous level or even to a new one (Christopher & Reck, 2004; Wong, Lirn, Yang, & Shang, 2020). This research explores the factors that cause supply chain disruption and develops a framework for supply chain resilience. The study focuses on an integrated approach towards quality assurance and risk management in the pharmaceutical supply chains.

**Literature Review**

**Supply Chain Disruptions and Uncertainty**

The overall performance of a supply chain is affected by both internal and external factors. When operating on a supply chain, the forces shift the smoothness of a supply chain and, if not countered, form the basis of disruption and risk environment in a supply chain, which can be explained by laws of Chaos (Doherty & Delener, 2001; Handfield, Graham, & Burns, 2020). Supply network disruption is defined as “unplanned and unanticipated events that disrupt the normal flow of goods and materials within a supply chain.” Supply chain disruptions are possibly socio-political factors, natural catastrophes, or terrorism (Brüning et al., 2014; Parast & Subramanian, 2021). By studying the elements, one can understand how each step and aspect existing in a supply chain can impact the supply chain positively or negatively.

Chaos has been used in business literature to describe a seemingly random disorder of customers’ product demand. Collins English dictionary translates the word Chaos as “complete disorder and confusion.” Chaos is defined as “a periodic bounded dynamics in a deterministic system with sensitivity dependence on initial conditions and has a structure in phase space (Kaplan & Glass, 1995). Wilding (1998) adopts the classical definition of Chaos as “stochastic behavior occurring in a deterministic system,” where stochastic means random or lawless. Exact unbreakable laws and rules govern deterministic systems. So Chaos is random behavior governed entirely by laws. Chaos is very closely related to the risks or, in other words, the risk is one of the precursors of Chaos. Risk can be defined as a “combination of probability or frequency of occurrence of a defined hazard and magnitude of the occurrence.” Several authors have defined supply chain risks which can be summarized as the acts and events which negatively impact the
supply chain operations and affects its performance” (Tummala & Schoenherr, 2011). Chaos also negatively impacts the supply chain performance, so the risks and Chaos are closely interrelated (Tang & Musa, 2011). Prater (2005) describes the micro and macro level uncertainties, which are risks and make the supply chain prone to Chaos. These micro and macro level uncertainties consist of available variations, foreseen uncertainty, unforeseen uncertainty, and chaotic uncertainty.
Supply Chain Resilience

Because of increasing interconnections in supply chains, to reduce the risks, the supply chain must be designed to consider preparedness of risk or disruption that can potentially occur, which gives the capability to the supply chain to recover or even grow from disorder (Ponomarov & Holcomb, 2009). Resilience is comprehensive and applies to multiple disciplines. It has become a subject of interest for supply chain and risk management procedures (Wong et al., 2020).

Resilience is better conceptualized as the ability or process rather than an outcome, and it is adaptability rather than stability (Matzenberger, 2013). Sheffi and Rice (2005) state that “Reducing vulnerability means reducing the chances of a disruption and increasing steps towards Resilience.” Hence, making the supply chain less vulnerable, uncertain, and more resilient is possible. It requires two main concepts of understanding the potential stress or risk and how to manage the trouble or counter it. It is based on the adaptive capability for both expected and unexpected events. A resilient system uses its adaptive capabilities as a surprise to explore new state systems, it is a learning process, and many authors have defined it differently (Matzenberger, 2013).

Disruptions can be countered by companies with better planning, strategies, and operations. Researchers propose that a resilient supply chain can be developed by implementing lean productions, proper planning, deploying six sigma practices, robustness, and pre-analysis of possible risks and threats (Mensah & Merkuryev, 2014). Resilient supply chains may or may not be cost-effective in the short run, but they are more capable and effective in the long run for the business. A resilient supply chain aims to recover the original or favorable state of the system disrupted within an acceptable period and at a fair cost (Carvalho et al., 2012). Table 1 provides a snapshot of the factors essential for resilience management.
Table 1 Management Factors for Resilience

<table>
<thead>
<tr>
<th>Situation Awareness</th>
<th>Roles, responsibilities, understanding hazards, consequences, connectivity awareness, insurance awareness, and recovery priorities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of Key Vulnerabilities</td>
<td>Planning Strategies, participation in exercises, capability and capacity of internal and external resources, organizational connectivity</td>
</tr>
<tr>
<td>Adaptive Capacity</td>
<td>Silo mentality, communications and relationships, strategic vision and outcome expectancy, information and knowledge leadership, management and governance structures.</td>
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Supply chain disruption (Figure 1) is a state of uncertainty that disrupts the normal flow of goods. Firms must seek new opportunities by modifying and reconfiguring their resources and risk management infrastructure. By doing so, firms can seek new options to deal with the disruption and convert the state of disruption into a state of resilience.

![Figure 1: Supply Chain Disruptions in Pharmaceuticals](image1)

Theoretical Underpinnings

Chaos theory, with its application, has led managers to understand the business from an entirely new perspective (Bonabeau & Meyer, 2001). Applying chaos theory to a complex supply chain network can reveal that a system initially designed to control fluctuations can generate complex dynamics. These dynamics can further destabilize the technique by converting the demand pattern into unpredictable.
small change in demand pattern can cause the entire system to behave stably. A system behaves stably with a particular strategy and demand levels. However, when change occurs, strategic structure and demand patterns can destabilize the system and can cause the system to behave chaotically. One of the primary reasons for such Chaos is the decision-making ability and computer-controlled algorithms used in predictive models (Wilding, 1998). A complex system consists of elements of connections and links; as a result, the designs show chaotic behavior, the supply chain is a link and relationship of tiny links, and in whole, it becomes complex and exhibits chaotic behavior. Supply chain performance levels are positively linked with the variables such as network visibility, predictability, and consistency (Wagner et al., 2002; Ganbold, Matsui, & Rotaru, 2020).

Chaos theory and complexity theory are two approaches that have commonalities discussed in the literature. The complexity theory explores that small changes to systems can cause unexpected results, while chaos theory explains how small changes to initial conditions or values can bring unpredictable impacts (Johnson & Burton, 1994). Chaos theory was first studied by Lorenz (1963) while checking the weather prediction models and examined that small changes to the initial values weather models had an unpredictable impact on the forecast and prediction of weather conditions. Today, complexity and Chaos theory are being applied to almost all areas of study, including management and SCM. Predictions of every aspect have become difficult between connections, and most events are beyond the controls of any manager or organization. Most researchers suggest it as a more chaotic and complex system. Organizations that can better identify and adapt to changes can better cope with the changes and fluctuations. The supply chain is between order and complete randomness (Seeger, 2002).

**Determinants of Supply Chain Disruptions**

Tse et al. (2016) describe uncertainty as related to the supply chains, and it conveys the risks into three significant categories describing as “demand uncertainty,” “quality uncertainty,” and “logistics uncertainty.” Demand uncertainty relates to the actual demand of the product for the market and its customers. It directly impacts the supply chain; poor management or even misreading the situation can lead to disruption all across the supply chain. Quality uncertainty is one of the significant risks associated with the supply chain. The quality defects of products or received well at one end of the supply chain for further manufacturing, and when reaching the final customers can cause the supply chain to disrupt in the form of complaints. And eventually a sale loss or even product withdrawal. Logistics uncertainty is concerned with the supply of products to the customers. The logistics uncertainty caused by transportation of goods or any disaster causing hindrance in transportation can lead to a disruption in the supply chain.

Companies in a supply chain observe the risks related to the quality of the products, the non-compliance of the specifications, and market returns. The supply chain environment can disrupt and cause
a wave of change throughout the entire supply chain. Social risks are also there for the supply chain; the ethical and unethical practices are the things that impact the supply chains, the availability of resources timely and the delivery of the good to the final customers on time is the key for every supply chain. The supply chain’s security and safety are essential aspects of every supply chain, and risk is always associated. The financial risk is always hidden within every channel of the supply chain, and the impacts of prices are enormous when it encounters the chain’s nodes (Petersen & Lemke, 2015).

The study setting and methods
The pharmaceutical supply chain constitutes the roadmap through which essential drug products are delivered to the patients at the specified quality, at the required place, and at the required time (Mehralian et al., 2012). World Health Organization (2007) defines the drug as any substance or a mixture of substances manufactured, sold, offered for sale, or represented for use in the diagnosis, treatment, mitigation, and prevention of disease, abnormal physical state, or the symptoms thereof in man or animal. From the definition, it can be drawn that the drugs are susceptible as they require consistent, safe, effective, and high quality to be delivered to patients. With supply and demand across the globe, the interconnection and quality attributes are of greater importance in the pharmaceutical supply chain. The pharmaceutical supply chain is facing incrementing and challenging risks day by day. In addition to the pressures from the regulatory bodies, the pharmaceutical supply chains are changing legislations, customers, and intensive competition. Pharmaceutical supply chains also face counterfeiting, unfavorable reactions due to storage and transport conditions, issues caused by entities due to supply chain operations such as manufacturing and suppliers, transportation, warehousing and storage, and retailer and distributor issues (Abdallah, 2013).

Quality Assurance in pharmaceuticals is the arrangement of the organized system made to make a product highly effective and available for its intended use (Gough, 1989). The pharmaceutical supply chain provides medicine in the required quantity with the specified quality, to the required place and customers at the required time and with optimum cost to be consistent with health systems objectives. The pharmaceutical supply chain is a bunch of complex, technical processes that transfer raw materials and components to the final form and deliver it to the patients. It includes suppliers, manufacturers, intermediate stakeholders, distributor services, and patients (Jaberidoost et al., 2013).

This study adopts a qualitative research approach, including 21 in-depth interviews with pharmaceutical industry quality assurance and supply chain personnel. The participants were interviewed
in a semi-structured style, and personal observations were part of these sessions. They were asked open-ended questions. The reliability of the research is ensured by triangulation (Burke, 1997) of semi-structured interviews with other sources of data such as documents and archival records. The interviews were conducted informally to ensure maximum convenience for the respondents. On average, Interviews lasted for 20-30 minutes each. Data were analyzed using the thematic analysis technique (Gavin, 2008).

**Findings**

Respondents revealed risks they were facing in the specific supply chains (Table 2), and most of the dangers were experienced-based rather than documented risks. Participants answered the associated risks from their domains, and identified risks were more specified to the pharmaceutical supply chains than generalized risks as discussed in the literature. As discussed earlier in the literature, the respondents considered quality assurance essential in the pharmaceutical supply chain. Being mandatory by the regulatory authority, the role of quality assurance is very well established in large-scale companies (Table 3). The aspect of overall quality assurance and overall monitoring of quality in the supply chain is very well managed. However, quality assurance functions are not very well established in smaller companies. An advanced quality assurance function was not found on the distribution side, and only the elements as desired by the regulatory authority were fulfilled.

<table>
<thead>
<tr>
<th>Risk Types</th>
<th>Answers from Interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning Risks</td>
<td>Irrational forecast, suppliers miss-commitments, shortages of supplies, production delays, market dryness, freeze point risk, market urgency risk, basis of planning risk (Marketing &amp; Distributor Stock), Shortages, Pilferage, Random audits and regulatory inspections, New site &amp; product risks, and Shortages of imported products due to yearly Plan</td>
</tr>
<tr>
<td>Source Risks</td>
<td>Variation in quality of material, Unauthorized changes in the process of suppliers, Selection of the wrong source, Controlling inventory carrying cost resting in urgency risk and non-compliance of lead time for the release of materials, source back out due to the breach of agreement, Non-conformance of agreement, Discontinuation of business, Mishandling during transit, Theft, Cold chain breakage., Lead time risks, Non-localized suppliers’ risks, Short production risks, Underestimated productions, Non-compliance of regulatory laws, Backup sources risks.</td>
</tr>
</tbody>
</table>

**Table 2: Risks Identified by Respondents**
### Make Risks
- Non-qualified processes,
- Deviations not recorded,
- No impact assessments,
- Wrong quantity usage,
- Wrong material usage,
- Variation of quality of materials,
- Changes of too many sources,
- Settlements of outdated products,
- Packaging problems,
- Equipment risks.

### Delivery Risks
- Variation in lead times,
- Unqualified channels of shipment,
- Shipments worthy packing,
- Storage in transit,
- Short supplies,
- Pilferage,
- Storage conditions,
- Dishonor of orders,
- Attitude of staff,
- Law and order situations,
- Product consistency risks,
- Variations in ETA,
- and Packaging intactness.

### Return Risks
- Reprocess by supplier,
- Redistribution,
- Destruction,
- Rejection of claims,
- Non-satisfaction of end-user,
- Pressure to achieve targets,
- Damaged returns,
- Demand & supply gap risk.

<table>
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<th>Table 3: Role of Quality Assurance in Supply Chain</th>
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<tbody>
<tr>
<td><strong>Function</strong></td>
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<tr>
<td>Quality Assurance</td>
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Talking about the issues in the quality assurance function in an organization, respondents mentioned the following keywords “staff training,” “adherence to the guidelines/procedures,” “recording deviations,” “management to comprehend rules of the business,” “delegation of powers at right levels,” “compliance to international guidelines,” “business deadlines,” “turnovers,” “understanding/communication issues,” “lack of experience in the supply chain,” “delayed information system,” “underdeveloped quality assurance function” and “understanding in terms of ownership of quality.” In larger companies, the idea of quality assurance was more critical. The issues observed were only in ongoing training of quality function and adherence to guidelines because of the fast-moving business commitments. In smaller companies, the QA function is more considered a burden and only fulfilled because of the regulatory requirement. At the same time, practically, the power does not fall in the hands of the quality assurance function.

Respondents highlighted the issues between the quality assurance and supply chain functions such as “not respecting quality guidelines,” “making financial decisions instead of quality,” “maintenance of quality and sustaining quality vendors over cost issues,” “lead time of supplies and release of materials due to business urgencies,” “technical education issue in the supply chain in terms of quality assurance” “rejections and shortages issues” “quality assurance underdeveloped in terms of supply chain perspective.” The relation between the quality assurance and supply chain functions was not as coordinated as required and described in the literature. The coordination system existed in larger organizations. The quality assurance function takes the quality decisions, and the supply chain function is bound to adhere to the guidelines outlined by the quality assurance department. The data analysis also identified and evaluated its supply chain risks (Table 4).

### Table 4: Risk at Different Ends

<table>
<thead>
<tr>
<th>Risks at suppliers’ end</th>
<th>At the manufacturers’ end</th>
<th>At the distributors’ end</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not respecting quality agreements</td>
<td>Not using a qualified process</td>
<td>None qualified mode of shipment.</td>
</tr>
<tr>
<td>Variation in lead times.</td>
<td>Not recording deviations</td>
<td>None qualified storage conditions.</td>
</tr>
<tr>
<td>Inaccurate communication</td>
<td>Compliance with specifications.</td>
<td>Handling of returned/expired stocks.</td>
</tr>
<tr>
<td></td>
<td>Rejections.</td>
<td>Pilferage.</td>
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<td></td>
<td></td>
<td>Wrong communications of claims.</td>
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</tbody>
</table>
The practical identification or risk analysis was not observed in any organization participating in the interviews. All of the risks reported were more from past experiences of the managers and the company, and practically very rarely any documented action was taken to counter these risks. The data analysis also unpacked the processes used to identify, measure, and eliminate supply chain risks. No specific practice is explicitly used to measure and eliminate threats, particularly in small firms. Larger firms use qualified systems and processes, training of staff, deviation management system, team discussions, and risk assessment programs. Moreover, stability testing, trend analysis, vendor qualifications, self-inspections, and gap analysis from audits were also reported by respondents from larger organizations.

The actual concept of resilience, identifying risks before they arise, and the role of quality assurance in these risks are not very well established in smaller firms. The quantification of risk to the impact of rectification is not done in an absolute sense. The answers from larger organizations were more theoretical and documental. At the same time, in the real sense, the implemented evidence of the quantification of those risks and improvement points was only found within the specific plants and not in the whole supply chain in terms of documented deviation and customer complaints. Risk measurement before the emergence of risks is not practically done by any organization participating in this research. Most of the participants almost agreed on the possibility of measuring the role of quality assurance in countering risks. All participants agreed on monitoring all aspects of the supply chain and identifying the potential risks. Still, the answers remain theoretical in smaller organizations, where quality assurance did not exist practically.

Talking about countering risks before occurring, only the larger companies could give practical examples of resilience. Also, these examples came up from the top-level managers from quality assurance departments. Risks exist in the pharmaceutical supply chain and vary according to the company’s size. Most risks reported in interviews are non-documentated and experience-based. Quality assurance function is mandatory for pharmaceuticals but less empowered in smaller organizations and has more priority towards manufacturing than the whole supply chain. In the case of multinationals, quality assurance looks after the entire supply chain processes from supplier to distributor. The quality assurance function has gaps of communication and data sharing with supply chains as of different working domains, cost, and quality, lack of technical training of supply chains, and decisions of cost over quality.

Larger organizations have reported using systems to counter risks: deviation management, corrective and preventive actions (CAPA), annual performance reports (APR), quarterly progress reviews (QPR), stability
studies, and trend analysis. To counter risk, companies perform a quality assessment of the possible excursions and define recovery in the system. The participants agreed on countering risks in the supply chain in assessing and monitoring all steps of product supply. However, these measures were practically observed only in large companies (logistics qualification, temperature mapping records, data loggings, SAP monitoring). Resilience can be achieved by adequately assessing risks and predefining the recovery plans by considering all ends by qualifications and change applications and by using mock-up techniques. Quality assurance must be proactive to achieve resilience.

Discussion

It has been analyzed through the research and interviews conducted in pharmaceutical companies that the pharmaceutical supply chain is a critical and complex chain of processes because of its direct impact on patients’ health. So the methods are more technical. The risks associated with the pharmaceutical supply chain directly impact the patient health or the firm business. The risks identified through the research are more specified to the pharmaceutical plants and supply chains. Most of the identified risks are shared with other manufacturing supply chains. Some of them, like cold chain materials, regulatory requirements, and product expiry specifying only short lead time, are more concerned.

The quality assurance functions are mandatory for the pharmaceutical supply chain as by the regulatory and international guidelines for pharmaceutical manufacturing and distributions; the quality assurance department at the manufacturing site is compulsory to oversee all the matters related to the site. Still, the supply chain relationships with the quality assurance function are not hard and fast written in regulatory requirements. All these matters are in strict control of the quality assurance function. The supply chain department provides a support function to the quality assurance function in terms of providing the availability of materials/vendors in terms of cost only and ensuring the availability of materials and stocks at the right time and place.

In the case of small companies, the quality assurance functions are not very well established or are under the developmental phase. More reliance is on the supply chain function for the availability of materials. As being more technical and scientific, the pharmaceutical supply chain gets more prone to the risks of materials as identified. The concept of resilience for a pharmaceutical supply chain is new, and it does not bear any certified or practical document evidence. Here in Pakistan, the pharmaceutical sector is far behind the international level of acceptance. The basic concepts of risk and supply chain management are only very rare to see in only larger firms, primarily with global brands and sales. In contrast, the firms with local sales and shorter volumes do not have rudimentary risk and supply chain management systems.
Conclusion

The quality assurance department has to be an integral part of the supply chain, and the main goal of the supply chain should be to make a quality product in terms of the whole supply chain than just the manufacturing process. It can only be achieved by implementing a proper risk management system at the supply chain level and applying the concept of resilience at the same time by identifying the possibilities and quantifying the risks even before their practical arrivals and mitigating them. A proposed framework for supply chain resilience through quality assurance and risk management is given in Appendix (Figure 2).

From the current research, it can be concluded that Pakistan’s existing pharmaceutical supply chain is not in the direction of resilience. The supply chains in the pharmaceutical sector are more running towards business and are more focusing on the manufacturing sites and marketing areas, while the supply chain side is suffering because of the lack of technical and quality assurance aspects.

In the local pharmaceutical supply chains, it is considered that ordering and supplying the material to the manufacturing plant is the essential role and responsibility of the supply chain function. While in an actual sense, the supply chain’s role is to provide suitable materials at the right time and place, from starting point of the supply chain to its end customer. Through this research, conducted on the supply chain resilience and role of quality assurance in the pharmaceutical sector, the proposed framework should be practically applied and established to achieve stability. It can also be replicated and used in other local markets and supply chains sectors. Separately, the role of quality assurance in the pharmaceutical supply chain can be elaborated and studied to develop more quality assurance models.

One of the primary constraints observed during the research is the availability of quality suppliers in Pakistan. Most of the suppliers contacted were third-party intenders who import the materials from the international market and supply them locally. The knowledge of quality assurance to these suppliers is minimal, and all of the contacted suppliers could not answer the fundamental questions of interviews. Their answers were all negative regarding any system followed for quality assurance. The supplier side of the pharmaceutical supply chain requires more development and support to deal with the issues and risks that the current supply chain is already suffering and achieve the real goal of the supply chain. Moreover, the primary constraint of this research is that the supplier side needs even more attention. It can be independently studied as the role of quality assurance in suppliers’ supply chains and the achievement
of resilience through supplier qualifications and assessments. The framework developed at the end of this research can also be practically implemented and tested for future research in the pharmaceutical sector and implementation in other sectors. The concept of resilience is new, and as in a complex pharmaceutical industry, it needs more study and expansion of ideas for the future development of pharmaceutical supply chains. Addressing supply chain resilience opportunities and monitoring methods can be developed and applied in different sectors for further research.

References


Appendix:

<table>
<thead>
<tr>
<th>Planning Risks</th>
<th>Making Risks</th>
<th>Sourcing Risks</th>
<th>Delivery Risks</th>
<th>Return Risks</th>
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<tr>
<td>Irrational forecast</td>
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Figure 2: Proposed Framework for Achieving Supply Chain Resilience through Quality Assurance