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Supply Chain Resilience Assessment (SCRA): A Methodology for Strengthening Global Supply Chains in Regulated Industrial Environments

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Abstract- In response to frequent global disruptions, resilient supply chains are essential to maintaining operations in regulated industrial environments. Such disruptions—ranging from natural disasters and pandemics to geopolitical instability, technical failures, financial crises, and regulatory changes—pose serious threats to business continuity. This paper introduces the Supply Chain Resilience Assessment (SCRA), a structured methodology for evaluating resilience across the five core processes of the Supply Chain Operations Reference (SCOR) model: *Plan*, *Source*, *Make*, *Deliver*, and *Return*.

Developed from established assessment tools, refined through literature review, and validated via expert interviews and multiple industry applications, the SCRA provides a two-day, expert-led evaluation tailored to manufacturing sites and their connected supply networks. By integrating resilience into the traditional performance dimensions of quality, cost, and time, it identifies vulnerabilities and defines actionable improvements as part of holistic Business Continuity Management (BCM).

While applied here using the medical device sector as a reference case—where validated and compliant processes are essential—the methodology is designed to be transferable to other regulated industrial domains. The SCRA advances existing resilience assessment tools by combining SCOR-aligned process evaluation with Lean and Industry 4.0 maturity dimensions, enabling rapid diagnosis and targeted recommendations to improve both structural and operational resilience in regulated production environments.

Keywords: Supply Chain Management, Business Continuity Management, Resilience Assessment, Medical Device Manufacturing, Smart Factory, Operational Excellence.

I. INTRODUCTION

Resilient global supply chains are now a competitive imperative, particularly for industries where uninterrupted production is critical. Business Continuity Management (BCM) provides a structured framework for anticipating threats, mitigating risks, and maintaining operations under adverse conditions. Defined by ISO 22301 (2019) as "a holistic management process that identifies potential threats to an organization and the impacts those threats might cause, providing a framework for building organizational resilience and an effective response," BCM integrates both proactive and reactive measures to sustain productivity during disruptions. This proactive–reactive approach makes BCM indispensable for maintaining operations during disruptions.

Recent years have underscored the urgency of this balance. The COVID-19 pandemic disrupted labour availability, closed factories, and created cascading effects across logistics networks worldwide. The blockage of the Suez Canal in 2021 further exposed the vulnerabilities of just-in-time shipping, delaying global trade flows and stranding critical goods. More recently, the war in Ukraine has highlighted geopolitical dependencies, leading to energy shortages, agricultural supply shocks, and disruptions in the availability of semiconductor-grade neon. Combined with long-standing bottlenecks in semiconductor production, these events have demonstrated that global supply chains are not only exposed to sudden shocks but also to prolonged structural vulnerabilities. Together, they illustrate why resilience must be embedded as a core dimension of supply chain strategy, rather than treated as an afterthought.

At the same time, supply chains operate in an increasingly volatile global environment characterized by geopolitical instability, material shortages, fluctuating demand, and systemic risks. The adaptive capability of the supply chain—its ability to prepare for, respond to, and recover from unexpected events (Ponomarov& Holcomb, 2009)—has therefore become a defining factor in organizational competitiveness. Ponomarov and Holcomb emphasize that resilience goes beyond traditional risk management: it is not only about reducing the likelihood of disruptions but also about enabling organizations to bounce back more quickly and even emerge stronger after adverse events. This notion of resilience highlights the importance of flexibility, learning capacity, and system-wide coordination as integral features of modern supply networks.

In the manufacturing domain, the past three decades have been heavily shaped by the adoption of Lean Management and Industry 4.0. Lean principles, as articulated by Womack, Jones, and Roos (1991), target the elimination of waste, optimization of workflows, and the pursuit of efficiency across production systems. These ideas revolutionized industrial operations and enabled unprecedented levels of productivity and cost reduction. However, an exclusive focus on lean practices has often increased vulnerability to disruptions. Lean supply chains are typically characterized by reduced buffers, minimal inventories, and strong reliance on just-in-time flows. While these practices maximize efficiency under stable conditions, they also reduce the system’s ability to absorb shocks, creating fragility when unexpected events occur.

The digital transformation of manufacturing, often framed under the umbrella of Industry 4.0, has introduced a complementary set of capabilities. Oesterreich and Teuteberg (2016) describe how digitalization, automation, and cyber-physical systems enhance visibility, responsiveness, and predictive capabilities across supply chains. Advanced analytics and real-time data exchange provide managers with the ability to detect emerging risks earlier and adapt more swiftly to disruptions. Yet, the authors also caution that digital systems can introduce new forms of risk, such as cybersecurity threats and dependencies on technological infrastructures, which need to be managed in tandem with operational improvements. Taken together, Lean Management and Industry 4.0 provide a powerful foundation for operational excellence, but without a deliberate resilience perspective, they remain incomplete.

The tension between efficiency and resilience has been well documented in the literature. Christopher and Peck (2004), for instance, argue that resilience requires designing supply chains that are not only lean but also agile and adaptive. This involves building redundancy in critical areas, developing flexible sourcing strategies, and fostering collaboration across supply networks. Similarly, Kleindorfer and Saad (2005) show that systemic supply chain risks—ranging from natural disasters to supplier failures—cannot be managed solely through efficiency-oriented practices; they demand broader resilience strategies that integrate risk awareness into day-to-day decision-making. These insights underscore the necessity of moving beyond optimization for cost and speed alone, towards a more balanced approach that incorporates resilience against uncertainty.

The current paper introduces the Supply Chain Resilience Assessment (SCRA)—a structured method designed to systematically evaluate and strengthen resilience in manufacturing and logistics. Developed as an extension of established assessment tools and refined through expert practice, the SCRA focuses on making resilience measurable and actionable. Using the medical device manufacturing industry as a reference case, the paper demonstrates how the SCRA aligns with the Supply Chain Operations Reference (SCOR) model’s five core processes (*Plan*, *Source*, *Make*, *Deliver*, and *Return*) and embeds resilience into operational excellence(Supply Chain Council, 2012). While the SCOR model also includes “*Enable*” as a supporting process, it was deliberately excluded from the SCRA as a standalone category. This is because *Enable* focuses primarily on governance, performance management, and data infrastructure—elements that, while essential, are integrated within the core process evaluations wherever they directly affect resilience (e.g., in planning accuracy or supplier monitoring). The medical device manufacturing sector provides a particularly rigorous testing ground, as it is defined by stringent regulatory requirements, long lead times for approvals, and the necessity of validated processes. In such environments, the ability to withstand disruptions without compromising compliance or product quality is not merely desirable but essential.

By positioning resilience alongside traditional performance dimensions such as quality, cost, and time, the SCRA contributes to closing the gap identified in the literature between abstract resilience concepts and their practical implementation in industrial settings. The following sections analyse the nature of supply chain disruptions, explain the conceptual underpinnings of the SCRA, and present practical results from its application in medical device manufacturing environments.

II. UNDERSTANDING SUPPLY CHAIN DISRUPTIONS

Supply chain disruptions are no longer isolated but recurring and complex. Supply chain disruptions can be broadly defined as “unplanned and unanticipated events that disrupt the normal flow of goods and materials within a supply chain” (Craighead, 2007). These events occur across all industries and geographies and are increasingly shaped by the interconnectedness of global markets. As Christopher and Peck (2004) emphasize, disruption risks are not confined to single companies but ripple across entire networks of suppliers, customers, and logistics providers, making resilience a system-wide concern.In today's environment, the critical question is no longer whether disruptions will occur, but how organizations prepare for and respond when they inevitably do.

While the specific nature of disruptions varies, they often share two characteristics: unpredictability and nonlinearity. Unpredictability means that disruptions frequently emerge outside the scope of traditional planning assumptions, while nonlinearity refers to the disproportionate impact a seemingly small disturbance can have on an extended supply chain. A local supplier failure, for example, may cascade into a global production halt if no redundancy or contingency arrangements exist. Understanding these patterns is essential for designing strategies that go beyond efficiency and explicitly incorporate resilience.

To illustrate the diverse nature of supply chain risks, Table 1 summarizes a selection of common disruption categories and their implications.

Table 1: Selection of current challenges faced by companies that require an increase in resilience.

Risk category	Description
Natural catastrophes	Natural disasters such as earthquakes, floods, hurricanes, and wildfires can severely disrupt supply chains by damaging critical infrastructure, production facilities, and transportation routes. These events often lead to prolonged production shutdowns, delivery delays, and interruptions in the flow of goods, requiring substantial risk mitigation measures to ensure continuity (Kleindorfer and Saad, 2005).
Geopolitical risks	Political and geopolitical disruptions, including trade conflicts, economic sanctions, wars, political unrest, and sudden changes in trade policies, can significantly impact global supply chains. These risks can result in abrupt shifts in the supplier base, changes in transportation routes, and the need to navigate complex customs regulations, all of which can destabilize networks (Christopher and Peck, 2004).
Supplier bottlenecks	Supply chains are vulnerable to bottlenecks caused by issues such as supplier failures, quality problems, or insolvencies. Companies that rely heavily on a small number of suppliers or geographic regions are particularly at risk. Regulatory certifications, especially in industries like medical technology, make it difficult to rapidly shift suppliers or establish alternatives, increasing vulnerability (Tang, 2006).
Transportation issues	Disruptions in transportation, including capacity shortages, delays at customs, labour strikes, and infrastructure constraints, can severely impede the movement of goods. Such disruptions affect not only the delivery of goods but also the overall efficiency and reliability of operations (Sheffi and Rice, 2005).
Fluctuations in demand	Sudden and unpredictable shifts in demand, perhaps driven by seasonal changes, evolving customer preferences, market trends, or political decisions, can create significant challenges for supply chain management. Companies must be agile in responding to these fluctuations to avoid overstocking, stockouts, or bottlenecks (Ivanov and Sokolov, 2013).
Technical risks	Increasing digitization introduces new risks such as IT system failures, cyber-attacks, and data breaches, which can have widespread consequences for supply chain operations. As supply chains become more reliant on real-time data and interconnected systems, these risks must be managed with advanced technologies to ensure resilience and prevent significant operational disruptions (World Economic Forum, 2012; Ivanov et al., 2019).
Personnel insecurities	Workforce-related challenges, such as labour shortages, strikes, or other forms of industrial action, can significantly disrupt supply chain operations by delaying production, transport, and installation processes. The availability of skilled labour, particularly in sectors like medical equipment production and logistics, is critical for ensuring timely deliveries and operational continuity. Personnel shortages during crises or disruptions can lead to extended downtime and reduced service levels, further exacerbating supply chain vulnerabilities (Craighead, 2007).
Financial risks	Economic disruptions, including currency fluctuations, liquidity issues, or economic downturns, pose significant risks to global organizations. These financial uncertainties can affect everything from the cost of raw materials to the ability to invest in resilience measures. Companies need to maintain financial flexibility to manage cost volatility and ensure that supply chain strategies are economically sustainable during disruptions (Sodhi and Tang, 2011).
Regulatory risks	Compliance with regulatory changes or new legal requirements (such as environmental regulations, trade policies, and safety standards) can disrupt supply chains by forcing companies to alter their processes, suppliers, or distribution networks. These risks are particularly significant in compliance-critical sectors like pharmaceuticals, medical devices, and food production. Failure to meet regulatory standards can lead to delays, fines, and reputational damage (Manuj and Mentzer, 2008a).

Beyond categorization, it is important to recognize that these risks often interact in complex ways. For example, a geopolitical crisis may trigger financial volatility, transportation bottlenecks, and regulatory changes all at once, creating a compound disruption scenario. Similarly, natural disasters may not only damage infrastructure but also result in sudden shifts in demand for medical supplies or emergency equipment, stressing both supply and distribution channels. These interdependencies make resilience a cross-cutting requirement across all supply chain processes.

Another way of understanding disruptions is by considering their probability and impact. Natural disasters tend to be low-probability but high-impact events, with consequences that can paralyze global supply networks for extended periods (Kleindorfer& Saad, 2005). In contrast, high-probability but moderate-impact disruptions—such as unanticipated demand fluctuations, supplier delays, or sourcing constraints—occur more frequently but can often be absorbed if resilience measures such as safety stocks, dual sourcing, or flexible logistics are in place (Craighead, 2007). Effective resilience strategies must therefore be tailored to the type of disruption, balancing cost against preparedness.

The duration of disruptions is another decisive factor in resilience planning. Grzybowska (2022) differentiates short-term disruptions (lasting a few days to weeks), medium-term disruptions (weeks to months), and long-term disruptions (months or even years). Short-term events can typically be managed through existing buffers and contingency plans, while long-term disruptions often demand structural adjustments such as supplier diversification, capacity relocation, or regulatory renegotiation. The cumulative losses associated with prolonged disruptions can far exceed the immediate operational impact, particularly in industries with high compliance and quality assurance requirements.

For highly regulated sectors such as medical device manufacturing, the implications of disruptions are particularly acute. Supplier bottlenecks cannot be addressed simply by switching to an alternative vendor, as regulatory certifications and quality audits may take months or even years to complete. Similarly, disruptions in transportation or workforce availability can directly jeopardize compliance with product traceability and safety regulations. Financial and regulatory risks, in this context, are not just external pressures but fundamental constraints on how resilience can be operationalized.

Most of these challenges can be mitigated through deliberate resilience-building in global production and supply networks. Effective risk mitigation—defined as "the strategies, practices, and processes organizations use to manage risks and vulnerabilities in the supply chain" (Manuj& Mentzer, 2008b)—is therefore central to reducing the impact of disruptions. However, resilience requires more than simply listing risks; it demands structured approaches to measuring, prioritizing, and improving capabilities across the supply chain. To support this objective, the Supply Chain Resilience Assessment (SCRA) was developed and has already been successfully applied in 12 industry cases to date (Roessler, Gebhardt, & Augustin, 2023). The methodology provides a systematic framework for evaluating vulnerabilities, benchmarking resilience levels, and defining targeted measures—topics that will be explored in the following chapter.

III. CONCEPTUALIZATION OF THE SUPPLY CHAIN RESILIENCE ASSESSMENT (SCRA)

To systematically strengthen supply chain resilience within complex manufacturing environments, organizations require structured methodologies that extend beyond ad hoc responses or siloed risk mitigation strategies. The Supply Chain Resilience Assessment (SCRA) was developed to meet this need by offering a comprehensive and operationally grounded approach to resilience evaluation, tailored specifically to the realities of regulated manufacturing sectors. Conceptually rooted in the SCOR model and aligned with broader operational excellence frameworks, the SCRA enables organizations to identify vulnerabilities and define prioritized improvement measures across the five core supply chain processes: *Plan*, *Source*, *Make*, *Deliver*, and *Return*.

The SCRA does not exist in isolation but forms one of three core modules within the established Smart Factory Assessment framework (Roessler &Haschemi, 2017; Ziegler, 2017; Roessler &Haschemi, 2019). This broader assessment framework evaluates manufacturing and logistics maturity across Lean Production and Industry 4.0 dimensions. By integrating resilience as a third dimension, the Smart Factory Assessment ensures that organizations are not merely optimized for efficiency under stable conditions but are also prepared to absorb and recover from disruptions. While the SCRA can be implemented independently, it is strongly recommended to conduct the full Smart Factory Assessment. Only through this comprehensive evaluation—combining Lean, digitalization, and resilience—can organizations fully exploit synergies and achieve a robust, agile, and high-performing supply chain. The modular structure of the overall framework, with SCRA as a distinct module, is illustrated in Figure 1.

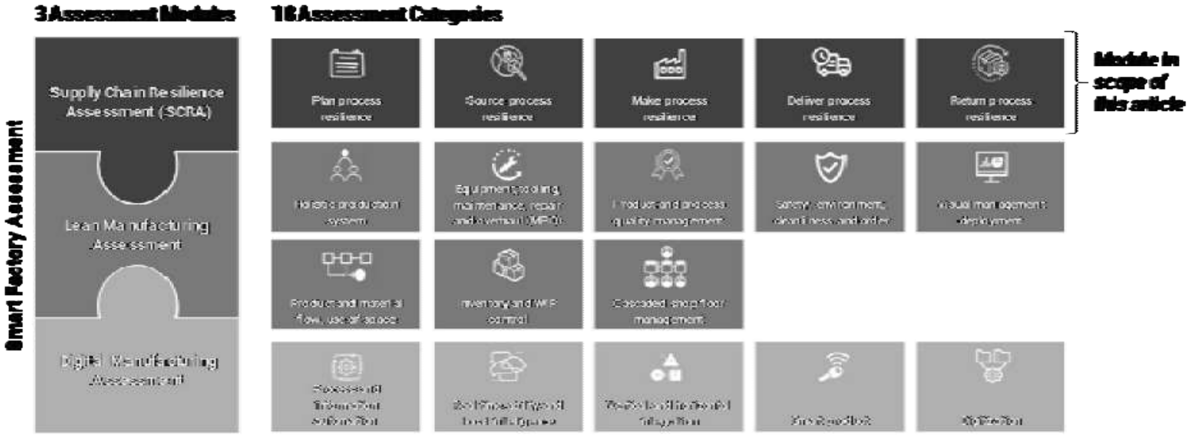

Figure 1: The Supply Chain Resilience Assessment (SCRA) forms an independent module within the comprehensive Smart Factory Assessment.

Conceptually, the full Smart Factory Assessment builds upon a set of foundational maturity models and tools. These include the Rapid Plant Assessment developed by the University of Michigan, the Siemens Production System Screening, the VDMA Guide Industry 4.0 (VDMA, 2015), the Industry 4.0 Readiness Check (Lichtblau & Stich, 2015), McKinsey's digitalization navigation guide (McKinsey & Company, 2015), and the Industry 4.0 Maturity Model (Jodlbauer&Schagerl, 2016). Each of these tools contributes structural elements to the Smart Factory Assessment while the SCRA extends them by incorporating resilience-oriented criteria.
Moreover, the SCRA translates abstract concepts of resilience—often described in academic literature (e.g., Ponomarov& Holcomb, 2009; Pettit, Fiksel, & Croxton, 2013; Linkov& Trump, 2019; Katsaliaki, Galetsi, & Kumar, 2022)—into a practical, expert-led evaluation framework. Unlike conventional risk assessments that emphasize the identification of potential hazards, the SCRA focuses on diagnosing process-level capabilities that determine how well an organization can respond to and recover from disruptions. This shift aligns with current thinking in resilience research, which advocates for embedding adaptive and absorptive capacities directly into supply chain processes (Christopher & Peck, 2004; Kleindorfer& Saad, 2005). The structured concept and systematic data capturing approach underlying the SCRA are outlined in Figure 2.

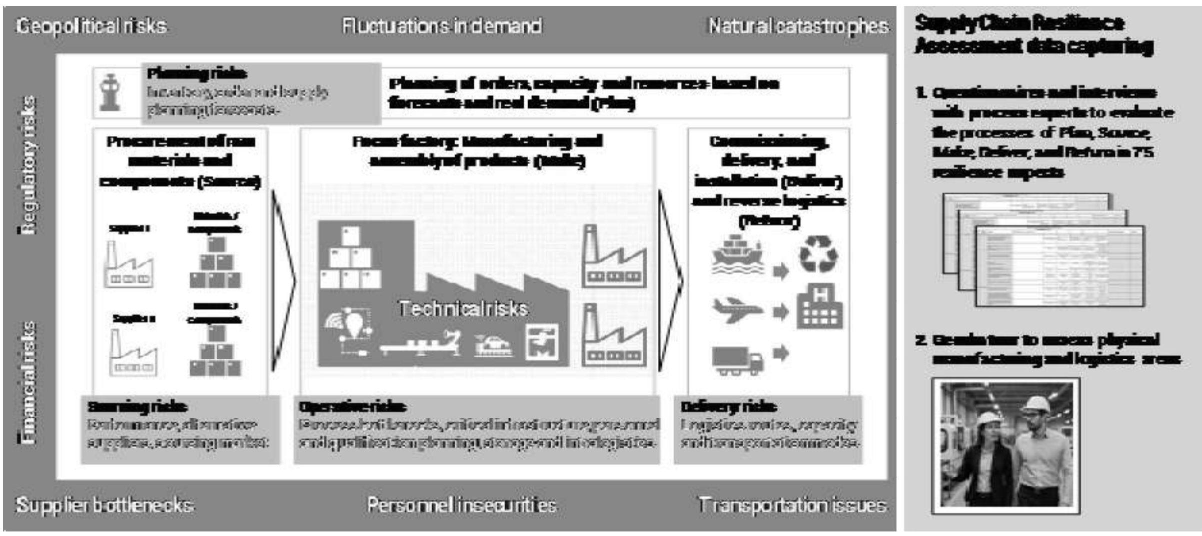

Figure 2: Systematics, concept, and approach of the Supply Chain Resilience Assessment.

In methodological terms, the assessment comprises 75 resilience aspects, categorized under the five SCOR processes. These aspects are adapted from existing resilience frameworks and contextualized for industrial application, see further Roessler (2025). The SCRA also supports integration into Lean Production Systems (VDI, 2012), allowing deployment through existing operational excellence structures. This enhances not only the consistency of implementation across sites but also promotes organizational learning by fostering cross-functional dialogue and benchmarking.

The following sections (3.1–3.5) detail how resilience is conceptualized and assessed within each SCOR process. By embedding resilience into planning, sourcing, production, delivery, and reverse logistics, the SCRA offers a holistic yet operationally actionable methodology that enhances supply chain resilience without compromising performance or compliance—particularly in highly regulated industries such as medical device manufacturing.

3.1 Core process: Plan:

Planning is a foundational activity in supply chain management, serving as the strategic compass that allows organizations to navigate uncertainties, optimize resource allocation, and accurately forecast and schedule customer demand. Effective planning ensures that upstream procurement, production, and downstream logistics processes are synchronized, thereby reducing variability and inefficiency. A resilient planning process not only supports day-to-day operational stability but also strengthens the supply chain's ability to adapt to sudden shocks. Beyond short-term forecasting, resilient planning includes scenario analysis, sensitivity assessments, and stress testing of assumptions to identify weak points before disruptions occur.

Sales and demand forecasting are particularly crucial subcomponents. A mature planning system should provide end-to-end transparency, ideally digitized and capable of incorporating real-time data and scenario-based approaches. This enables organizations to account for uncertainties such as volatile demand, fluctuating lead times, or regulatory delays. Mentzer et al. (2006) emphasize that accuracy and transparency in forecasting are vital to ensure that companies can maintain service levels under volatility. The ability to rapidly update plans and communicate them across the organization is equally important, as delays in information flow often exacerbate disruptions.

In compliance-critical sectors such as medical devices, planning must also integrate compliance-related milestones. Long approval cycles for new products or process changes, clinical validation requirements, and market-entry licenses necessitate careful alignment of capacity, demand forecasts, and regulatory timelines. Failure to incorporate these regulatory lead times into planning processes can result in bottlenecks that are difficult to resolve once disruptions occur. Thus, resilient planning in this context is not only about efficiency but about compliance assurance, ensuring that production and market supply remain stable even when disruptions occur elsewhere in the value chain.

3.2 Core process: Source:

Sourcing represents a critical pillar of resilience because it determines the continuity of input flows into the supply chain. Effective sourcing ensures that the materials, components, and services required for production are consistently available in the right quality, at the right cost, and at the right time. Disruptions in sourcing can have a disproportionate impact because they directly affect the ability of manufacturing systems to operate, making procurement risk management a cornerstone of resilience.

Key resilience strategies in sourcing include supplier diversification, dual- or multi-sourcing arrangements, and continuous supplier monitoring. These strategies reduce dependency on single suppliers or regions, mitigating the risk of bottlenecks caused by political instability, natural disasters, or quality failures. Kraljic's (1983) seminal work underlines the importance of segmenting suppliers and strategically managing risks in order to strengthen resilience. In practice, this involves not only securing secondary suppliers but also regularly validating them to ensure readiness when disruptions occur.

Supplier relationship management also plays a significant role in sourcing resilience. Transparent and collaborative relationships with suppliers enable quicker communication, faster response to disruptions, and greater alignment on risk mitigation measures such as safety stock levels or contingency transport options. On the inbound logistics side, effective sourcing also requires contingency plans with Third-Party Logistics providers to ensure that raw materials can reach production sites despite potential transportation disruptions.

In medical device manufacturing, sourcing resilience faces additional complexity due to regulatory obligations. Suppliers must be qualified according to standards such as ISO 13485, and audits must be conducted to ensure compliance with quality management systems. This makes rapid supplier switching difficult during disruptions. Documentation requirements, validation processes, and requalification procedures must therefore be built into sourcing resilience strategies. As a result, successful sourcing resilience in this industry balances regulatory rigor with flexibility, ensuring that approved alternative suppliers can be activated swiftly without compromising compliance.

3.3 Core process: Make:

The make process is the operational core of production companies, determining both the quantity and quality of output. Its resilience directly influences the ability of organizations to sustain deliveries under stress. Evaluating this process helps firms to optimize workflows, minimize costs, and safeguard product quality, while at the same time ensuring that production systems can adapt to unexpected conditions.

Agility within manufacturing is a defining feature of resilience. Christopher (2000) highlights that flexible production processes, modular setups, and the ability to reconfigure production lines quickly are essential to respond to disruptions. Resilience in make processes is shaped by the availability of critical inputs (materials, personnel, equipment) as well as infrastructure elements such as energy, internet connectivity, and climate control. Building redundancy in these areas—through backup systems, preventive maintenance, and cross-trained staff—ensures that disruptions in one resource do not halt the entire operation.

Support systems are equally important for enhancing resilience in make processes. Real-time production monitoring allows deviations to be detected and corrected early, while rapid maintenance and repair systems minimize downtime when equipment fails. Quality feedback loops also play a resilience role by ensuring that defects are identified and contained before they propagate across the production chain.

For medical device manufacturing, resilience in make processes is closely linked to regulatory requirements. Production lines often operate under Good Manufacturing Practice (GMP) regulations, which require validated and documented processes. Deviations or process changes can trigger lengthy requalification procedures. Consequently, resilient make processes must include predefined strategies for rapid requalification, ensuring compliance while maintaining output. In this way, resilience in make is not only about flexibility but also about regulatory agility, ensuring that operational continuity can be sustained without compromising patient safety or product approval status.

3.4 Core process: Deliver:

The delivery process is the customer-facing component of the supply chain and directly shapes perceptions of reliability and trustworthiness. Even when production operates smoothly, failures in delivery can severely affect customer satisfaction, revenue flow, and regulatory compliance. Delivery resilience therefore encompasses the ability to ensure order fulfilment despite disruptions in logistics, transport, or distribution infrastructure.

Several measures enhance delivery resilience. These include identifying potential bottlenecks in transport routes, maintaining backup distribution centres, and securing access to alternative transportation modes such as rail, air, or multimodal options. McKinnon et al. (2015) highlight the importance of real-time tracking systems, which allow companies to monitor the location and condition of shipments and to communicate proactively with customers in case of delays. Effective communication is in fact one of the most important resilience levers in delivery, as transparent updates reduce uncertainty and maintain trust even when disruptions cannot be fully avoided.

Delivery resilience also benefits from data integration across the supply chain. Seamless information exchange between production, warehousing, transport, and customer-facing systems enables organizations to react faster when issues occur. This prevents fragmented responses and ensures that mitigation strategies—such as rerouting shipments or prioritizing critical orders—are implemented consistently.

In medical device supply chains, delivery resilience is further challenged by regulatory requirements for traceability and product integrity. Certain devices require temperature-controlled transport or special packaging to ensure sterility. Documentation requirements may also mandate that every step in the delivery chain is traceable and auditable. Disruptions therefore not only delay deliveries but also risk non-compliance, amplifying the consequences. Building resilience in this context means implementing robust monitoring systems, validated transport processes, and alternative logistics networks capable of meeting stringent quality requirements.

3.5 Core process: Return:

The return process, including reverse logistics, is an often overlooked but strategically significant element of supply chain resilience. Effective return systems ensure that products requiring repairs, replacements, or recalls are managed efficiently, while also supporting recycling and end-of-life management. In resilience terms, returns safeguard customer trust and brand reputation, as they determine how quickly and effectively a company can respond when products fail in the field or when regulatory interventions necessitate recalls.

Guide & Van Wassenhove (2009) emphasize that closed-loop supply chains, which integrate forward and reverse flows, transform returns into opportunities for value recovery and risk mitigation. In practice, resilient return systems require well-documented procedures, trained personnel, and IT systems capable of full traceability. Coordination across departments—logistics, customer service, quality assurance, and regulatory affairs—is essential to ensure timely and consistent execution.
In regulated industries such as medical devices, returns carry additional weight due to strict compliance obligations. ISO 13485 (2016) and FDA 21 CFR Part 820 (2020) mandate documented recall procedures, traceability across the product lifecycle, and adherence to reporting timelines. Delays or errors in the return process can lead not only to customer dissatisfaction but also to regulatory penalties and reputational damage. A resilient return process must therefore be both efficient and compliant, capable of handling large-scale recalls if required.
To strengthen resilience in returns, organizations should invest in proactive training, integrate reverse logistics into overall supply chain strategies, and conduct regular stress tests of recall procedures. When these measures are in place, the return process becomes more than a risk management function: it becomes a differentiator, demonstrating reliability and responsibility even in crisis situations.

Together, these five SCOR-based core processes provide a comprehensive foundation for evaluating resilience across all operational dimensions of a manufacturing supply chain, not only in the medical device industry. By structuring the assessment around well-defined and industry-relevant criteria, the SCRA ensures that vulnerabilities are identified not only in isolated functions but across the entire end-to-end value chain. However, the methodology's value lies not only in its conceptual resilience but also in its practical application. The following chapter outlines the procedural framework and real-world implementation of the SCRA, demonstrating how the approach translates into actionable insights and measurable improvements within industrial settings.

IV. PROCEDURE AND PRACTICAL APPLICATION

4.1 Procedure

The SCRA is structured into four clearly defined steps, each designed to build on the previous phase and to ensure that the assessment is comprehensive, evidence-based, and actionable. These steps are not purely sequential but include intermediate reflection points that allow for feedback, alignment, and validation. Figure 3 illustrates the process, which typically spans two to three weeks from initial planning to final presentation of results.

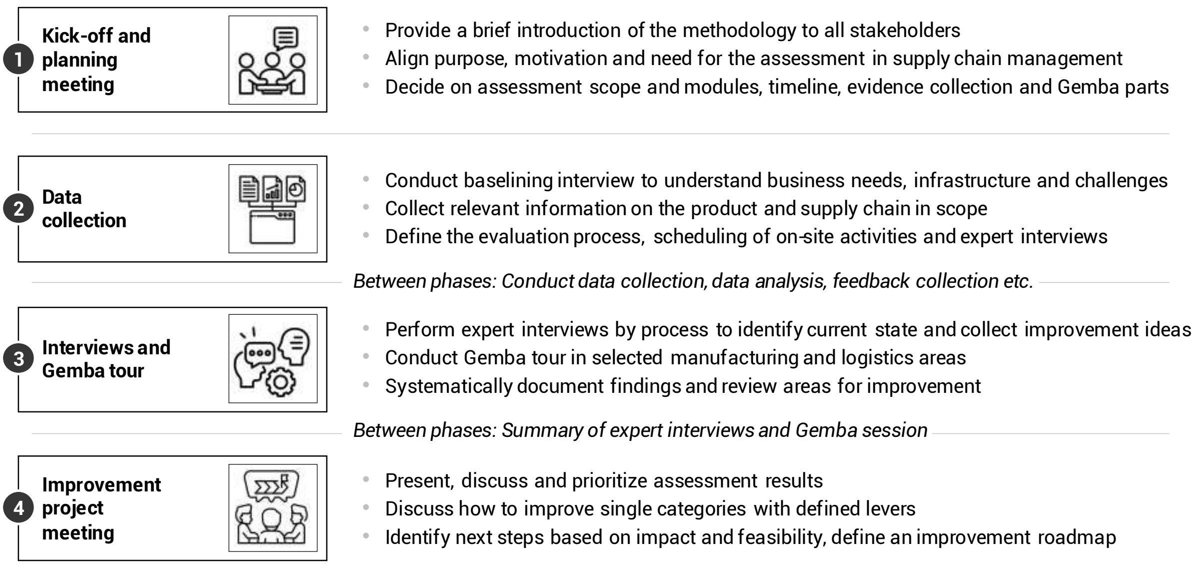

Figure 3: The four-stage process for the expert-based SCRA.

The **first step** of the process is a structured kick-off meeting, bringing together the assessment experts and the core team of the participating organization. The objectives of this step are to clarify the assessment scope, agree on the relevant supply chain processes to be examined, and identify the stakeholders who will participate in interviews and workshops. At this stage, the assessment team also reviews available documentation, such as organizational charts, supply chain and process maps, floor plans, performance KPIs, and business continuity plans. This ensures that the experts enter the data collection phase with a clear understanding of the organization's structure and challenges. Equally important, the kick-off serves to align expectations: management defines its priorities and concerns, while the assessment team explains the methodology and the scoring system. This early alignment fosters trust and reduces resistance later in the process.

Following the kick-off, the **second step** focuses on collecting structured information on the organization's current resilience practices. Data collection is carried out both remotely and on-site, using standardized templates to capture information across prioritized resilience aspects of the SCRA framework. This includes reviewing policies, risk registers, audit reports, logistics data, and supplier lists. The purpose is to establish a factual baseline that complements the qualitative insights later obtained in interviews. Between steps, preliminary data analysis is conducted, identifying potential strengths and weaknesses that will be explored in greater detail during the interviews. This iterative approach ensures that the later discussions with stakeholders are focused and evidence-driven rather than exploratory alone.

The **third step** represents the heart of the SCRA, where the assessment team conducts in-depth expert interviews and a Gemba walk through the production and logistics facilities. The interviews are structured around the SCOR processes—*Plan, Source, Make, Deliver*, and *Return*—and follow lead questions tailored to each resilience aspect. Involving both managers and operational staff ensures that findings reflect the organization's reality rather than only management's perspective. The Gemba tour allows the assessors to validate interview responses through direct observation, for example, checking whether safety stocks are actively managed, whether alternative transport routes are documented, or how quickly equipment reconfigurations could be performed. After the interviews and walk, the assessment team consolidates and summarizes key observations, often in direct discussion with stakeholders, to confirm accuracy and avoid misinterpretations. Table 2 provides a sample of five selected resilience aspects from the assessment sheet, demonstrating how these aspects are evaluated to measure resilience in different operational areas, simplified based on Roessler (2025).Each of the 75 resilience aspects is rated, and the supply chain's overall maturity level is assessed on a scale from "Level 0: No implementation" to "Level 4: Part of the culture". The rating is supported by a set of relevant lead questions. Following the evaluation, the assessment experts work in close collaboration with process experts from *Plan*, *Source*, *Make, Deliver*, and *Return* to develop specific recommendations and actionable measures. These results are compiled into a final report, which includes a presentation of the current and target maturity levels for each subcategory. Maturity levels, initially assessed on a 0–4 scale, were linearly transformed to a 0–100 % scale for improved readability and cross-site comparison.

Table 2: Selected resilience aspects of the SCRA, lead questions and their manifestations in five levels (Lvl.).

Resilience aspect	**Lead questions**	**Lvl. 0: No implementation**	**Lvl. 1: First implementation**	**Lvl. 2: Standard implementation**	**Lvl. 3: Broad implementation**	**Lvl. 4: Part of the culture**
***Plan* process: Forecast accuracy monitoring**	- Are you measuring forecast accuracy? - Are actions taken based on deviations?	No KPIs or forecast metrics are used.	KPIs defined, but accuracy inconsistently tracked.	Forecast accuracy measured and actions are reactive.	Regular accuracy monitoring with defined corrective actions.	Continuous improvement via PDCA, benchmarking, and predictive monitoring.
***Source* process: Multi/dual sourcing strategy**	- Do you have multi or dual sourcing for critical components? - Are second sources regularly tested and validated?	No secondary sourcing options exist.	Alternatives considered but not implemented.	Some second sources are implemented but untested.	Second sources are available and validated for most critical parts.	Dual sourcing is a strategic standard with continuous improvement.

Make **process: Robot work cell reconfiguration**	- How are robots and tools standardized for quick reconfiguration? - Is reconfiguration potential reviewed and planned?	Reconfigurability is not systematically planned or reviewed, no standard robot or tool suppliers defined	Standard robot and tool suppliers defined and considered during planning, no structured reconfiguration approach	Standard robots and tools considered during planning, potential for reconfiguration evaluated for majority of robot cells	Design for reconfigurability is a standard, reconfiguration potential known for all robot cells	Design for reconfigurability and scenario planning are standards, sophisticated plans how to deal with challenges exist for all robot cells
Deliver **process: Contingency planning with Third-Party Logistics (TPL)**	- Are your TPL providers required to maintain contingency plans? - How often are these plans validated or tested?	No contingency plan exists.	Plans exist for high-risk TPLs but unverified.	Documented plans exist for some high-risk TPLs.	Verified plans exist for most critical TPLs.	Comprehensive, regularly tested plans for all high-risk TPLs.
Return **process: Employee training on returns**	- Are employees trained in reverse logistics procedures? - How often is this training updated?	No training for return processes.	Basic training for logistics team only.	Training includes staff in customer service and ops.	Regular training and updates provided.	Integrated returns training as part of onboarding and broader learning and development programs.

The **fourth step** is the improvement project meeting, where results and recommendations are presented to the management team. In this meeting, the current maturity scores are shown alongside target levels for each resilience category, typically using spider charts and traffic-light visuals for clarity. Crucially, the focus is not on abstract scores but on concrete improvement measures. The recommendations are prioritized into quick wins (short-term, low-cost measures that yield rapid results) and strategic initiatives (longer-term projects requiring investment and cross-functional coordination). Examples include introducing forecast accuracy monitoring, establishing secondary sourcing arrangements, or integrating resilience into supplier audits. The meeting also encourages dialogue: management and operational leaders can question, refine, or adapt recommendations, ensuring ownership and commitment to follow-up actions.

Overall, the four steps create a balance between analytical rigor and practical feasibility. The process does not require large-scale digital infrastructures but leverages structured templates, expert facilitation, and site-specific validation. By the end of the cycle, organizations receive both a quantitative resilience score and a qualitative roadmap of improvement measures, creating a foundation for continuous monitoring and benchmarking across sites.

4.2 Practical application results

This section presents practical findings from the assessment's application in multiple industrial settings.The SCRA has been applied in several medical device manufacturing environments, providing both site-specific insights and broader lessons across the industry. A representative case study involved a mid-sized facilitythat produces diagnostic equipment and relies on a global supplier base for critical components. The site faced challenges such as dependency on a handful of highly specialized suppliers and limited visibility into its inbound logistics. These vulnerabilities became particularly evident during the COVID-19 pandemic, when disruptions in transportation and supplier reliability threatened production continuity.

The assessment revealed that the most significant weaknesses were concentrated in the *Source* process. Over-reliance on single-source suppliers, insufficient transparency in supplier risk profiles, and a lack of contingency plans were identified as key concerns. Together with the site's procurement and supply chain managers, the assessment team developed a set of targeted measures, including the optimization of safety stock policies, systematic reviews of critical suppliers, and the exploration of alternative outbound transport routes. Within just four months of implementation, these measures raised the sourcing resilience score from 49% to 68%. Figure 4 provides an illustration of how such results are visualized

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within the SCRA, showing current versus target maturity levels and listing illustrative improvement measures.

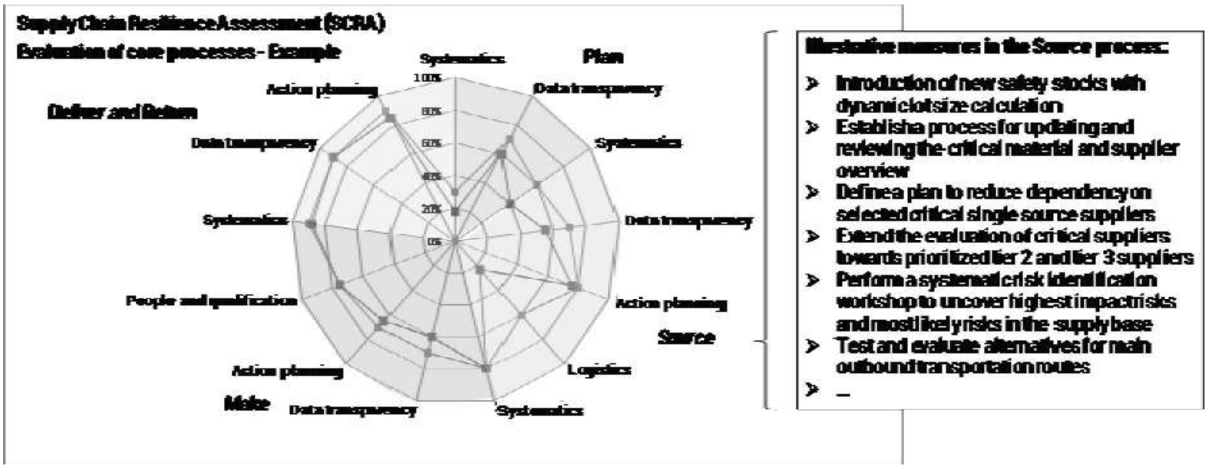

Figure 4: Illustrative result presentation of the SCRA (with current and target values) and example measures in the *Source*process.

The experience at this site demonstrates how the SCRA moves beyond abstract evaluation to generate actionable outcomes. Importantly, the recommendations are not uniform but tailored to the facility's operational context and regulatory requirements. Short-term operational improvements, such as updating supplier databases and introducing risk workshops, can be implemented in weeks, while strategic initiatives like dual sourcing or supplier requalification require longer horizons and more resources. This distinction ensures that resilience improvements are practical and realistically achievable.
Looking beyond this single example, aggregated results from four more SCRA implementations over a two-year period provide a more comprehensive perspective on the methodology's impact. Table 3 summarizes the average maturity scores across the five SCOR processes at the time of the initial assessments and six months later. Consistent improvements are visible in all areas, ranging from +6 to +10 percentage points. The largest gains in percentage points (p.p.) were observed in *Plan* (+10 p.p.) and *Source* (+9 p.p.), underscoring the critical importance of accurate forecasting, scenario planning, supplier diversification, and transparent risk monitoring.

Table 3: Average maturity score improvements across four manufacturing sites in the medical device manufacturing industry.

Process	Start (%)	After 6 months (%)	Change
Plan	64	74	+10
Source	67	76	+9
Make	72	78	+6
Deliver	66	73	+7
Return	65	72	+7

Improvements in the *Make* process (+6 p.p.) were more modest but nonetheless meaningful. Progress was most evident in areas such as equipment reconfigurability, faster maintenance procedures, and cross-training of personnel. However, regulatory requirements and the need for validated processes in medical device manufacturing limit the speed of change in production compared to planning or sourcing. Similarly, the *Deliver* (+7 p.p.) and *Return* (+7 p.p.) processes showed incremental improvements. Measures such as strengthening contingency plans with logistics providers, introducing alternative transportation modes, and formalizing reverse logistics procedures contributed to these gains. Although the improvements in these processes are less pronounced, they play an essential role in maintaining customer trust and regulatory compliance during disruptions.
Beyond numerical outcomes, participants consistently emphasized the cultural benefits of the SCRA. The structured interviews and workshops encouraged dialogue between departments that often operated in isolation, such as procurement, logistics, and quality management. This cross-functional exchange fostered a shared language around resilience and helped align management priorities with operational realities. Several managers highlighted that the process itself—particularly the Gemba sessions—raised awareness of resilience challenges in ways that internal discussions alone had not achieved.

Taken together, both the site-level and aggregated findings demonstrate that the SCRA serves a dual role: it provides a relatively objective measurement of resilience maturity while also acting as a catalyst for organizational learning and change. By combining structured assessment with practical recommendations, the methodology ensures that resilience becomes not just an abstract ambition but a concrete element of operational excellence.These results underscore the assessment's capacity to drive both structural and cultural transformation in supply chain resilience.

V. CONCLUSION

The Supply Chain Resilience Assessment (SCRA) is an expert-led methodology tailored to production facilities and their connected supply networks, focusing on strengthening resilience. As an integral element of holistic Business Continuity Management (BCM), the assessment identifies systemic vulnerabilities and defines actionable, site-specific improvement measures. Conducted within approximately two days (excluding preparation), the approach extends traditional optimization goals—such as quality, cost, and time—by explicitly incorporating resilience as a fourth performance dimension. This enables organizations not only to sustain operational efficiency, but also to adapt more effectively to disruption.

Applications of the SCRA in regulated industrial environments have demonstrated tangible benefits. Aggregated follow-up assessments across multiple sites revealed average maturity gains of 6–10 percentage points within six months, with the largest improvements observed in the Plan and Source processes. These values, normalized from a 0–4 scale, support the recommendation of an 80% resilience maturity target as an economically balanced benchmark. Achieving full resilience may be theoretically possible but is often impractical due to diminishing returns.

Beyond measurable outcomes, the SCRA fosters cross-functional awareness and promotes a shared understanding of resilience among decision-makers and operational staff. It translates abstract concepts—such as resilience and continuity—into practical, manageable steps at the site level. The method's diagnostic rigor and low implementation threshold make it particularly valuable in regulated settings, where responsiveness must be balanced with compliance.

To fully leverage synergies between Lean, digitalization, and resilience, organizations are encouraged to embed the SCRA within a broader Smart Factory Assessment framework. Even in the absence of extensive digital infrastructure, the resulting insights are directly linked to performance and readily actionable. For policymakers and regulators, the methodology offers a means to operationalize resilience beyond abstract principles, providing measurable indicators that could support audits, certifications, and policy initiatives.

While the present study demonstrates the SCRA's utility in medical device manufacturing, its broader applicability to other regulated sectors—such as pharmaceuticals, aerospace, or food production—should be further investigated. Future research should also explore integration with digital supply chain twins, predictive analytics, and ERP systems to enhance responsiveness and scalability. In addition, the development of quantitative models to assess financial and operational outcomes before and after implementation would improve its empirical robustness and support investment decisions.

In sum, the SCRA offers a pragmatic, scalable pathway to embed resilience into supply chain operations—empowering organizations to withstand disruption without compromising efficiency or overinvesting in redundancy.

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