

Building A Resilient Supply Chain

How to Mitigate Supply Risk and Enhance Patient Care





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INTRODUCTION

Uncertainty in Healthcare Supply Chains and The Impact on Patient Care

More than ever before, supply chains face greater threats of disruption. Major events like the COVID-19 global pandemic and the resulting shortage of semiconductor chips, the closure of the Suez Canal, and the Russian invasion of Ukraine have demonstrated the fragility of global supply chains that has a far reaching impact on sectors everywhere.

The healthcare industry is not immune. Medical original equipment manufacturers (OEMs) need to understand these risks—and how to minimize and/or mitigate them.

“The pandemic highlighted how important medical devices are to our health care system and public health. The shortages hit hard... for such critical devices as ventilators, test supplies, and even some of the equipment needed to administer vaccines. When devices go into shortage, patients everywhere are impacted.”

- U.S. Food & Drug Administration¹



Supply chain disruptions are not merely an inconvenience - they can devastate a company's bottom line while also impacting patients who require life-saving medical devices.

- ! Resulting delays in production and product release can cause lasting damage to revenue and reputation
- ! Interruption of supply chain and alternative components may impact the efficacy, safety and longevity of medical devices
- ! Ad-hoc suppliers in the healthcare supply chain without proper qualification and management may lead to enforcement actions from the US Food and Drug Administration (FDA) and other international regulatory bodies
- ! The interconnectivity of many medical devices can introduce additional and liabilities, such as cybersecurity and data privacy, from suppliers to OEMs
- ! Counterfeit parts pose a significant risk to overall product quality and regulatory compliance, and can also negatively impact patient outcomes and safety

But perhaps most significantly, supply chain volatility can delay the delivery of life-saving medical devices and equipment to healthcare professionals around the world.

Fortunately, medical device companies can anticipate uncertainties and strengthen resilience to cope with the inevitable supply chain disruptions.

Strategies to Mitigate Supply Chain Disruptions:



Design for Supply Chain



Qualify Alternative Supplier Base



Align Sources Early



Plan for Scale



Anticipate and Proactively Manage Risk

The Healthcare Supply Chain is Unique

The latest version of the nonprofit safety group Emergency Care Research Institute's (ECRI) annual health technology hazards report identifies 'supply chain shortfalls' as one of the greatest dangers facing the healthcare industry, an enduring remnant of the global coronavirus pandemic. According to ECRI's researchers, the lingering supply chain management issues point to, "the need to progress from just trying to cope during the pandemic to building stronger and more resilient processes, leveraging the innovations developed, and the lessons learned along the way."²

"When supply chain issues strike, the resulting production and delivery delays compromise patient care", says Geoff Gates, Cleveland Clinic's Senior Director of Technology for supply chain and support services.

"As one clinical department head put it, 'You could literally shut down our department if we don't get the supplies that we need.' We take that very seriously," Gates told HealthTech magazine in November 2022. "What we do and whether we get it right has a real impact on day-to-day operations."³

Overcoming supply chain management challenges begins with engaging the right suppliers during product research and development prior to manufacturing. This enables OEMs to identify local suppliers who can quickly deliver components during prototyping and the initial production run. The next step is to expand the supply base network to incorporate qualified suppliers, who can enable commercial scale-ups with optimal costs.

The goal is to strike the right balance of local and global suppliers and negotiate the best prices possible to support mass production.

Implement these best practices to build a comprehensive network of local and global suppliers to avoid sourcing issues:



Utilize Dual Sourcing

Apply dual sourcing strategies for volume or complex components to strike the necessary balance between cost optimization and risk reduction.



Avoid Supplier Risks

Ensure your supply chain consists of qualified suppliers and components to avoid unfortunate and potentially time-consuming obstacles due to regulatory compliance.



Bring Teams Together

Bring engineering and supply chain teams together to ensure the design incorporates readily available components and avoids high risk components.



Understand Early Sourcing Risks

Ensure there is a clear understanding of the potential impact of having to source qualified parts during the early stages of the design phase.



Establish Demand Forecasts

Engage the supply base during the design phase to establish clear demand visibility. This enables a fulfillment model that strategically positions inventory and establishes accurate replenishment lead-times across all supply chain nodes.

Design for Supply Chain

Mitigating supply chain disruptions starts at the drawing board. Product resilience requires alignment between engineering and the supply chain—and the best opportunity to succeed at this begins at the very early stages of product design.

Historically, the product design phase and supply chain management have existed in separate silos, with supply chain being introduced too late in the design phase. Today's supply chains are global, interconnected, and extremely complex, so it is imperative to incorporate the supply chain into the design phase early and often. This will improve production planning, demand forecasting and increase supply chain resilience.



Early engagement between your engineering and supply chain organizations during the design phase is critical to the product's successful ramp and ongoing production.

The processes and tools necessary to manage disruption are much easier and less costly to address during the design phase rather than toward the end of a product's lifecycle. Developing a proactive, end-to-end solution from the outset through the collaboration of design and engineering teams with an understanding of supply chain considerations will help manufacturers anticipate and manage risk.

A design for supply chain (DfSC) strategy provides the flexibility to manage ongoing changes to designs. It gives designers the visibility to recognize common mistakes that lead to an unstable supply chain. It enables a level of agility that avoids costly disruptions by planning for alternate parts and timely submission and approval from regulatory bodies. It can even extend product lifespan by ensuring the continuity of replaceable components.



Align Sources Early

Medical device manufacturing today requires OEMs to think ahead. It is important to consider the complete product lifecycle and use the upfront design process to identify and mitigate risks later in the product lifecycle that may impact the patient experience.

Therefore, addressing sourcing and other supply chain management considerations as a product moves through alpha and beta builds to volume builds is a must. That said, it can be difficult to answer the question, 'Where are we going to get our parts from?' due to the sheer volumes of sourcing options and wide variances in lead times and pricing.

That's why supply chain partners or sourcing engineers should be engaged early in the design process before functional architecture and block diagrams are completed. The right sourcing strategy takes into account availability, lead times, cost, and quality, and is top priority when it comes to securing parts.

"Before 2020, many engineering teams viewed the supply chain as part of manufacturing transfer on the back-end of development. Now, product development teams are driving more supply chain awareness early in the design phase, thinking more about multi-sourcing and how to have redundancy. The ultimate goal is ensuring healthcare providers around the world have the medical devices they need to deliver the highest level of patient care."

— Kevin McFarlin, Design Engineering
Director of HealthTech, Celestica



Manufacturers need to know where critical supply chain vulnerabilities exist within the design. These include components like power supplies and multiprocessors that are core to the function of the device. Critical parts also include elements that differentiate the product. As soon as the critical components are known, the right suppliers must be chosen carefully.

Consideration must also be given to passive components. Although considered commodity items, they could pose a struggle if they became scarce, delayed, or unobtainable. When sourcing such supplies, designers should have not just two alternates, but five or six to prevent the production line from shutting down due to the lack of a small component such as a capacitor or a resistor.

For optimal effectiveness, the design team should include the sourcing engineer and suppliers. Suppliers can contribute in a positive way to design by guiding engineers towards materials and components that are more stable than others. With such upfront awareness, designers can consider options such as incorporating dual footprints or using a series of processors of the same core but different variants.

Scale With an Eye to Supply

Advance planning is also critical to avoiding supply chain disruptions between prototyping, new product introduction, and ramping production. For rapid prototyping during the “learn-and-burn” phase, engineers should not only collaborate with prototyping suppliers, but also with their final production volume suppliers. Their feedback is essential before committing to a design and investing in verification testing and is a critical step in meeting all qualifications and avoiding cost overruns and delivery delays.

“Supply base development and a company’s revenue growth roadmap need to work hand in hand. Developing a supply base is not a sequential process; it needs to be an iterative process that works in conjunction with a company’s growth plans. It is crucial to understand how the revenue growth strategy affects an organization’s commodity spend profile, how much the commodity profile changes and what strategies are needed to deploy for a future supply base. Coordination of these two processes ensures companies establish a stable foundation for commodities which in turn supports revenue growth plans. Collaboration between an organization’s sales and supplier development teams will accelerate time-to-market and deliver quality that improves patient care.”

— James Reif, Director of Supply Chain Management Solutions, Celestica

For scaling production, preparation is key. One good practice is maintaining a preferred supplier list for all key commodities. These strategic partners have capacity reserves and tooling in place, especially for the production of hard tools that may have a long lead time. When it comes to fast-ramping, it's critical to get an early understanding of the short- and long-term manufacturing strategies and the clear-to-build plan. How many suppliers will be needed on your available list to really enable rapid scaling?

“Companies should be sharing research and development roadmaps with their supply chain and sourcing engineering teams to ensure they are aware of both the current projects but also the upcoming plans for the next 3-5 years.”

— James Reif, Director of Supply Chain
Management Solutions, Celestica

Regionalization

Supplier strategies have to consider end-market requirements, overall landed cost, local and global trade regulations and government policies. In some cases, a product may launch in one region and transfer to another as production ramps (e.g. to a lower cost region). It is also important to understand the form factor and utilize total landed cost analytics. There is a correlation to the size of the component and logistics costs, so applying total landed cost analytics will help in your decision-making process and help determine how the supplier location is factored in.



Ensure Supply Chain Flexibility

Creating a plan for supply chain resilience requires additional considerations even after the design freeze. Buffering inventory and looking for alternative parts and more suitable suppliers can provide the flexibility needed to mitigate possible risks and react to future constrained markets. Additionally, consider long-term partnerships with suppliers who have the desire to grow with you.

When changing components in the healthcare industry, it's particularly important to meet US and international regulations and ISO standards. Change becomes more challenging downstream in the design cycle after investing effort into verification testing and regulatory approval. Having well-established design failure modes and effects analyses can help manufacturers weigh the risks against the effort. Some components are easier to qualify and replace. Critical parts such as ones contributing to the primary function or a differentiating feature of the product need to be identified and de-risked early, backed by a robust supply chain.

"For those critical items, you're probably going to write a letter to file with the FDA, with some verification evidence that says, 'This is a like-for-like replacement,'" says Celestica's Kevin McFarlin. "Most design iterations take about three months to turn through the system and test. For greater efficiency, it is better to build those up in a bulk change."

Build a Resilient Supply Chain



Fully managing supply chain risk across the entire product lifecycle involves early planning, continuous measurement, and a balance of both proactive and reactive strategies.

Proactive risk management involves understanding where components are derived from, assessing their potential risks, and considering alternate source selections. Having the ability to react quickly in the case of unforeseen instances is essential for a resilient supply chain.

Historically, supply chain performance was measured in terms of on-time delivery and quality. However, issues with delivery or quality only appear after the adverse event has already occurred. Mitigating these issues requires shifting to a proactive approach.

Manufacturers can use predictive analytics to measure the elements that cause risk (leading to delivery delays or quality issues) and develop metrics around those elements. For instance, if a part is sole-sourced from a supplier that only has one manufacturing facility, that is a multiplier of risk. If there's an issue at that facility, they can't transfer the production to another location. A proactive approach to understanding where potential risk lies will help OEMs to understand, monitor, and mitigate the elements that cause such a stacking effect.

You also need to have a nimble supply chain to manage the reactionary effects. By mapping out your supply base, you can quickly look and see where you're potentially exposed in the supply chain. Picking the right suppliers, finding alternates—and developing the means to shift between them—provides that balance between proactive and reactive sides.



Stay Ahead with Predictive Analytics and KPIs

It's essential to measure the resilience of a supply chain—as well as the sub-supply nodes that reside within it. Predictive analytics begins by asking the right questions to help you itemize the possible elements of risk.

These may include:

- What parts are sole-sourced?
- Which supplier are they coming from?
- Are they coming from a region that's geographically known to have disruptions?
- What is the lead time of the part and is it changing all the time?
- Is it a constrained material?
- Does it involve regulatory compliance?

Once these elements are understood, risk becomes more quantifiable and more predictable for the short and long term. Informed tactics can be developed to address these risks and maintain business continuity.



“It is important to establish a Supplier Management Toolkit that engages with your suppliers through developing capability and value; open, two-way transparent communication; focusing on preventing defects; measuring performance and delivering excellence.”

— Paul Kelly, Senior Director of Strategic Sourcing, Celestica

Plan and Partner for Success

In summary, Celestica recommends medical device OEMs embrace a holistic supply chain strategy:

1. Bring the supply chain into the design phase early in the process.
2. Gain full understanding of supply chain vulnerabilities.
3. Develop tools, processes and organizational alignment that focus on supply chain risk management.
4. Continuously monitor supply chain resilience by leveraging market intelligence and predictive analytics.
5. Build in a proactive plan for qualifying alternative sourcing strategies with regulatory approval and compliance in mind.

The actions recommended in this guide will help you achieve a more predictable, nimble, and resilient supply chain - and a compelling competitive advantage.



Delivering Innovative Solutions That Matter

As a global provider of product lifecycle solutions, Celestica has over 15 years experience working with the world's leading healthcare companies.

From early-stage companies to multinational healthcare brands, we partner with leading healthcare companies to drive better patient outcomes. We provide solutions for design, engineering, manufacturing and supply chain services, combined with a strong commitment to quality and regulatory compliance.

Learn more: www.celestica.com/healthtech

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