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White Paper

How to Improve Resiliency in the Medical Device Supply Chain

Abstract

Supply chain breakdowns in product quality, delivery or availability are a major disruption in the medical device supply industry. In addition to adding time and cost to the device procurement process, insufficient supply of accurately performing parts could endanger patients' health. There are options for second-sourcing resilience, but the most efficient one is to partner with an expert that knows the industry, values existing relationships with manufacturers, and can coordinate the resiliency for the healthcare facility to remove the supply chain management burden from them.

Facilities have tried several methods to address this pressing issue, from managing the supply chains themselves to employing an on-demand method, expanding and contracting primary and secondary suppliers as demand dictates. A movement toward value-based supply chain management, a more holistic view of the entire picture, has gained traction. The consensus is that facilities and manufacturers know they can realize efficiencies by utilizing this method, but some have held off converting due to the fear of relinquishing control or not understanding how to quantify the improvements.

Slowly but surely, engineers and executives are discovering that there are quality partners who can support the technical performance while optimizing the product supply flow. In a survey of 200 C-level executives, 73% indicated that their health systems prioritized value-based supply chain management when targeting ROI. As not all supply chain partners are created equal, teaming up with an ISO-certified company to manage business continuity can provide the one-stop sourcing solution they need to ensure supply chain resiliency, technical quality and cost efficiency.

Challenges with alternative back-up sourcing methods

The Internal Option

The importance of ensuring that the medical device supply chain is running smoothly is obvious. Providing the best possible patient care without interruption takes precedence over all other considerations. Due to the significance of ensuring a resiliency, a healthcare facility may elect to manage its supply chain internally. While at the surface this may seem like a way to decrease steps between inventory shortage and subsequent replenishment, the burden of managing this huge, evolving product suite creates numerous supply chain challenges for facilities.

Integration of merging healthcare facilities

The movement toward rapid consolidation of healthcare facilities creates a lag in merging systems. Newly joined facilities continue operating as essentially independent entities though under one parent organization. The supply chain of each original facility often remains independent from others, and thus does not take advantage of the scale economies on which the new, larger company had planned.

Poor workflow design

Another symptom of having portions of a facility's supply chain disconnected is inefficiency due to poor workflow. Operating multiple supply chain strategies for various products can create redundancy, introducing the simultaneous risk of over-constraining some processes and underspecifying others. Despite these risks, 78% of hospital workers (surveyed by Cardinal Health) still manage their supply chain manually.

Insufficient healthcare IT

Providing decision-makers with supply chain data helps quantify the opportunity of integration. Simply by tracking and analyzing data, healthcare supply chain costs tend to decrease – by 6.54% in one case cited by JAMA Surgery.

Physician preferences

Keeping the supply chain management in-house increases the risk of outside influence on supplier selection. A seasoned physician may prefer a specific product due to personal experience, despite the fact that it might not offer the best patient outcome. While a physician-preferred product might have been the best choice years ago, there might be a newer product that is better for a specific application. Removing individual

physician preference from the product selection process enables the best outcome for the patient. This risk is increasingly difficult when a facility manages its own supply chain.

Cost

After compromised patient care, cost is the next-most prevalent indicator of a non-resilient supply chain. Emergency overnight shipments, fees due to scarce availability of a drug and batched are three examples of excessive costs due to inefficiently managed inventory.

Modular Contracting

Additional Supply Partners

An increasingly popular option to allow the supplier network to absorb the ebbs and flows of demand is to build a modular network of contract suppliers, each of which can be turned on and off. The attraction is obvious; you can adopt a perfectly scalable supplier network with short order periods. In principle, exposure to risk is limited by the nature of the supply agreement if the supplier is not a good fit. However, a Band-Aid solution to a variation in part demand is not usually an optimal solution. Because flexing to a new supplier is typically done in emergency situations, it may not be possible to fully validate a new supplier. Other challenges of a modular contracting model include:

- Competency of contract firms: firms may prioritize agility over delivery accuracy by compromising the skill of temporary workers
- Renewing the contract of a well-matched supplier is dependent on its availability for future orders, not your timing needs
- Communication between ad hoc suppliers and their integration into the entire supply strategy will not be perfectly smooth; this could lead to downstream errors and/or delays

Most importantly, a hastily added supply partner carries with it the risk to a patient's care (and with that, a facility's reputation), with no assurance that the new partner will deliver on its commitments. The level of risk with an ad hoc solution is far higher than the potential gain.

The External Option

The Ideal State (in improvement terms) is to adopt a supply chain strategy that will employ an optimized supply base of reputable firms with minimized time-to-market and cost, leveraging state-of-the-art systems to deliver the best customer solution possible. Known as value-based, this model

aligns the supply partner's goals exactly with the customer's objectives. While the Ideal State is, by definition, never completely achievable, you need a partner with certified expertise to manage your entire supply chain in order to continuously move toward the Ideal State. This will take the burden off of the end user (realizing the benefit of the modular approach), while leveraging the cohesiveness of a single-party coordinator (primary benefit of internal management). Not all supply partners are created equal, however. Ensuring your selected partner is appropriately certified provides confidence in its ability to deliver on commitments and to maintain your reputation.

ISO 22301:2012 – Business Continuity Management System – was written to protect companies from risks stemming from unplanned supply chain disruptions.

Why is ISO-22301:2012 certification important?

No matter the level of preparation, supply chain disruptions are inevitable. Teaming with a certified supply chain partner will ensure the proper level of training for its team to recover from a breakdown or product delivery flow emergency as fast as possible. A recent study in Today's Medical Developments outlined 5 key management metrics for medical device manufacturers:

1. **Corrective action** – automating root cause identification and preventive management improves quality systems
2. **Complaints** – expedience of addressing complaints, using data to understand cycle time for receiving and addressing complaints
3. **Audit findings** – were the audits effective, and what did they find? Outcomes of internal and external audits can lead to new tracking parameters
4. **Medical device reporting** – what percentage of MDRs are being sent to the FDA on time, and can they be automated to improve accuracy?
5. **Nonconformance** – number of nonconforming instances in an audit

The study also stated that 92% of respondent manufacturers viewed quality as defining success for their customers, while only about half stated that

on-time delivery defined success. As a result, it is important to note that a disruption can occur as either a product issue or one due to timing or availability. The above metrics point to a need to collect data to reduce likelihood of a "failure" (or supply chain disruption, in this case).

ISO 22301 does just that. A compliant partner maintains a comprehensive list of mandatory documentation and information, primarily focused around communication channels, risk assessments, business case impacts, data and results of go-and-see monitoring activities. There is significant time and cost investment needed to achieve the certification, including standard procurement, training, documentation management software and internal/external auditing. An ISO 22301-certified partner has committed to the discipline you need to ensure the supply chain solution is as secure and smooth as possible.

There are countless benefits of the certification, including:

- Optimal quality and efficiency centered around Plan-Do-Check-Act (PDCA) loops
- Flexibility during supply interruptions, with the managing partner enacting a continuity plan to minimize damage from the disruption
- The competitive differentiator for customer confidence that accompanies ISO compliance
- Opportunities for continuous improvement through various audit steps and PDCA findings
- Legal and regulatory compliance, decreasing risk of liability that could be found with a modular supply chain

Value Propositions of a Third-Party ISO-Certified Supply Chain Partner

Partnering with an ISO-certified supplier means that the partner company will continuously improve its process as an output of the business continuity plan, meaning that the end user will always enjoy industry-leading best practices. Along with supply chain expertise, a qualified external partner can also provide engineering expertise, regulatory compliance and support for the products they provide as an extension to your team.

With the ever-increasing demands on engineers, a certified, technically proficient supply partner can offer many additional value propositions

to reduce the customer's supply chain-related burden. High-value firms provide CAD models, so their customers can download native files in file formats that match their packaging models. To ensure that each product has a comprehensive technical specification, your engineers should expect a managing supply partner to provide material safety and data sheets, technical data sheets, material certification and compatibility information on all of its products. An ideal one-stop supplier would offer samples for evaluation, packaging and testing in advance of purchase, removing technical risk from the product development process.

The best supply partners maintain embedded engineering and product development support. On the manufacturing side, experienced supplier partners may tool various products if an engineer's desired part geometry is not commercially available.

A high-value supply partner stocks a large inventory, providing rapid sourcing opportunities for a variety of product choices. This model significantly mitigates risk during a supply disruption. Maintaining high inventory quantities also reduces inventory management and storage burdens for a customer's operations team.

As a sourcing partner, there are many value propositions offered by a certified one-stop sourcing partner. The large inventory quantities can enable lower minimum order amounts by passing through volume price breaks from the large orders placed to device manufacturers. Developing a best-practice supply chain resiliency plan also enables a smoother year-over-year budgeting process. Active management of sub-suppliers, ensuring resiliency and streamlining the total number of suppliers help eliminate waste and inefficiency in the supply chain. The supply management team should handle the vetting of second-source suppliers, adding reputable supply partners to the team while protecting your reputation.

The most significant benefit of a one-stop supplier is that the customer's engineers and sourcing agents have one point of contact, which can manage the full supply chain and optimize inventory flow to minimize disruption. By maintaining a huge inventory and managing the supply chain network, a single-source partner addresses the timing and availability components of the process. Further, implementing ISO 22301-certified documentation standards ensures the fastest possible mitigation to a supply disruption when it occurs.

Conclusion

Backup sourcing options are critical in the healthcare industry. Supply chain disruptions endanger patient safety, compromise the reputation of facilities and their device suppliers, and can grossly inflate costs. Facilities have historically employed different methods to mitigate these disruptions, from managing the supply chain internally to adding suppliers on demand. Each approach has benefits and drawbacks.

The most effective alternative to reduce risk of supply chain disruption is to partner with a value-based ISO-certified external partner, passively (to you) addressing a facility's supply chain resiliency. This results in reduced risk, coupled with time and cost savings. An external partner with technical expertise would bring your engineering staff added engineering, product development, operations and sourcing competency without requiring more of your experts' invaluable time.

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