MedAccred℠
Administered by PRI

SUPPLY CHAIN RESILIENCY IN MEDICAL DEVICE MANUFACTURING: THE CORE FOUNDATIONS

INTRODUCTION

The Covid-19 pandemic, combined with regional conflicts, severe weather events, economic and political factors, have all contributed towards a shift in focus from efficiency to resiliency within global manufacturing supply chains.

This is no different for the medical device manufacturing industry, though there are additional challenges for this industry which can create a burden when overseeing current suppliers and selecting new suppliers; and competition with much larger volume industries such as automotive, and consumer, for the same critical components. The key difference for the medical device industry however is that disruptions to the manufacturing supply chain impact patients and potentially cause fatalities. A significant percentage of these disruptions, some as high as 80%, are being caused by a lack of visibility and transparency to lower tier suppliers in the chain, a lack of tools to assess supplier capacity, capability and risk, and a lack of internal OEM resources to work on active risk mitigation strategies.

Tools and resources are available to medical device companies to improve supply chain resiliency, such as adjusting supply chain management strategies, or using artificial intelligence-enabled logistics software, but there are limitations for the OEM attempting to go it alone. A number of collaborative industry initiatives have been developed since Covid-19 to improve resiliency of the supply chain, whether it is AdvaMed's Supply Chain Working Group, FDA Resiliency Supply Chain Program, or others. Acknowledging this challenge of addressing disruptions down the tiers in the supply chain, leading medical device companies, suppliers, regulatory bodies, government agencies, and trade associations came together to form the Best Practices in Supply Chain Resiliency and Quality Working Group to determine best practices for driving quality and resiliency into the supply chain, and to look at ways to maximize the awareness and adoption of the MedAccred® industry-managed approach.

For companies engaging with the broader medical device industry in a collaborative environment there is a unique opportunity to create an industry-consensus approach towards assurance of critical manufacturing processes and suppliers that will create resilient global supply chains.

CORE FOUNDATIONS FOR BUILDING RESILIENT SUPPLY CHAINS

There are many ways to build and enhance medical device supply chain resiliency, but there is general consensus on the core foundations required for companies to establish truly resilient supply chains. Here are four key areas companies should be addressing:

- Visibility
- Control
- Flexibility
- Collaboration.

Visibility across the supply chain

As a prerequisite for developing resilient supply chains, OEMs need to know who their Suppliers are and their capabilities through the tiers of the supply chain, beyond Tiers 1 and 2. An OEM then needs a precise understanding of the level of performance and capability of each of the Suppliers in their supply chain. Flowdown of technical requirements ensures that Suppliers know who they are doing work for and what the requirements are.

Control of the supply base

OEMs can exercise control within the supply chain by using up-to-date Supplier performance and capability data, with metrics such as Defective Parts per Million (DPPM), to ensure that known risks are addressed, and to inform supply chain management strategies. This may help OEMs to address issues with current suppliers as well as gauge risk posed by potential suppliers. Having access to supplier performance data allows the OEM to minimize potential risks, as well as take timely and appropriate action when a disruption occurs. OEMs cannot prepare enough for shortages of critical components and are realizing that business continuity depends on a plan to second- or third-source critical components.

Flexibility to handling risk

As part of their supply chain strategies, OEMs may minimize risk by using multiple Suppliers for critical or high-risk components and materials. This assumes that the OEM has an extensive network of Suppliers to source from in the first place. They may also retain the flexibility to switch or onboard Suppliers at short notice, to support personnel, materials, equipment, or other issues, if a disruption occurs. To be flexible in this way, and to act with agility, OEMs should have a defined supplier risk evaluation and response program in place.

Cross-industry collaboration

Collaboration starts within the OEM itself and the relationships between internal business units, ensuring critical information is shared and actioned across the organization. Looking externally, an OEM requires good communication and responsiveness from its Suppliers, enabling a flow of timely and accurate information when a disruption arises. More widely, OEMs are well positioned if they can tap into medical device industry relationships, including other OEMs, supplier networks, government, regulators, and associations.

MEDACCRED PROGRAM – SUPPLY CHAIN QUALITY PROGRAM ENHANCING SUPPLY CHAIN RESILIENCY

The MedAccred program meets the requirements of the core foundations as previously described. The program is an industry-managed approach to critical process supply chain oversight, that reduces risk to patient safety, assures quality products and verifies compliance with requirements. It includes OEM Subscribers such as Baxter, Becton Dickinson, Boston Scientific, Edwards Lifesciences, Medtronic, Philips Healthcare, Roche Diagnostics and Stryker, which fund and manage the accreditation program and determine audit criteria, interview and select subject matter expert (SME) Auditors, and determine which Suppliers are granted accreditation.

Visibility

Medical device OEMs and Contract Manufacturers which subscribe to the MedAccred program (known as 'Subscribers'), have greater end-to-end supply chain visibility through real-time access to a list of MedAccred Accredited manufacturers that cover a wide range of critical process technologies, including Sterilization (Ethylene Oxide and Radiation), Plastics Injection Molding, Printed Circuit Board Assembly (PCBA), Sterile Packaging, Heat Treating, and many others. MedAccred Subscriber company departments, including sourcing, supply chain, quality, engineering, research and development, also have access to the MedAccred Qualified Manufacturer List (QML) database. It can support the management of their supply base or identify new highly capable Suppliers. Having access to the QML across a corporate enterprise can remove silos and enhance communication with Suppliers and internal stakeholders.

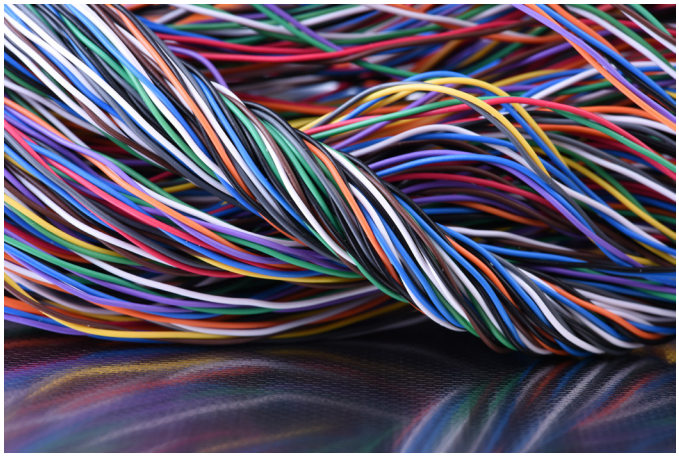
With its focus on conducting deep-dive technical assessments of a Supplier's manufacturing capability, commodity management is at the core of the MedAccred industry-managed program approach. Medical device companies have greater confidence that MedAccred-Accredited Suppliers can consistently and reliably manufacture at the highest level, regardless of their size or location. Some of these processes, like heat treating, are typically applied by companies at lower tiers in the supply chain and are relatively unknown to OEMs in the manufacturing process. MedAccred gives visibility as to who those companies are and provides Subscribers access to audit information from those Suppliers, while non-subscribing medical device companies also have access to the company names, locations, and accreditation scope on the QML, though are restricted from viewing specific audit details of those companies.

Ed Engelhard, Vice President of Corporate Quality at Solar Atmospheres Inc., one of the world's largest providers of commercial vacuum heat treating services for medical devices, aerospace, and other industries, says, "From my end of the supply chain, I need to be sure that I know and understand the needs of the OEM so I can produce the quality requirements that were intended in the original design". "The stronger that is within the supply chain the less prone to disruption it is likely to be. What information am I going to get from the OEM to meet their intended design requirements? Normally, a lot of it gets filtered by the time it gets to us as we're pretty far down the supply chain."

Control

Companies have greater Supplier controls and can ensure that their critical Suppliers are consistently and reliably meeting industry standards and customer requirements: MedAccred provides Supplier audit reports, Non-Conformance Reports (NCRs), and Supplier action plans, all of which can be assessed to identify trends and potential supplier quality issues. In addition, early warning notifications are generated and shared with Subscriber companies when NCRs are identified that could potentially impact products.

In one recent example at a US-based Cable and Wire Harness Assembly supplier facility, an issue with out-of-tolerance Nickel levels was identified by a MedAccred audit, prompting a Subscriber to coordinate an internal tiger-team to address the issue with that Supplier. This issue would not have been caught by their company's regular audit program.



Audit data can be also linked to a company's ERP system to support supply chain, sourcing, new product development, and quality-related decision-making. This allows a company to have finger-on-the-pulse awareness of their most critical suppliers around the world. When onboarding and developing new Suppliers, companies should require higher level quality processes and performance, as well as flowdown of documentation of critical technical requirements. MedAccred helps to ensure these processes and requirements are in place to minimize supply chain disruptions.

Alberto Romeu, Professional Engineer, Manager, Global Supplier Engineering, at Stryker said, "MedAccred focuses on specific, and critical processes which also includes Lower Tier suppliers like Heat Treating. Criteria for these processes can and should be used to assess and evaluate risk on supply chain disruptions, quality events, and performance."

Flexibility

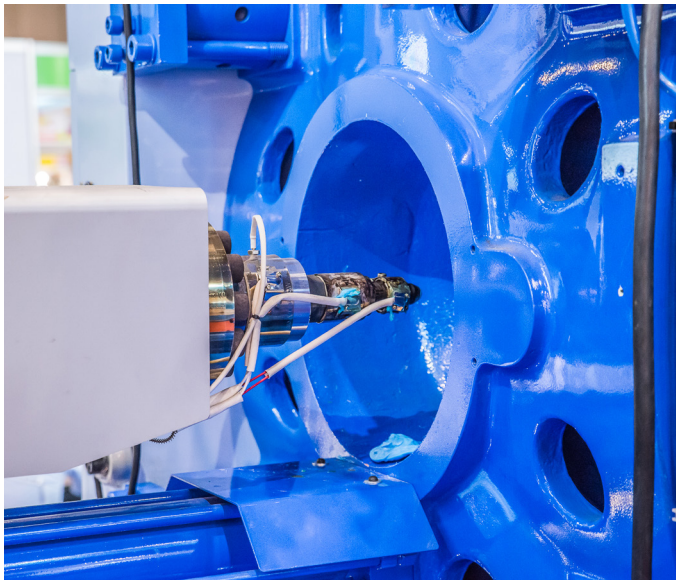
Supplier relationship management and sourcing activities are enhanced for companies as the MedAccred program extends their supply networks to reduce supply chain risk, enhancing oversight of their supply base, and bolstering sourcing decisions for new Suppliers. The MedAccred program strengthens OEM strategies to move away from single-source Suppliers and shortens ramp-up time when onboarding new Suppliers. MedAccred audits enable medical device companies

to maintain, and in some instances increase, oversight of a Supplier's technical performance while eliminating costly travel to a Supplier's physical manufacturing location, and potentially reduces time needed to manage the corrective and preventative action process with a Supplier. OEMs can rely on the MedAccred SME auditor (who they have interviewed and approved) to conduct a deep dive three-to-four day technical assessment at a Supplier's manufacturing facility every 12-18 months.

They can also rely on the MedAccred SME Staff Engineer to manage the corrective action and preventative action process with the auditee for any identified nonconformances. OEMs have full visibility of the entire audit process in the MedAccred online audit management system (www.eAuditNet.com), and once the audit report is generated and all nonconformances have been addressed, they vote with their peers from other medical device companies on whether or not to grant a MedAccred Accreditation to that particular Supplier.

When a medical device company develops a new product or moves production to a new region and is looking to source a highly capable Supplier for a specific critical process, a Supplier Quality Engineer, Quality Director, Procurement Manager, or New Product Development Director can easily assess the capability and maturity of a specific manufacturing facility.

In a recent example, a manufacturer of orthopedic products was looking for injection molding companies to assist with new product development. After a review of the MedAccred QML it showed there were 25 Suppliers globally that had gained the MedAccred Accreditation for this critical process. From this list it was able to pare the list down to three. It reviewed the MedAccred audit history for each of those Suppliers, and saw how they responded to every question, including objective evidence, in the MedAccred Plastics Injection Molding Audit Criteria (which runs to over 100 pages). They looked for details of any major and minor nonconformances identified during audits and how Suppliers resolved issues and implemented effective corrective and preventative actions. They could also see how long, and how many cycles, it may have taken for Suppliers to resolve the nonconformance with the MedAccred Plastics Staff Engineer prior to a vote by the medical device OEMs to grant Accreditation. Based on this information, the manufacturer moved ahead with two Suppliers.



Credit: Solar Atmospheres

Collaboration

A defining feature of the MedAccred program and what makes it unique is that it brings people and organizations together to work towards a common goal. Indeed, MedAccred was created following a medical device industry roundtable in held in Chicago, Illinois in 2012. Since then it has grown, with more Subscribers and Suppliers, and with support from the U.S. Government's Food and Drug Administration which financially assists companies' to gain MedAccred Accreditation through the MedMAPP (Medical Manufacturers MedAccred Accreditation Pathway).

The program has a robust global network of Auditor SMEs that can supplement a medical device company's technical personnel resources. The program has established technical Task Groups in numerous critical process areas with active participation from SME representatives from medical device OEMs, contract manufacturers, and Suppliers.

Technical experts from each of these key stakeholder groups collaborate to develop technical audit criteria, select SME auditors, and vote on Accreditation decisions, which ultimately leads to higher quality and more resilient Suppliers through the tiers in the supply chain. MedAccred accredited Suppliers have reported that their involvement in the program has been pivotal in establishing and increasing trust, and strengthening relationships with their customers. In a recent MedAccred customer survey, 85% of Supplier respondents reported improved customer satisfaction, following their involvement in the MedAccred program. As a result, medical device companies are providing accredited Suppliers with new and/or expanded business opportunities. Indeed, in the same survey, 52% of all Supplier respondents said they had won new business from current or new customers.

Preethi Kasthuri, Director, Global Procurement Packaging, Metals and Supplier Quality, at Becton Dickinson, noted that, "The MedAccred program performs deep-dives into, and across, Subscriber OEMs' supply chains, probing into internal quality of individual Suppliers, enabling them to be scored and incorporated into our resiliency efforts.

CONCLUDING COMMENTS

Addressing risks posed by interruptions to global medical device manufacturing supply chains requires certain core foundations to be in place: visibility across the supply chain, control of the supply base, flexibility to handling risk, and cross-industry collaboration.

The MedAccred program addresses all of these and is uniquely positioned as an industry-managed approach to critical process supply chain oversight, proven to reduce risk for OEMs, Contract Manufacturers and suppliers.

By joining the MedAccred program as an OEM Subscriber, Contract Manufacturer or Supplier, and/or becoming part of the ongoing resiliency conversation through the Best Practices in Supply Chain Resiliency and Quality Working Group, you can collaborate at a global and industry level, towards creating more resilient supply chains, and improving patient safety.

ABOUT THE AUTHOR

Justin McCabe serves as Operations Manager, MedAccred for the Performance Review Institute, a not-for-profit trade association that facilitates industry-managed programs and administers critical process accreditation programs for the aerospace and medical device industries. The MedAccred program is an innovative supply chain oversight audit program managed by medical device OEMs and Contract Manufacturers which improves product quality, enhances resiliency, and reduces cost.

He also co-leads the Best Practices in Supply Chain Resiliency Working Group with participation from U.S. FDA, U.S. Department of Commerce, MDIC and MedTech companies to enhance supply chain resiliency by driving quality through the tiers in the MedTech supply chain. Justin also supports the management of the Medical Device Manufacturers MedAccred Accreditation Pathway (MedMMAP), a U.S. Department of Commerce-funded program that helps small- and medium-sized U.S. manufacturers on their MedAccred journey.

Prior to entering the life sciences industry, Justin served as a teacher trainer with the U.S. Peace Corps in Mozambique and was an ESL (English as a Second Language) teacher in Japan. He received his Master's in International development from the University of Pittsburgh and holds a Bachelors of Arts degree in Business Administration from Mercyhurst University in Erie.

PERFORMANCE REVIEW INSTITUTE

The Performance Review Institute is the world leader in facilitating collaborative supply chain oversight programs, quality management systems approvals and professional development in industries where safety and quality are shared values.

Established as a not-for-profit trade association in 1990, PRI serves customers globally through our offices in the USA, UK, China and Japan. Our work helps to improve product quality and safety while reducing costs, and is aligned with the most technologically advanced companies and engineering efforts in the world.

PRI is trusted by stakeholders in critical industries globally to provide superior technical accreditations, management systems auditing, and professional development opportunities. Our people are acknowledged as the elite in their respective industries and are counted among the foremost technical experts in their field, based on level of education and technical experience.

For more information on the MedAccred program, or the work of the Best Practices in Supply Chain Resiliency and Quality Working Group, please contact MedAccred@p-r-i.org, or visit https://p-r-i.org/medaccred/.

MDA-RES-WP-101-001-2023.09