RESILIENCY IN THE MEDICAL DEVICE MANUFACTURING SUPPLY CHAIN:
Supplier Perspective Provided to Best Practices in Supply Chain Resiliency and Quality Working Group
Resiliency interruptions are often seen in terms of those internal to the Supplier, such as defective parts and product recalls, or in terms of external factors such as natural disasters, political, economic, or pandemic-related. According to Mr. Engelhard, while all these factors can interrupt the supply chain, an assumption of business stability exists when these events are not taking place.

“Most of the focus in the Resiliency group is from the OEM perspective: something big happens in the world, and it turns their supply chain upside down. That can happen from a global economic perspective, or it can be that lower-tier Supplier that you didn’t really know about, suffering some catastrophe, and suddenly you are getting calls that the product you need for your production line isn’t going to be able to make it,” he says.

“From a Supplier’s perspective, we talk about ‘business as usual’ with the assumption that it performs as intended but often it does not, even without additional disruptors. Many OEMs aren’t aware of how tenuous their connection is to handling resiliency until it fails and all of a sudden they are very aware, and panic, asking ‘Why is it this way?’”

Mr. Engelhard, says that from his position as a Supplier many levels down the supply chain, this can be due to various factors:

1. OEM knowledge of the critical processes affecting the final medical device product.
2. Flow down of OEM technical source information.
3. Quality of the Supplier’s processes, systems, equipment, and capability.
4. Competency of the Supplier’s employees.

Ed Engelhard is Vice President of Corporate Quality at Solar Atmospheres Inc., one of the world’s largest providers of commercial vacuum heat-treating services for medical device, aerospace, and other industries. He is also a member of the Best Practices in Supply Chain Resiliency and Quality Working Group, established earlier this year to identify and recommend best practices to improve medical device quality and enhance supply chain resiliency. It comprises representatives from the medical device industry, including leading OEMs and Suppliers, as well as government and industry associations.

In one of the early meetings of the working group, Mr. Engelhard provided useful insights into the nature of supply chain resiliency within the medical device supply chain, giving his perspective as a lower-tier Supplier looking up through the supply chain. “Most of the members are from the top end of the supply chain, but I thought it would be useful for them to hear about the far end of the supply chain which they are concerned about,” he explains.
RESILIENCY IN THE MEDICAL DEVICE MANUFACTURING SUPPLY CHAIN: A SUPPLIER’S PERSPECTIVE

OEMs

FLOW DOWN OEM REQUIREMENTS

SUPPLY CHAIN

OEM knowledge of the critical processes that affect the final product.

Competency of the Supplier’s Employees

Quality of the Supplier’s processes, systems, equipment and capability.

SUPPLIERS

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“It’s very often not known, at the OEM or regulatory level, as to what critical manufacturing processes go towards completing the final medical device product,” says Mr. Engelhard. “My company is concerned with heat treating, so companies like us are providing the final metallurgical condition of the devices that will be used at the medical provider-patient interface.”

Typical medical device products subject to heat treating include orthopedic joint components for knees, hips and shoulders; implantable battery and other device packaging; surgical tools for heart wires, tunnelers, drill bits, screwdrivers, clamps and staplers; stents; and stabilization devices for screws, plates, and structural supports. As Mr. Engelhard notes, “A failure here is almost impossible to detect, except by destructive means. Yet a failure here could be devastating to the medical procedure and patient.”

“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 intended in the original design,” says Mr. Engelhard. “The stronger that is within the supply chain, the less prone to disruption it is likely to be. It’s a subtle point but I don’t think people appreciate it enough.

“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, and sometimes we’re missing that original intent due to the ‘whisper down the lane’ approach used with a lot of supply chain flow down.”

On the part of the lower tier Supplier, they should have the OEM source documents, “not an intervening party’s interpretation of them”, he says. The Supplier should also have “a documented system of contract review,” “adequate competent personnel to assure the proper contract review and processing,” and “an ability to match equipment capability to process requirements (from the designer) which will produce the intended result.”

Mr. Engelhard has witnessed situations where very serious interruptions occurred, and the “inability to properly communicate was a huge issue. It didn’t need to be compounded by a system that was not so good to start with. So, part of resiliency is having a robust system of communication in the supply chain from the outset.”

OEM KNOWLEDGE OF CRITICAL PROCESSES AFFECTING MEDICAL DEVICE PRODUCTS
“If you are the OEM, you want to know that your supplies will be predictable, on time and readily available when needed, and that you are going to receive the product ready to use, that is to say, it's been prepared correctly. This is the quality side of it," Mr. Engelhard explains. “From my end of it, it becomes a matter of being sure I know and understand the needs of the OEM so I can meet the quality requirements that were intended from the original design.”

The OEM design authority must specify whether there are particular process control requirements (for example AMS2750 Pyrometry Heat Treating standard), that need to be met to produce the desired outcome, along with determining any specific metallurgical, mechanical, and/or physical tests required to demonstrate compliance to design requirements, he says.

“The heat treating Supplier needs to objectively demonstrate that equipment is validated to meet the process-control needs of the OEM. If differences exist between specified process parameters and the Supplier’s installed capability, can acceptable variances be communicated and resolved?” asks Mr. Engelhard.

COMPETENCY OF THE SUPPLIER’S EMPLOYEES

The OEM will also want to know if the Supplier possesses a hiring, training, and evaluation process that assures competent personnel are in place. “Can the Supplier objectively demonstrate that personnel operating the equipment and their supervisory staff have the wherewithal to operate the equipment to meet requirements?” he asks.

The Supplier also must demonstrate its competency, he adds. “If you say you are expert at heat treating, can you objectively demonstrate that capability beyond the traditional Quality Management System (QMS) level? Does the Supplier have a subject-matter expert to actively oversee that area of critical process expertise? Can the Supplier manage change in relation to the declared area of expertise, and is there sufficient management oversight of, and responsibility for, this?”

QUALITY OF THE SUPPLIER’S PROCESSES, SYSTEMS, EQUIPMENT AND CAPABILITY
“The MedAccred program answers all my four main concerns,” he asserts. “To become a MedAccred Accredited Supplier, you must meet certain criteria, all of which address the four key areas that I have highlighted.”

Mr. Engelhard says that all the following will be tested by knowledgeable MedAccred Auditors, the audit criteria and job audits:

- The Supplier must have a registered, or approved, QMS in good standing, no matter the level in the supply chain, to be considered a candidate for Accreditation. Examples are ISO 13485, ISO 9001, TS 16949, or AS9100.
- The QMS must have a robust contract-review system, and competent personnel in place, that respects the need for source information in flow down.
- Equipment must be appropriately qualified and validated to meet well-vetted industry requirements, and have the capability to meet contract requirements, at a detailed level.
- Personnel responsible for the qualified and validated equipment must be available to demonstrate conformance, as well as the people responsible for following job instructions derived in contract review.

“For some OEMs, there may not be visibility to the farthest end of the supply chain. This may be especially true if manufacturing has been turned over to another party,” says Mr. Engelhard. Yet, Suppliers may conduct critical processes during manufacture that cannot 100% be verified for compliance using inspection, so a lot of trust must be placed on the Supplier’s process capability to meet application requirements.”

Mr. Engelhard concludes, “QMS certification as a sole-quality oversight program is lacking in the technical rigor needed to assure that declared technical competencies by Suppliers are being met, but the MedAccred program fills that gap with subject-specific and highly-experienced auditors focused solely on the technical matters at hand, using industry-agreed audit criteria developed by recognized industry subject-matter experts, looking at a mix of witnessed and historical jobs processed by the Supplier to assure compliance to a highly detailed level.”
About Ed Engelhard

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About MedAccred®

The MedAccred 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 auditors, and determine which Supplier are granted accreditation.

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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 p-r-i.org/medaccred.