MedAccred: Addressing Process Capability through Supply Chain Control

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PERFORMANCE Review Institute

Importance of Supplier Selection for OEMs

- It is critical to **evaluate and select** the right supplier for your needs!
- It is important to match up your **requirements** with the **process capabilities and capacities** of your prospective Critical Processes suppliers
- Critical process suppliers provide **significant processes** that contribute to the success of your device

Ensure they **understand your requirements** and evaluate their capabilities

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Ensuring Part Quality through Oversight of **Critical Process Manufacturing**

- **MedAccred** is an **industry managed** approach to accomplish this objective.
- The program supports Industry by providing a mechanism to identify the **critical manufacturing processes** used by the device industry, specify industry standards and OEM requirements for these processes and oversee the supply chain's ability to meet these requirements through a **surveillance and accreditation process**.
- **MedAccred** brings together technical experts from both Industry and Government to establish requirements for accreditation, conduct in-depth audits by **subject matter experts** and accredit Suppliers.
- This results in a **standardized approach** to **critical manufacturing process** quality assurance and a reduction in redundant auditing throughout the industry.
- Medical device program is based on success of the aerospace program, **Nadcap**

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What is MedAccred and it's Scope

- An industry-managed audit program that **addresses critical manufacturing process issues** in the supply chain and **reduces risk to patient safety** by enhancing compliance to critical process manufacturing requirements
- MedAccred is a **tool** for Medical Device OEMs to use in the **oversight of their supply base** while they **maintain ultimate responsibility** for quality and compliance
- MedAccred program provides **in-depth, critical process, audits** that are compliant and consistent to accepted industry/technical standards and conducted by industry recognized and approved **Subject Matter Experts**
- Scope of audit
  - Critical, process-focused, technical audits with sampling of product audits to ensure process capability to meet requirements
  - Assesses effectiveness of suppliers' Quality Management System (QMS) at the critical process level (e.g. PCBA, Heat Treating, Welding, Sterilization, etc.)
  - Audits based on robust core and OEM-specific checklists

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Using MedAccred for Critical Process Oversight

ESTABLISH REQUIREMENTS AND ENSURE OVERSIGHT

OEMs and Industry establish **process requirements** in addition to the **design requirements** and **final part acceptance**.

OEMs **flow-down** (design requirements, Industry specifications and **process requirements)** to process providers(Suppliers and/or Contract Manufacturers). In addition, OEMs establish requirement for process providers to be **MedAccred** Accredited.

MAINTAIN COMPLIANCE TO REQUIREMENTS

Critical Process Providers (Suppliers) are responsible for ensuring all requirements, as flowed down by the OEM, are met. This includes ensuring compliance to **all process requirements**. Receiving **MedAccred** Accreditation is a mechanism to show compliance

PROVIDE OVERSIGHT TO VERIFY COMPLIANCE TO REQUIREMENTS

MedAccred Audit verifies the Suppliers have the **process capability, necessary equipment, controls, qualified personnel, sub-tier control**, etc. and the ability to perform the **critical processes** to the requirements defined by the OEMs and/or Industry specifications.

For those Suppliers that outsource a critical manufacturing process, the **MedAccred QSL** can be used to identify other Suppliers who have the capability and are **MedAccred Accredited** – ensuring flow-down of the process requirements and supplier process capabilities.

Establish Requirements And Provide Oversight

- For devices to meet the industry and FDA requirements, OEMs must:
  - Define design specifications for the products to be manufactured
  - Understand which of the manufacturing processes used in making the device or its components are Critical to Quality (CTQ) and hence safety of the device
  - Define industry standards and OEM specific requirements for these critical processes
  - Communicate (i.e. Flow-Down) these requirements to all levels of the Critical Process Supply Chain
  - Understand who are the Contract Manufacturers, as well as sub-tier suppliers that are providing Critical Manufacturing Processes for the devices or their components
  - Define requirements for periodic oversight via the MedAccred program

Critical Process Providers Must Maintain Compliance To Requirements

- Critical Process Providers (Suppliers) are responsible for ensuring all requirements (Industry Standards, OEM specifications, etc.) as flowed down by the OEM are met.
  - This includes ensuring compliance to all critical process requirements.
  - Receiving and maintaining MedAccred Accreditation is a mechanism for Suppliers to demonstrate they have been verified as having the necessary processing capabilities and controls to ensure compliance.
    - *Flow Down: A systematic approach that ensures OEMS specifications and expectations of quality are effectively communicated to critical manufacturing process providers for devices and device components at all tiers of the supply chain*

MedAccred Can Provide Oversight To Verify Compliance To Requirements

- The MedAccred Audit verifies the Suppliers have the process capability, necessary equipment, controls, qualified personnel, sub-tier controls, etc. and the ability to follow the process requirements as defined by the OEM and/or industry specifications.
- Critical Process Task Groups, made up of Industry Representatives, create industry agreed audit criteria which drive supplier process compliance to customer requirements.
  - Auditors review OEM requirements and ensure the supplier is in compliance
  - Subscribing OEMs can maintain oversight and ensure effective flow-down of their requirements by participating in the Critical Process Task Groups and the audit process.

MedAccred Can Provide Oversight To Verify Compliance To Requirements

- For those Suppliers that outsource a critical manufacturing process, the MedAccred QSL allows them selected accredited sub-tier suppliers
- The MedAccred QSL (Qualified Supplier List):
  - A publicly available list of accredited MedAccred Suppliers to specific Critical Process technologies
  - Display of all Audits/Certificates for a supplier

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MedAccred Critical Manufacturing Processes

Critical Processes (in development)	Drivers
Electronic Circuits – Printed Circuit Board Assemblies (PCBA)	• Able to leverage existing audit criteria developed for aerospace • Area in which issues with supply chain control have been identified • Significant interest from large number of OEMs
Electronic Circuits – Cable and Harness	• Able to leverage existing audit criteria developed for aerospace • Area in which issues with supply chain control have been identified • Significant interest from large number of OEMs
Heat Treating	• Able to leverage existing audit criteria developed for aerospace • Driven by orthopaedics manufacturers
Sterilization	• Identified as applicable to majority of OEMs – crosses many sectors of the industry (diagnostics, orthopaedics etc.)
Welding	• Able to leverage existing audit criteria developed for aerospace • Driven by orthopaedics manufacturers

Future Critical Process Areas of Interest with Industry and FDA Input and Trending (potential development)

- **Batteries**
- **Casting/Forging**
- **Chemical Processing**
- **Cleaning**
- **Coatings**
- **Electronics**
  - Displays
- **Fluidics**
- **Machining**
  - Laser Etch
- **Material Testing Laboratories**
- **Measurement/Inspection**
- **Non-Destructive Testing**
- **Optics**
- **Packaging**
  - Sterile
  - Sealing
- **Power sources/supplies (batteries)**
- **Raw Materials**
- **Reagents**
- **Resins**
  - Composites
  - Injection Molding
  - Extrusion Molding
- **Software**

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MedAccred Benefits

- **OEMs and Suppliers with the encouragement of Government representatives have joined forces to develop a program that:**
  - Establishes stringent **industry consensus documents** (audit criteria) that satisfy the requirements of all participants
  - Replaces routine auditing of suppliers with **one audit** per process
  - Provides more frequent audits on behalf of OEMs; fewer audits for Suppliers
  - Conduct in-depth, technically superior **critical process audits** by **experienced subject matter experts** in critical processes
  - **Improves supplier quality and therefore device quality** through compliance to stringent requirements
  - **Reduces costs** through improved standardization

Benefits to Medical Device Industry

- Promotes a philosophy of continuous improvement and a **culture of patient safety and product quality** for all participants
- Enhances **compliance and quality management system** effectiveness throughout the supply chain process
- **Aligns with FDA "Case for Quality"** strategic initiative and **promotes best practices**
- Provides improved **opportunity for collaboration** between suppliers and OEMs
- Improves **visibility of industry requirements** to sub-tier suppliers
- Promotes **least burdensome approach** by reducing redundant process audits by multiple customers
- Provides **real-time and consistent visibility** of supply chain quality
- Shared pool of experienced, trained, and **approved Subject Matter Experts** among OEMs

Benefits to Medical Device OEMs

- Provides **greater visibility of the supply chain** to all levels and sub-tiers that provide critical processes, consistent with regulatory requirements (e.g. Quality System regulation (21CFR Part 820), ISO 13485, MDD, IMDRF)
- Ability to identify gaps in communication of standards and OEM requirements (**flow-down**) to all Suppliers
- Identify and **reduce risk** of exposure to lower-quality suppliers
- Provides **early warning notification** to OEMs of potential supplier quality issues
- Program **frees up OEM resources** to focus on supplier development opportunities and/or problem area resolution
- Provides **Global Supply Chain visibility** through a web based system to support and improve efficiency (eAuditNet)
- Procurement can identify **accredited suppliers** (Qualified Supplier List – QSL)
- **Smaller Manufacturers** can utilize the QSL to identify accredited suppliers for critical processes

Benefits to Medical Device Industry Suppliers

- Provides **consistent/standardized** critical process audits accepted by the medical device industry **resulting in the need for fewer redundant onsite audits by multiple OEMs**
- Provides suppliers the opportunity to have input into development of audit criteria
- Enhance **Suppliers ability to understand** industry standards and OEM specific requirements
- Enhances the **quality of the products and services** provided by establishing industry expectations about quality and consistency
- Helps develop a **structured approach** to providing special processes and products leading to process discipline, greater **operational efficiency** and **continuous improvement**. Result in higher quality and lower overall cost
- Can use accreditation to **increase client-base** and opportunities across the medical device industry
- Enhances the supplier's **compliance** status

In Summary

- Manufacturers always bear the **ultimate responsibility** for their purchasing controls
- It is critical that you **evaluate your suppliers** to assure their process capabilities and capacities meet your needs and requirements
- It is important to **communicate your requirements** to your suppliers and develop a partnership to ensure success
- Industry managed supply chain programs provides
  - OEMs the opportunity to **collaborate on the development of industry requirements** to improve the quality of their devices
  - The ability for OEMs to define requirements and assure **consistent flow-down to Suppliers**
  - **Standardized** critical process audits conducted by experienced **Subject Matter Experts**
  - A more **efficient and global approach** to supplier quality

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Thank You
Questions and Feedback

Details on upcoming MedAccred meetings, and access to supporting information on the program (including this presentation), can be found on the MedAccred website:

http://www.p-r-i.org/other-programs/medaccred/

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