MedAccred℠

Advancing Medical Device Quality Through Supply Chain Process Accreditation

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In today's world of global manufacturing, supply chain oversight is challenging and costly. Like other rapidly expanding, high volume industries defined by safety and quality, the Medical Device Industry demands the highest level of assurance for Supplier critical processes.

MedAccred is a cost-effective, industry-managed supply chain oversight program that reduces risk to patient safety by addressing many of the challenges posed by today's global, multi-tiered supply chain.

Why has MedAccred been created?

Issues of end user safety and quality are faced by all sectors of the Medical Device Industry and are well documented.

Below are examples of issues highlighted by industry:

- Increased number of recalls attributed to Supplier quality issues
- Overall increased interest in outsourcing and globalization of the supply chain, thereby increasing the challenge of oversight
- Purchasing control is one of the top ten cited FDA 483 observations for Medical Device quality system violations
- Purchasing controls has been the target of several enforcement actions (warning letters, consent decrees)

In order to prevent output deficiencies, critical processes and products must be validated in order to prove that they are fit for purpose, satisfy regulatory requirements and reduce patient and business risk.

Definition: Critical Process

Critical processes are those processes where the parameters are directly influenced by component geometry and/or the results cannot be confirmed by inspection. Examples include sterilization, heat treating, welding and electronic circuits.

Industry-Managed Approach

An Industry-managed supply chain oversight program improves safety, quality and reduces risk via critical process compliance audits:

- Critical process audits are conducted using collaboratively created, Industry-managed performance standards and manufacturer specifications which lead to an accreditation granted by the Industry

- In-process job audits are conducted by Industry approved and trained auditors, who have extensive experience and knowledge of their process speciality

- Verification of compliance to an appropriate general quality system is a pre-requisite for current PRI programs
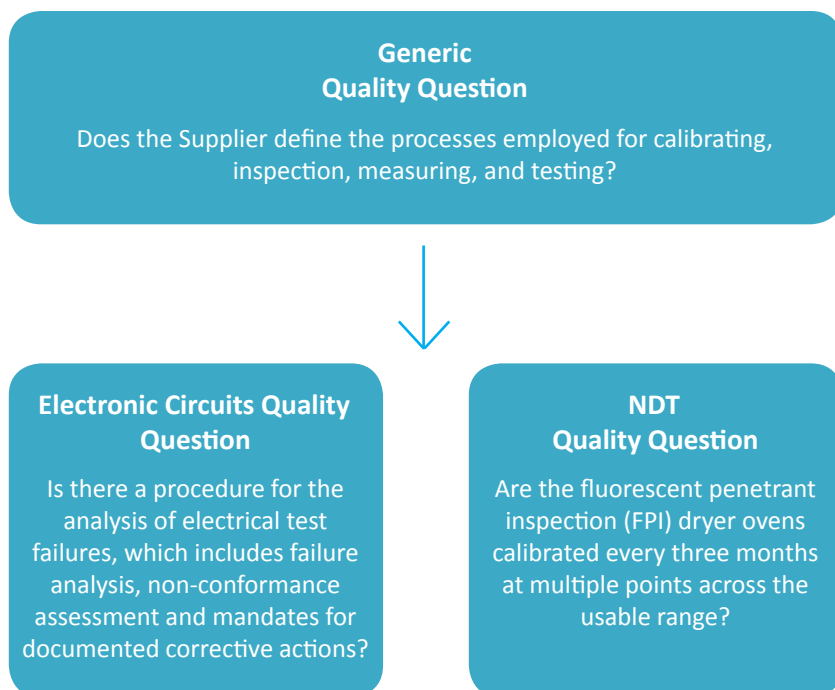
MedAccred offers this solution, which does not shift liability away from the subscribing manufacturers, who retain overall strategic control of the program.

Definition: Job Audit

A job audit is a step-by-step review of all processing on actual hardware to evaluate how a Supplier meets customer requirements and Industry standards

Quality System Audit vs. Critical Process/Product Audit

A critical process or product compliance audit differs significantly from an audit for general quality or for compliance to an ISO standard.

Generic Quality Question

Does the Supplier define the processes employed for calibrating, inspection, measuring, and testing?

Electronic Circuits Quality Question

Is there a procedure for the analysis of electrical test failures, which includes failure analysis, non-conformance assessment and mandates for documented corrective actions?

NDT Quality Question

Are the fluorescent penetrant inspection (FPI) dryer ovens calibrated every three months at multiple points across the usable range?

Key Subscribing Member Benefits

- Establish stringent Industry consensus audit criteria based on Industry and specific OEM requirements that ensure compliance and quality of devices, reduce the risk to patient safety and satisfy requirements of all participants

- Conduct 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

- Provide greater visibility of the supply chain to all levels and sub-tiers that provide critical processes, consistent with regulatory requirements

- Identify and reduce risk of exposure to quality issues from the supply chain and reduce the risk of costly recalls

- Provide early warning notification to OEMs of supply chain quality issues

- Provide complete visibility of audit results and corrective actions taken in a secure and retrievable format

Key Accredited Supplier Benefits

- Provide consistent/standardized process audits accepted by the Medical Device Industry resulting in fewer redundant onsite audits by multiple OEMs

- Enhances the Supplier's compliance status

- Medical Device Industry accepted and consistent technical requirements leading to process discipline, greater operational efficiency and continuous improvement resulting in higher quality and lower overall costs

- Helps Suppliers develop a structured approach to critical process and product manufacturing

- Can use accreditation to increase client base and opportunities across the Medical Device Industry

- Opportunity to participate in the development of audit criteria and the accreditation program

Initial Focus Areas

Electronics - PCBA and Cable and Wire Harnesses

Heat Treatment

Plastics - Injection Molding and Resins

Sterilization

Welding

Potential Development Areas

Casting/Forging

Chemical Processing

Cleaning

Coatings

Electronics - Displays and Power Sources/Suppliers

Fluidics

Machining - Laser Etch

Materials Testing Laboratories

Measurement/Inspection

Non-Destructive Testing

Optics

Packaging - Sterile

Raw Materials

Re-agent Manufacturing

Software - Hosted Services

Get Involved

To be at the forefront of this new program for supply chain oversight and take the opportunity to shape its direction and content, you are invited to contact:

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About the Performance Review Institute

The Performance Review Institute (PRI) administers MedAccred on behalf of the Medical Devices Industry. Created in 1990 by SAE International, PRI is a global, not-for-profit organization providing customer focused solutions. Designed to improve process and product quality, PRI products and services add value, reduce total cost and promote collaboration among stakeholders in industries where safety and quality are shared goals.

A Proven Track Record

PRI administers the Nadcap program on behalf of the Aerospace Industry (established 1990) and conducted over 5,300 critical process audits in 2014. The Nadcap program offers oversight of the critical process and product supply chain. On average, audits take between three and five days. Nadcap is an integral part of supply chain risk management for the global Aerospace Industry.

PRI's Core Competencies

- Satisfying regulatory requirements
- Anticipating & responding to industry need
- Risk mitigation
- Data analysis
- Audit scheduling and processing
- In-house informatics solutions