

STERILE DEVICE PACKAGING ACCREDITATION

What is MedAccred?

MedAccred is an industry-managed supply chain oversight program which identifies and verifies compliance to critical manufacturing process requirements. Leveraging their considerable collective experience, subject matter experts have collaborated to create a deep dive technical audit system which provides exceptional supply chain oversight.

Why MedAccred?

- To improve the quality of products and most importantly patient safety
- The need to reach through the sub-tiers in the complex global critical process supply chain
- To improve the reliability of the supply chain

MedAccred Sterile Device Packaging Accreditation

The MedAccred Sterile Device Packaging audit assesses a supplier's ability to consistently manufacture components that comply to applicable technical specifications and customer requirements. A MedAccred audit is conducted by a subject matter expert and verifies that an accredited supplier has the:

- Process Capability
- Qualified personnel
- Applicable Equipment
- Process validation
- Controls and Monitors
- Sub-tier controls

Sterile Device Packaging Audit Scopes

Process:

- Assembly and Closure / Sealing of Packaging Systems
- Forming Preformed Sterile Barrier System

Packaging Type:

- Bags / Pouches
- Blisters / Trays with Lidding Material
- Thermoformed Plastic Trays & Lids
- Thermoformed Clam Shells
- Flexible Header Bags / Pouches

Benefits to Participation

- Improves quality of products
- Reduces scrap and re-work
- Exposure to participating OEMs and potential to expand business

MedAccred Subscribers

- Baxter Healthcare
- BD
- Boston Scientific
- Edwards Lifesciences
- Johnson & Johnson
- Medtronic
- Philips
- Roche Diagnostics
- Stryker



Subscribers fund MedAccred, determine audit criteria, select auditors, have full access to audit findings, and determine who is granted MedAccred Accreditation.

Audit Quick Facts:

- Audit Length: 3 days
- Audit Frequency: Annual
- Audit Prerequisites: ISO 13485, ISO 9001, or ISO/TS/IATF TS16949
- Other Available MedAccred Accreditations: Cable and Harness, Heat Treating, Plastics Injection Molding, Plastics Extrusion, Plastics Mechanical Assembly, Printed Board (Bare Board), Printed Circuit Board Assembly (PCBA), Sterilization, Welding

To Schedule an Audit or Learn More: www.MedAccred.org

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