

STERILE DEVICE PACKAGING ACCREDITATION

The MedAccred[®] sterile device packaging audit provides an independent assessment of a facility's compliance with the consistent manufacture and assembly of sterile medical device packaging and barrier systems, according to customer specifications and MedAccred requirements. The MedAccred audit takes a deep dive into the packaging process, the end-to-end manufacturing supply chain, tooling, quality control, support functions, and process validation.

AUDIT SCOPE

MedAccred sterile device packaging audits cover:

- Assembly of packaging systems
- Sealing/closure
- Forming of sterile barriers
- Packaging job audits including blisters, trays, bags, pouches, and more
- Process development and validation

INDUSTRY SUPPORT

Subscribing medical device OEMs utilize MedAccred to reduce scope and frequency of audits conducted at their packaging suppliers and contractors. Some OEMs also eliminate internal audits, absent a compelling reason to perform one, while others incorporate MedAccred into their procurement process and award new business to accredited suppliers. Subscribing OEMs include:

- Baxter
- Becton Dickinson
- Boston Scientific
- Edwards Lifesciences
- Medtronic
- Philips
- Stryker
- W.L. Gore

HISTORY OF THE MEDACCRED SDP TASK GROUP

The Sterile Device Packaging Task Group, formed in 2017, brought together subject matter experts from subscribing OEM organizations, as well as sterile device packaging contract manufacturers and suppliers. The MedAccred program follows the very successful Nadcap[®] aerospace model, where technical experts from participating organizations collaboratively develop detailed technical audit criteria, select expert auditors, review audit reports, and vote on accreditation decisions. Following development of the audit criteria document, AC81111, the first sterile device packaging supplier received accreditation in 2019.

SUPPLIER BENEFITS

- Opportunities to build business relationships with leading medical device OEMs
- Improved product quality through compliance and adherence to PM schedules, the comprehensive inspection, and the critical review of IQ, OQ, and PQ process validation
- Improved process efficiency, reduced scrap, and rework
- Reduced number and frequency of customer audits
- Increased insights from audits performed by subject matter experts

AUDIT CRITERIA

MedAccred® sterile device packaging audit criteria aligns with the following industry standards:

1. ISO 11607-1, -2 (Packaging for Terminally Sterilized Medical Devices)
2. GHTF/SG3/N99-10:2004 Edition 2 (Quality Management Systems - Process Validation Guidance)
3. ISO 13485 (Medical devices QMS)
4. 21 CFR Part 820 (Quality System Regulations)

In addition to examining the process, audit criteria cover maintenance, calibration, qualified personnel, training, and the critically important phases of process validation (IQ, OQ, and PQ).

OEM SUBSCRIBER BENEFITS

- Enhance rigorous oversight of critical manufacturing processes
- Reduce risk by providing higher level of compliance assurance and greater visibility of the global supply chain
- Improve capability to meet regulatory purchasing control requirements
- Build a more robust and resilient supply chain
- Collaboration across many different medical device companies



COMMON NON-CONFORMANCES FOUND DURING INITIAL AUDITS

Initial MedAccred sterile device packaging audits often identify common findings, including:

- **Gaps in existing procedures:** As the auditor observes every step of the process, the procedures and work instructions must match the auditor's observations. Gaps are particularly noted in areas where information is shared via "tribal knowledge," rather than documented procedures and work instructions. All procedures must provide well-defined and in-depth instructions
- **Clean room/white room procedures:** The auditor often notes subtle omissions from work instructions, procedures, and scheduled maintenance, such as cleaning of ceilings, computer vents, and keyboards
- **Process Settings:** The auditor verifies process settings versus the process set-up sheet. Clearly, the settings must lie within the validated process window. In addition, there must be proper tolerances, as well as proper process alarm settings
- **Master Validation Plan (MVP):** Process validation is a key element of a MedAccred audit. The supplier must have a documented master validation plan, which defines the overall strategic approach to validation and must address the requirements for each phase of validation (IQ, OQ, PQ)

International Headquarters

Telephone: +1 724 772 1616
Email: PRIAmericas@p-r-i.org

Europe, Middle East and Africa

Telephone: +44 (0) 870 350 5011
Email: PRIEMEA@p-r-i.org

Asia Office (China)

Telephone: +86 10 6463 6008
Email: PRIAsia@p-r-i.org

Asia Office (Japan)

Telephone: +81 80-6911-1154
Email: PRIAsia@p-r-i.org



PERFORMANCE REVIEW INSTITUTE

GET INVOLVED

medaccred@p-r-i.org
www.p-r-i.org/medaccred