

PLASTICS INJECTION MOLDING

What is a MedAccred® Plastics Injection Molding audit?

The MedAccred Plastics Injection Molding audit is an independent assessment of the Plastics Injection Molding facility's compliance with customer specifications, as well as compliance with MedAccred requirements. The audit takes a deep dive into the molding process and at the same time looks at additional critical areas, including the end-to-end manufacturing supply chain, tooling, quality control, support functions, and process validation.

The MedAccred Plastics Task Group was formed in 2016. The Task Group brought together subject-matter experts from the subscribing OEM organizations, as well as medical device contract manufacturers and suppliers. The MedAccred program follows the very successful Nadcap® aerospace industry-managed model that brings together technical experts from participating organizations to collaboratively develop detailed technical audit criteria, select SME auditors, review the audit reports, and vote on accreditation decisions.

MedAccred Plastics Injection Molding audits cover:

- Basic injection molding processes
- Insert molding
- Over-molding
- Injection blow molding
- Transfer molding
- Compression molding

Further, the audit covers different molding materials, such as thermoplastics, thermosets, elastomers, and silicones.

INDUSTRY SUPPORT

Medical Device OEM Subscribing companies are utilizing the MedAccred program to reduce scope and frequency of audits conducted at their Plastics Injection Molder suppliers. Some are also eliminating interval audits, unless there is a strong reason to conduct the audit. Others are building MedAccred into their procurement process and awarding new business to accredited suppliers.

Subscribers

- Baxter
- Becton Dickinson
- Boston Scientific
- Edwards Lifesciences
- Medtronic
- Philips
- Roche Diagnostics
- Stryker

Accredited Suppliers

- EPC-Columbia, Inc.
- Eimo Technologies
- Elcam Medical ACAL
- Fabrik Molded Plastic
- Flextronics Medical Molding Co., Ltd.
- Hilco Technologies
- Hoffer Plastics
- Intertech Medical, LLC
- Jabil Healthcare
- Kaysun Corporation
- Kimball Electronics
- MRPC
- PTA Plastics
- PTI Engineered Plastics
- Pliant Plastics
- Scientific Molding Corp Ltd.
- Technimark Healthcare
- Trident Manufacturing
- Vaupell Midwest Molding and Tooling

AUDIT CRITERIA

MedAccred® Plastics Injection Molding audit criteria are aligned with the following industry standards:

1. 21 CFR Part 820 (Quality system regulations)
2. GHTF/SG3/N99-10:2004 Edition 2 (QMS and process validation guidance)
3. ISO 13485 (Medical devices QMS)

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

The MedAccred program provides benefits to both suppliers and OEM subscribers to the program.

SUBSCRIBER BENEFITS

- Enhanced rigorous oversight of critical manufacturing processes
- Enhanced oversight of the supply chain
- Improved capability to meet FDA purchasing control requirements
- Increased confidence that the supplier can consistently meet customer specifications, as well as regulatory requirements

SUPPLIER BENEFITS

- Improved product quality through compliance and adherence to Plastics Molding schedules, the rigorous inspection, and the critical review of IQ, OQ, & PQ process validation
- Increased process efficiency
- Reduced scrap and rework
- Decreased frequency and number of audits
- Gained insights from audits performed by injection molding subject-matter experts

COMMON NON-CONFORMANCES FOUND DURING AN AUDIT

Initial MedAccred Plastics Injection Molding audits often identify some common findings.

Typically, these include areas such as:

- **Gaps in the existing procedures:** As the auditor observes every step of the molding process, the procedures and work instructions must match the observations of the auditor. 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. Examples may include cleaning of ceilings, and cleaning of computer vents and keyboards.
- **Process Settings:** The auditor verifies process settings versus the molding 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 the MedAccred audit. The supplier must have a documented Master Validation Plan defining the overall strategic approach to validation and addressing 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



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MedAccred@p-r-i.org