



MedAccredSM
Administered by PRI

MEDACCRED® OVERVIEW MEDTECH OEMs

MedAccred, a program led by global medical technology companies, provides a business- and industry-wide solution to improve the quality and reliability of medical device products delivered to patients, while creating a more resilient critical process supply chain. Controlling critical manufacturing processes within the global medical device supply chain is essential to ensuring the highest-quality products, establishing a resilient supply chain, and enhancing patient safety. Global medical device industry stakeholders are currently working together to stabilize and strengthen the supply chain through MedAccred.

MedAccred is built on the highly successful Nadcap® program used by all major aerospace and defense companies and agencies (Boeing, Airbus, NASA, etc.). For more than 30 years, Nadcap has been a central player in providing critical supplier oversight, and has become recognized as a prerequisite to do business with the aerospace industry. Nadcap conducts more than 6,000 audits a year globally, impacting over 25 critical-process technologies.



“This marks an important milestone in Hoffer Plastics’ history of earned credibility. Receiving MedAccred certification from PRI is a testament to our tradition of commitment to maintaining best-in-class status in plastics injection molding. We know that in the end, customers are looking for peace of mind though product safety, quality, and consistency that a trusted, capable, accredited partner can bring. We are proud to be recognized as an integral part of the trust in that process.”

Alex Hoffer
Chief Revenue Officer
Hoffer Plastics
Accredited Supplier

“We are continuously asked about the scrutiny and oversight we have for suppliers. We need to look at creative ways, like using an accreditation [MedAccred] to get further into the process to show FDA and other regulators outside the United States that we have good control and good partnership with our suppliers and that we are driving quality.”

Ann Sheldon
Vice President
Global Supplier Quality
Medtronic

Benefits to MedTech OEMs

- Enhances rigorous oversight of critical manufacturing processes
- Reduces risk by providing greater visibility of the global supply chain
- Improves capability to meet regulatory purchasing control requirements
- Builds a more robust and resilient supply chain
- Fosters collaboration across many different medical device companies

MedAccred:



Provides consistent/standardized critical process accreditation, resulting in more robust and fewer redundant onsite audits



Conducts expert, in-depth critical process audits compliant and consistent with accepted industry/technical standards



Provides greater visibility of the global supply chain to all levels and sub-tiers, consistent with regulatory requirements (e.g. FDA, ISO 13485, MDD, etc.)



Improves operational efficiency and continuous improvement, resulting in higher quality and lower overall cost

Supply Chain Resiliency

MedAccred ensures a more resilient medical device supply chain by providing greater visibility of the supply chain, along with flexibility when identifying new highly capable suppliers around the globe. MedAccred also enhances collaboration with suppliers, ensuring that medical device company specifications flow through lower tiers in the supply chain.

Supplier Perspective

Available MedAccred® Accreditations

Leveraging their considerable collective experience in this field, industry experts have collaborated to create a thorough technical audit process, which provides exceptional supply chain oversight in the following areas:

- Cable & Wire Harness
- Heat Treating
- Plastics
 - Injection Molding
 - Extrusion
 - Mechanical Assembly
- Printed Boards (Bare Boards)
- Printed Circuit Board Assemblies
- Sterilization
 - Ethylene Oxide
 - Radiation: Gamma
 - Radiation: E-Beam
 - Radiation: X-Ray
- Sterilization Laboratory Testing
- Sterile Device Packaging
- Welding

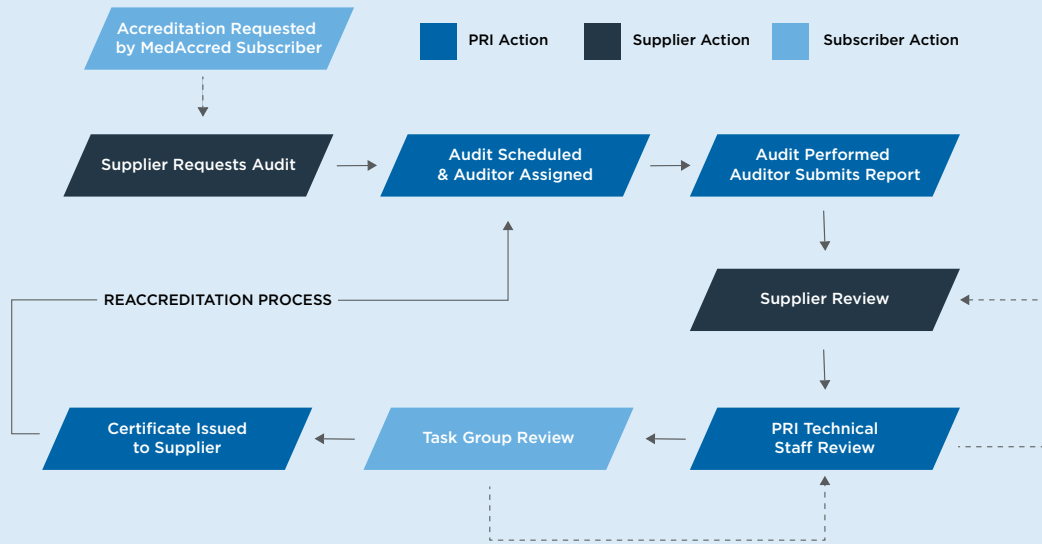
Processes accredited by MedAccred will continue to grow, based on industry and FDA input.

Current Subscribers

Medical device OEMs manage the MedAccred program, determine all critical process audit criteria, interview and select the SME auditors, maintain full access to audit findings, and determine who is granted MedAccred Accreditation. Subscription is open to large and small OEMs, as well as contract manufacturers. MedAccred OEM managers include:

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|-----------------------------|----------------------|
| Becton Dickinson | Philips |
| Boston Scientific | Stryker |
| Edwards Lifesciences | W.L. Gore |
| Medtronic | Zimmer Biomet |

The MedAccred Audit Process



To schedule an audit, or to learn more about how your company or organization can begin the MedAccred journey, visit: <https://www.p-r-i.org/medaccred>

Case Studies

Learn more about the impact MedAccred Accreditation has had on global critical manufacturing process suppliers:

[See Our Impact](#)

Call to Action

Become a MedAccred Subscriber and enhance your supplier quality while reducing manufacturing risk by insisting your suppliers are MedAccred Accredited.

USA/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 (Japan)

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

Asia Office (China)

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