



Mitigate Risks > Validate Performance > Ensure Compliance > Enhance Patient Safety



Innovating Critical Process  
Supplier Oversight  
for Medical Device Manufacturing

# WHAT IS THE MEDACCRED® PROGRAM?

**Controlling critical manufacturing processes within the Medical Device supply chain is essential to ensuring patient safety.** MedAccred is an industry-managed, consensus-driven approach to ensuring critical manufacturing process quality through the medical device supply chain. The MedAccred program is administered by the Performance Review Institute<sup>SM</sup> (PRI).

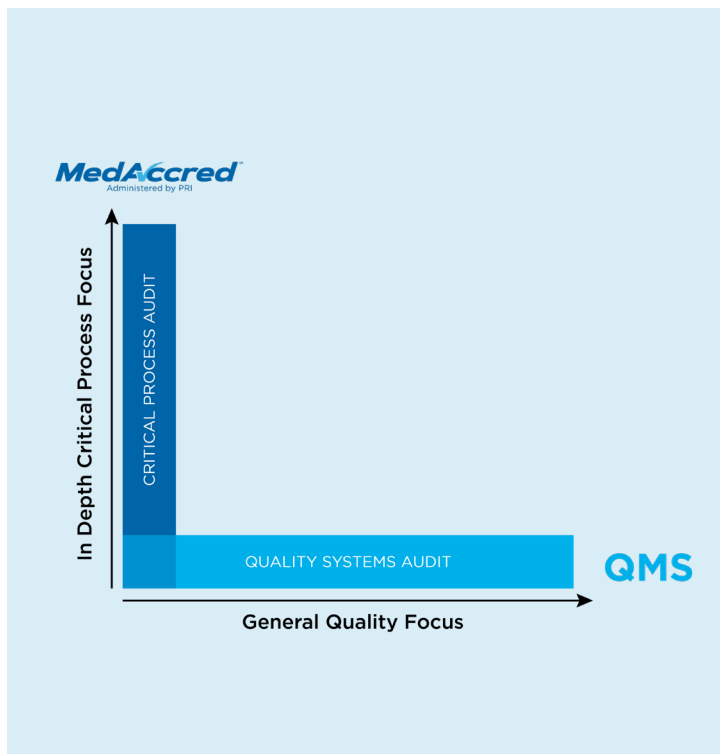


## Why is it important to participate?

- Provides consistent/standardized critical process accreditation resulting in fewer redundant onsite audits
- Conducts expert, in-depth critical process audits that are compliant and consistent to accepted industry/technical standards
- Provides greater visibility of the supply chain to all levels and sub-tiers consistent with regulatory requirements (e.g. FDA, ISO 13485, MDD, etc.)
- Greater operational efficiency and continuous improvement resulting in higher quality and lower overall cost

## How is a MedAccred audit different from a Quality Management System Audit?

The MedAccred audit is a thorough, vertical manufacturing process audit. A quality system is an excellent foundation, and a current valid quality system certification, such as ISO 13485, is required before scheduling a MedAccred Accreditation audit. The two types of audits together, both the QMS and process audit, ensure that the highest product quality standards have been achieved.



“It is very different—a QMS audit is broad but shallow. A MedAccred audit is deep in terms of a process area—a mile deep, inch wide, versus an inch deep, mile wide.”

**David Vazquez**  
Director

Quality Engineering and Supplier Quality  
*Becton Dickinson*

## CURRENT SUBSCRIBERS

Subscribers provide governance over the MedAccred® program, determine audit criteria, have full access to audit findings, and determine who is granted MedAccred accreditation.

**Baxter**

**BD**

**Boston Scientific**

**Edwards Lifesciences**

**Medtronic**

**Phillips**

**Roche Diagnostics**

**Stryker**



“MedAccred defines world class controls necessary to enable world class quality at the critical process manufacturers.”

**Scott Goolsbey**  
Sr. Program Manager  
Procurement Programs  
*Stryker*

## OEM SUBSCRIBERS BENEFIT FROM THE PROGRAM

OEMs can have confidence that their accredited suppliers, and sub-tier suppliers, can understand and consistently meet critical specifications.

- Enhances rigorous oversight of critical manufacturing processes
- Provides greater visibility of the supply chain
- Improves capability to meet FDA purchasing control requirements
- Collaboration across many different medical device companies to improve:
  - Final product quality
  - Patient safety
- Builds a more resilient and sustainable supply chain

By using the MedAccred accreditation program, **contract manufacturer subscribers can also benefit from the same level of supplier performance and assurance within their critical process supply chain as the OEMs.** Contract manufacturers with suppliers that deliver critical processes covered by the MedAccred Accreditation program can require these 2nd and 3rd tier suppliers to become MedAccred Accredited - ensuring a resilient and sustainable supply chain.



“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*





## SUPPLIERS BENEFIT FROM THE PROGRAM

Only the best companies in the medical device supply-chain achieve MedAccred<sup>®</sup> accreditation. MedAccred audits are a rigorous technical assessment of compliance to customer requirements and industry standards, conducted by industry experts.

- Improved process efficiency
- Improved quality of products
- Reduced scrap and rework
- Opportunity to leverage MedAccred Accreditation to gain new business

**85%**

of suppliers realized improved customer satisfaction\*

**65%**

of suppliers observed improved process efficiency\*

**76%**

of suppliers achieved critical process quality improvements\*

\*PRI Supplier Satisfaction Survey, 2022

## AVAILABLE MEDACCRED ACCREDITATIONS

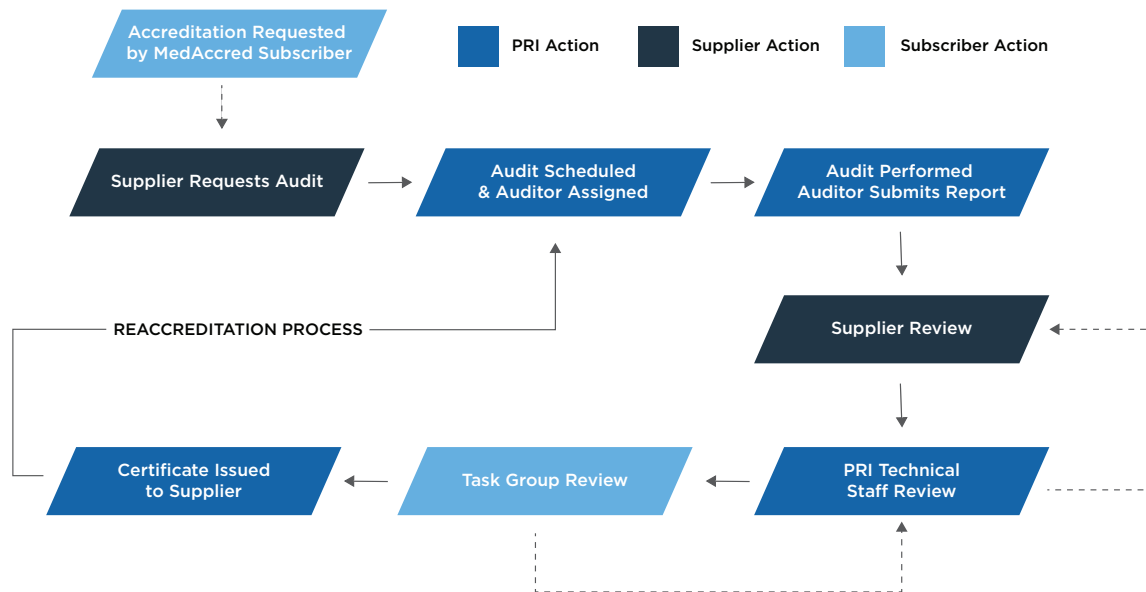
Leveraging their considerable collective experience in this field, industry experts have collaborated to create a thorough technical audit process which provides exceptional supply chain oversight in the following areas:

- 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
- Sterile Device Packaging
- Welding

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



## THE MEDACCRED® AUDIT PROCESS



MedAccred leverages over 30 years of best practices in the Aerospace industry Nadcap® program which conducts over 7,000 audits per year globally.



“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 through 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.”

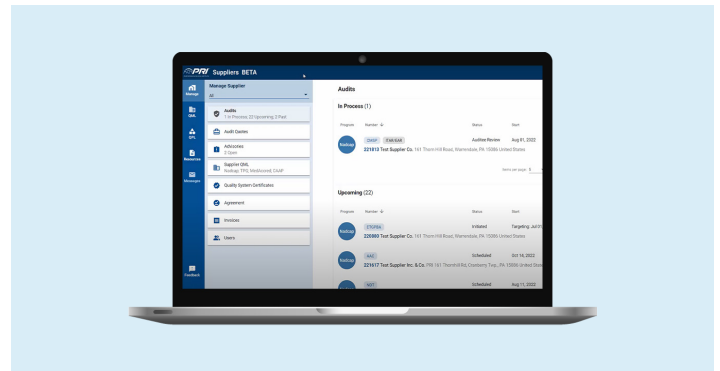
**Alex Hoffer**  
 Chief Revenue Officer  
 Hoffer Plastics  
 Accredited Supplier



## SUPPORT FOR SUPPLIERS

PRI EAN<sup>SM</sup> Online Audit Management System  
[eauditnet.com](http://eauditnet.com)

Overseeing and demonstrating supply chain compliance is a resource-intensive task. PRI EAN makes it easier for industries where safety and quality are shared values. PRI EAN is the online platform utilized by the MedAccred program. Suppliers use this tool to schedule their audits, manage the audit schedule, and view audit details. Program requirements, operating procedures, audit criteria, audit handbooks, pricing sheets, user guides, and Task Group specific documents can be accessed in one place. Registration is free.



- Web-based, intuitive workflow software used by all industry stakeholders: Subscribers, Auditors, Auditee/Facility quality managers, and PRI staff
- 24/7 secure global electronic access
- Upholds consistency in oversight and quality control

- Improves productivity for all users throughout the workflow
- Dedicated software development team exclusively supporting this system and continual enhancements
- PRI EAN support staff on site at PRI to help users with functionality and answer any questions

The greatest benefit of PRI EAN is the reduction in operating costs for the industry.





### MedMAPP

The US Department of Commerce NIST provides help to US manufacturers to achieve MedAccred<sup>®</sup> accreditation through MedMAPP.

Initial funding of \$1 million was awarded in 2018. Support is currently available to US manufacturers through August 2023.

For more information, visit: [www.medmmap.org](http://www.medmmap.org)



*The Elcam team was proud to celebrate their Plastics Injection Molding Accreditation for their facility in Israel.*

### Audit Preparation Support [p-r-i.org/pri-training](http://p-r-i.org/pri-training)

For help to prepare for a MedAccred audit or for professional development, Performance Review Institute<sup>SM</sup> (PRI) offers quality-related and technical training all over the world in multiple languages. Public sessions, webinars, onsite training, and hosted training with four core tracks of learning are offered: quality, MedAccred audit criteria review, MedAccred audit preparation, and critical processes.

To schedule an audit, or to learn more about how your company can begin the MedAccred journey to absolute quality, visit [medaccred@p-r-i.org](mailto:medaccred@p-r-i.org)



## ABOUT THE PERFORMANCE REVIEW INSTITUTE<sup>SM</sup>

PRI is the world leader in facilitating collaborative supply chain oversight programs, quality management systems approvals and professional development in industries where safety and quality are shared values.

Established as a not-for-profit trade association in 1990, PRI serves customers globally through its offices in the USA, UK, China and Japan. Our work helps to improve product quality and safety while reducing costs and is aligned with the most technologically advanced companies and engineering efforts in the world.

PRI is trusted by stakeholders in critical industries globally to provide superior technical accreditations, management systems auditing, and professional development opportunities. Our people are acknowledged as the elite in their respective industries and are counted among the foremost technical experts in their field, based on level of education and technical experience.

**p-r-i.org**

**Become a PRI Auditor**



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