

Free Guide

MedAccred: Standard for Production of Medical Devices



Skills management software
for frontline workers

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What is MedAccred?

MedAccred is a standard developed by the Performance Review Institute (PRI) [1] that encompasses the entire supply chain for the production of medical devices. It focuses heavily on aspects of critical manufacturing, or those that have a direct impact on the safety, effectiveness, and quality of the final product.

PRI offers MedAccred certifications in the following areas:

- Cable and wire harnesses
- Heat treatment
- Plastic extrusion
- Plastic injection molding
- Plastic mechanical assembly
- Printed boards
- Printed circuit board assembly
- Sterile device packaging
- Sterilization
- Welding

Who needs a MedAccred certification?

A MedAccred certification is not mandatory, but is medical device companies (known by PRI as “subscribers”) often require it for their suppliers. The standard is also internationally recognized, leading many organizations to consider it a de facto certification. As such, a MedAccred certification is extremely valuable in the medical device industry.

How to earn a MedAccred certification

Typically, subscribers recommend MedAccred certification to their suppliers. The supplier then works with PRI to schedule an audit from an approved auditor. PRI and the subscriber will consult on the outcome of the audit, after which PRI will issue a MedAccred certification to the supplier.

Renewal requirements for MedAccred certification

MedAccred certifications are usually valid for three years, after which time suppliers must undergo another audit. If passed, the supplier will be recertified.

The benefits of MedAccred certification

Adhering to MedAccred standards offers several benefits to organizations. Some key advantages include the following.



Improved process efficiency

MedAccred standards streamline medical device component suppliers' critical processes, reduce redundancies, and optimize workflows. This, in turn, can lead to faster production cycles and better resource utilization.



Improved product quality

MedAccred's stringent quality control measures help ensure that you are adhering to industry best practices. This results in higher-quality – and more reliable – components and assemblies.



Reduced waste

Adhering to MedAccred standards minimizes chances of errors and defects – and thus scrapping or reworking of parts, components, or assemblies. This not only works to improve product quality, as described above, but helps reduce waste and save costs.

Challenges in earning a MedAccred certification

Implementing MedAccred standards may pose several challenges to organizations. They include the following.



Documentation requirements

Meeting MedAccred's documentation standards requires meticulous record-keeping and process documentation. Ensuring accuracy, completeness, and traceability here can be challenging.



Specialized training

MedAccred often requires employees to receive specialized training in critical manufacturing processes. Obtaining and maintaining expertise in specific manufacturing techniques, testing methods, or compliance requirements can be time-consuming and costly.



Audit preparation

To adequately prepare for a MedAccred audit, organizations must ensure that all processes, procedures, and facilities align with MedAccred's standards. This usually extensive planning, resource allocation, and continuous monitoring.

Tips and strategies for earning a MedAccred certification

Here are a few tips for preparing for a MedAccred certification:

- Download the [MedAccred brochure](#)
- Familiarize yourself with [PRI's online audit management system](#)
- Attend a [PRI audit preparation training course](#)

Resources for MedAccred certification

For more information and guidance on MedAccred certification, you can refer to the following resources.

Performance Review Institute. The [PRI's website](#) should be the first stop for organizations seeking MedAccred certification. There, you can find a wealth of resources related to MedAccred, as well as request a quote for an audit or sign up for an audit preparation course.

Manufacturing skills matrices. AG5 offers [free, industry-specific skills matrices dedicated to various manufacturing practices](#). You can use them to identify, track, and manage skills related to a MedAccred certification in your organization.

ISO 9001 certification guide. AG5 offers a [free certification guide for ISO 9001](#) – a standard organizations often use as a starting point when seeking MedAccred certification.

Skills management for MedAccred certification

AG5 stores all certifications in the cloud, providing all authorized personnel with access to the right version of approved certifications. This helps you easily keep track of all data and documentation related to MedAccred certification across your organization.

Using AG5's skills management software, you can monitor the status of any type of certification that is relevant to your workforce, leveraging intuitive dashboards that provide you with a clear understanding of exactly what is needed to keep your employees skilled and safe.

[Book a demo](#)

Frequently asked questions about MedAccred

What is the scope of a MedAccred certification?

MedAccred focuses on various aspects of the supply chain in medical device manufacturing.

Is MedAccred certification mandatory?

It is not mandatory, but is internationally recognized and often considered a de facto certification by many organizations within the industry.

How long does it take to obtain a MedAccred certification?

This will vary, typically from weeks to months, depending on the preparedness of the organization seeking certification.

What are cost considerations for a MedAccred certification?

Cost considerations include audit costs and costs related to addressing and resolving nonconformances found during audits.

What is the validity period of a MedAccred certification?

MedAccred certifications are typically valid for three years.

Can MedAccred be integrated with any management systems?

Yes, MedAccred can be integrated with standards such as ISO 9001.

How can you learn more about ISO 14001 certification?

Visit the [PRI's website](#).

Sources

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#	Source title	Description	Publication Retrieved	Source URL
<u>1</u>	MedAccred	Performance Review Institute	- May 7, 2024	https://www.p-r-i.org/medaccre..

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