



MedAccred Program Implementation Playbook

MedAccredSM
Administered by PRI

Revision 1

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GOAL / PURPOSE / SCOPE

- Enhancing medical device quality and improving the supply chain that gets those devices to patients.
- Lessons learned from other industries, aerospace & automotive.
- Creating a more robust supply chain.
- Adapt best practices from across the medical device industry and develop practical recommendations towards improving patient safety while also reducing the cost to do business.
- Less defective products getting to market.

COMMUNICATION INTERNAL & EXTERNAL

Goal: Messaging should be tailored to those who are listening, but you need to get top leadership supportive of MedAccred for overall success.

- Organization approach – strategic planning, operational process where decisions are made and reinforce awareness to MedAccred.
- Has to be a priority for the business – move beyond a Quality initiative!
- Has to be bigger than just reducing audits.
- Be prepared to gather data to support your discussions.
 - Performance of MedAccred Accredited vs. non-accredited
 - Internal scrap and re-work at supplier
 - Defect rates at OEM
 - Security of supply chain
- Identify what are the concerns / risks and focus the message to address those concerns.
- Pain points to address:
 - Forcing MedAccred Accreditation will drive up the price of the part.
 - Worry around supply constraints.
 - Will slow down our development projects.

Note: Some industry leaders are going to need to stand behind it and push for it.

- Look for opportunities to advertise
 - Supplier summits
 - Supplier facing websites
 - Business reviews with suppliers
- Suppliers want to see case studies. “What’s in it for them?”
- Ensure your engineering teams are educated on MedAccred.

SUPPLIER ONBOARDING

Goal: Establish MedAccred registration for your supply base as a key input into driving new business to these suppliers.

Points to consider:

1. Advertise MedAccred on company supplier facing web pages.
 - a. Focus on company participation and expectations around certification.
 - b. Provide links to search additional information.
2. Educate internal teams on MedAccred
 - a. Ensure they can answer questions during assessment if asked by the suppliers.
 - b. Work to gain their buy in to the program.
 - c. Prepare materials to be shared with the supplier and include pointers / link to online materials.
3. Strategy Plans for Suppliers includes metrics around MedAccred
 - a. Identify suppliers with MedAccred Accreditation and percentage of business
 - b. Set targets around funneling business towards MedAccred certified suppliers.
 - c. Identify if there are any company funds / supports to help a supplier become certified and how that process works.
4. Request for Quotes / Bids includes identification of MedAccred Accreditation.
5. Early survey of potential suppliers include key elements of MedAccred. (possible survey questions below)
 - a. What % of your revenue is currently generated by the medical device sector?
 - b. Does your firm currently possess any of the production processes covered by MedAccred? (may need a menu of the processes – if none, please skip to ???)
 - c. Which of these processes are currently accredited by MedAccred?
 - d. Which processes do you plan to earn MedAccred Accreditation in the next 12-24 months?
 - e. If you possess processes covered by MedAccred and do not plan to earn accreditation, please explain. _____
6. Downgrade requirements to audit a supplier if MedAccred Accredited.
7. Priority should be given to suppliers that are MedAccred Accredited.
 - a. Embedded into sourcing structure.
 - b. Long-term should be minimum criteria to do business with Medical Device company.
 - c. Procurement system identifies MedAccred Accredited suppliers and pushes POs to these suppliers first.
8. Contracts with suppliers stipulate obtaining MedAccred Accreditation and/or retaining Accreditation



AUDITS

Goal: Leverage audits executed by MedAccred / Performance Review Institute (PRI) in lieu of performing audit by sourcing company.

Points to consider:

1. PRI should be listed as an approved supplier to your company.
 - a. Establish criteria to evaluate PRI against.
 - b. Execute assessment and determine if PRI is an acceptable supplier to your company for the service of supplier audits.
 - c. Release PRI to your Approved Supplier List.
2. Establish program to allow for incorporation of PRI audits into your supplier audit program.
 - a. Set up details on how to review the audit performed by PRI in comparison to your QMS requirements.
 - i. Is it a one-time assessment of PRI audit checklist per commodity type, ex. sterilization or is it a review per audit performed?
 - b. Determine when it can be leveraged:
 - i. Qualification of the supplier?
 - ii. Ongoing oversight and monitoring?
 - c. Are there triggers that would prevent use of the PRI audit?
 - i. Poor performance by the supplier?
 - ii. Length of time since onsite audit was performed by your company?
 - iii. New development projects?
 - d. Establish a process to record your review of the PRI audit against your QMS requirements.
 - i. A checklist walking through typical topics covered by your audit program per the supplier type being evaluated.
 - ii. Include review of any findings issued by PRI and status of closure.
 1. Can you close your audit if there are outstanding findings being addressed?
 - iii. Draw a conclusion once review is complete. Identify if any follow-up is needed by your company.
 1. Ensure triggers are established from this process to any relevant internal QMS.
 - iv. Determine how to file the package and close any audit requirements within your systems.

Reference Materials

- MedAccred Website:
 - <https://p-r-i.org/medaccred/>
- Communication Materials:
 - [MedAccred Capabilities Brochure](#)
 - MedAccred Elevator Pitch for MedTech Company Executives (see Appendix A)
 - Short MedAccred Overview Slide Deck
 - For MedAccred Subscriber companies only: Login to www.eAuditNet.com and follow this path: Task Group -> MedAccred Management Council -> Task Group Work Area: Group Resources
- Mandate Kit:
 - For MedAccred Subscribers planning to mandate MedAccred Accreditation for a particular commodity (or commodities), here are some tools to help with the roll-out.
 - For MedAccred Subscriber companies only: Login to www.eAuditNet.com and follow this path: Task Group -> MedAccred Management Council -> Task Group Work Area: Forum

MedAccred Elevator Pitch for MedTech Company Executives

How to use this document?

The contents of this document have been developed to **support brief (+/- 2-minute) interactions with Senior-level Executives** to explain MedAccred and the benefits to your company and the MedTech industry.

Tailor your message to the individual(s) you are speaking with and focus on the challenges/pain points they are currently facing, whether they sit in Quality, Engineering, Procurement, Operations, Legal, Regulatory Compliance, or other functional roles.

Highlight the key benefits up front - Utilize 1-2 key messaging pillars (see below). Save the finer program details and mechanics for later in the conversation or a follow-up discussion.

Include concrete examples, data and/or stories that highlight the impact of the program.

Use internal company parlance – For example, instead of saying “reduce audit cost”, use “reduce cost of poor execution”)

DO NOT include all of the information in this document in your short discussion. Only plan to use the most relevant and impactful details.

Practice your elevator pitch with colleagues/peers/friends ahead of time.

Send a follow-up after your discussion with more information, to potentially include:

- [MedAccred Capabilities Brochure](#).
- **Abbreviated Slide Deck** – This informational slide deck is meant to be a shared tool that MedAccred subscribers and program advocates can use for communication with stakeholders. It is a high-level template that can be modified to suit individual needs based on audience, company, setting, time available, etc.
- **Document location:**
 - Go to [eAuditNet](#) and follow this path:
Task Group --> MedAccred Management Council --> Task Group Work Area:
 - *Group Resources*
- **Schedule follow-up meeting with the MedAccred team**
 - Email: MedAccred@p-r-i.org
 - Call: +1-724-772-1616
 - Visit: p-r-i.org/medaccred

So, what is MedAccred?

Messaging Pillars:

- 1. Confidence in MedAccred based on Aerospace Best Practice (Suggested Audience: C-Suite, Quality)**

MedAccred is a program led by global MedTech companies, and administered by PRI, a not for profit trade association, that is a business and industry wide solution for improving the quality and reliability of our products delivered to patients while creating a more resilient critical process supply chain. MedAccred is built on the highly successful Nadcap program – used by all major aerospace and defense companies (Boeing, Airbus, NASA, etc.) for over 30 years to oversee their critical suppliers and as a prerequisite to do business with them – Nadcap conducts over 6,000 audits a year globally in over 25 critical process technologies.
- 2. Sterilization and U.S. FDA (Suggested Audience: Sterilization Leaders, Supplier Quality, Regulatory Affairs)**

Since 2013, MedAccred has been in dialogue with U.S. FDA about the program and benefits to the industry and patients. FDA has voiced strong support for MedAccred and proposed a pilot through Medical Device Innovation Consortium (MDIC) to potentially utilize MedAccred Sterilization audits as an alternative inspectional approach to existing FDA inspections at contract sterilizers. A detailed pilot was completed in 2023, after which MDIC released a **Final Pilot Report** that provided recommendations for FDA and the MedTech industry’s consideration regarding the potential use of MedAccred audit data in risk-based inspection planning and resource allocation. An FDA representative involved in the study commented, “The audit was thorough and covered all critical areas of an EO sterilization process...I was impressed with the MedAccred audit.” Another noted, “The audit was conducted well, in an organized and logical approach...Technical issues such as validation gaps were given high priority.”
- 3. Quality Improvement (Suggested Audience: Procurement, Supplier Quality, Operations)**

MedAccred improves the quality of our products by ensuring the highest level of technical capability from our most critical suppliers around the world (Sterilizers, Sterile Packagers, Injection Molders, etc.). We will see a reduction in nonconformances and defects that lead to CAPAs and FDA 483s. MedAccred brings together the best technical minds from across the medical device industry to collaborate with their peers and share best practices with the objective to develop detailed audit criteria, select auditors, and make decisions on accreditation. They conduct deep-dive 2-4 day onsite technical assessments annually of our most critical suppliers.

4. Cost and Audit Reduction
(Suggested Audience: Supplier Quality, Quality (QA), Audit Scheduling Teams)

MedAccred will reduce the cost of supplier oversight and supplier development. We can rely on MedAccred auditors to conduct the audits at critical suppliers around the world, while still maintaining control of what is included in the audit criteria (scope), who the auditors are, how nonconformances are closed out, and deciding on which suppliers achieve Accreditation. Requiring MedAccred for our suppliers ensures they are able to meet the highest standards of technical capability for a specific process. Our Engineering, Quality and New Product Development teams can then focus on challenging areas in our supply chain rather than using a broad-brush approach.

5. Resilient Supply Chain
(Suggested Audience: Procurement, Operations, Supplier Quality)

MedAccred ensures that we will have a more resilient supply chain. We will have greater visibility of our current supply base, and flexibility when identifying new suppliers when developing new products or moving our supply. MedAccred also increases our collaboration with suppliers and ensures that our specifications are being flowed down through the lower tiers in the supply chain. MedAccred was asked by FDA to chair the [Best Practices in Supply Chain Resiliency and Quality Working Group](#) to improve medical device quality and supply chain resiliency by expanding MedAccred adoption through the tiers in the supply chain, identifying best practices to supplement efforts in quality assurance and procurement strategies, and to help mitigate supply chain risks.

6. New Product Development
(Suggested Audience: R&D, NPD)

MedAccred will help us to get our new products to market faster. By using MedAccred Accredited suppliers, there is less handholding, we'll see less defects and re-work, and overall have companies that are easier to work with. There is also a list of highly capable suppliers we can choose from on the MedAccred QML when selecting new suppliers for new product development.











7. Reducing Risk in Assessing Acquisition Targets
(Suggested Audience: C-Suite, M&A, Supplier Quality, Procurement)

MedAccred can provide valuable information on the supply chains of acquisition targets to make more informed decisions regarding the "health" of their suppliers. If suppliers to the acquisition target are not MedAccred Accredited and deliver program critical processes, they can be required to be Accredited to reduce supply chain risks post-acquisition.

Appendix B





Unique Concept

How is MedAccred different from other accreditation programs?

Industry Controlled Other Party (ICOP)	MedAccred
 Industry Develops Quality Standard	 PRI works with Subscribers to develop Critica Process Audit Criteria
 Industry Approves Accrediting Bodies	 PRI Performs Audit with Auditor approved by Subscriber
 Certification Bodies Conduct Audits	 PRI Technical Experts Review and Resolve Audit Findings
 Certification Bodies Resolves Finding and Grants Certification	 Subscriber Approves Audit and Grants Accreditation
 Certification status published	 Accreditation Status Published

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Responsibilities

	PRI Provides	Subscribers Provide
	Technical experts that facilitate the program requirements	Technical experts create audit criteria and program requirements
	Conducting audits and review of audit findings prior to Subscriber approval	Approval of audit packages to grant accreditation and observation of audits
	Managing of industry approved technical auditors	Approves technical auditors, and can provide training to the auditors
	Performs Internal Audit of program	Oversight of the Program

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