Industry Managed Critical Process Supplier Quality Assurance Program for Medical Devices
Questions This Presentation Will Answer:

• What is the MedAccred Program?
• Which Companies are involved?
• Why was MedAccred created?
• What sets a MedAccred Audit apart?
• How does MedAccred align with current FDA initiatives?
• How does MedAccred work?
• How do Stakeholders utilize the MedAccred Program?
• What are the Benefits?
• What Critical Process technologies are covered?
• How are Process Validation and QMS addressed?
• How is the Audit Data stored?
• What are the Key Milestones since 2012?
• What is the Industry saying about MedAccred?
• How do I find out more information?
• How do I get involved?
What is MedAccred?

**MedAccred** is an industry-managed supply chain oversight program that reduces risk to patient safety, assures quality products and compliance with requirements as they apply to critical manufacturing processes.
Medical Device Companies Actively Participating…

- Abbott
- Applied Thermal Technologies
- Baxter Healthcare
- Becton, Dickinson & Company
- Boston Scientific Corporation
- Celestica HealthTech
- Covidien
- DePuy Synthes (Johnson & Johnson)
- DSM Biomedical
- Flextronics
- GE Healthcare
- Global Technologies
- GW Plastics
- Harterei Gerster
- Industrial Metal Finishing
- Jabil Nypro Healthcare
- Kimball Electronics
- Lake City Heat Treating
- Medtronic
- Merz Aesthetics
- Paragon Medical
- Paulo Products
- Philips HealthTech
- Plastikos
- Sanmina SCI
- Solar Atmospheres
- Stryker
- Synergy Health
- Techmetals
- Tecomet
- Terumo Cardiovascular Systems

Revised: 31JUL15
MedAccred is Managed by the Medical Device Industry

- Program Oversight / Development ✓ ✓ ✓
- Audit Criteria Development ✓ ✓ ✓
- Auditor Selection ✓ ✓
- Audit Package Review ✓ ✓
- Issue MedAccred Accreditation ✓ ✓
- Receive MedAccred Audit and Accreditation ✓ ✓ ✓
- Access to Supplier Audit Information (NCRs, CAPA, audit history, etc.) ✓ ✓
- Access to Qualified Suppliers List ✓ ✓ ✓ ✓

Performance Review Institute Staff administer all MedAccred Program activity
MedAccred Addresses Current Industry Challenges…

**Increased number of Recalls**

**Inadequate Flow Down** of design requirements from OEMs to first-tier and sub-tier suppliers

**Inadequate Purchasing Controls** (one of the top cited FDA-483 observations)

**Quality issues in specific technology areas:**

- Batteries, PCBAs, Power Sources, Sterilization, Cable & Wire Harnesses, etc.

**Outsourcing and Globalization** of the supply chain
MedAccred Differs from a Typical Quality Audit…

MedAccred provides in-depth critical process audits that are compliant and consistent to accepted industry/technical standards and conducted by industry recognized and approved Subject Matter Experts.

“1 mile deep on the critical process, 1 inch wide on the quality system”

“1 inch deep on the critical process, 1 mile wide on the quality system”
Aligning with Critical to Quality (CtQ)

Supplier Quality

FDA Case for Quality
FOCUS: Improve quality with a CtQ focus

Support

FOCUS: Ensure compliance to critical manufacturing process requirements

Support

Critical to Quality
FOCUS: Derived from DFMEA/ PFMEA
Aligning with FDA’s Case for Quality Initiative

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<th>Case for Quality</th>
<th>MedAccred Alignment</th>
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| Enhanced focus on quality while maintaining compliance                        | • Supplier preparation for audit will increase focus on quality, integrating it as part of day-to-day manufacturing best practice  
• Audit will ensure product quality and supplier compliance                       |
| Promotion of a root cause approach to quality challenges                       | • Root cause corrective action responses required for closure of all non-conformances  
• Audits will promote culture of root cause analysis                              
• PRI able to offer root cause training to support suppliers                       |
| Enhanced transparency                                                          | • eAuditNet will provide complete transparency of supplier audit data to subscribers  
• Early warning system will enable subscribers to take prompt preventative action in event of product defects and poor audit outcomes |
| Stakeholder engagement                                                         | • Collaboration on MedAccred will bring together suppliers, subscribers and other interested parties improving communication and information –sharing quality issues |
| Regulatory focus on preventative quality practices                             | • Improvements resulting from regular audit preparation will support a proactive culture of preventative quality practices |
| Critical to quality methodology (CTQ)                                          | • Ensuring compliance to critical manufacturing process requirements                 |

MedAccred recognizes that critical process auditing/oversight represents one method of control that will provide a solid foundation based on thorough process specific audit data to support a day-to-day culture of quality with patient safety and product quality being the ultimate result of increased oversight and compliance.
Subject Matter Experts from key industry stakeholders, facilitated by PRI, develop comprehensive, detailed, consensus Audit Criteria.

The most technically educated and experienced personnel for the specific critical processes trained as auditors, and continually provided additional training and oversight by Task Group (industry experts for each critical process).

Auditors simply perform the audit, freed from follow-on activities such as reviewing corrective actions, fixing problems, etc.

Supplier audits are conducted by different auditors each year.

Professional staff hired by PRI manage all Root Cause Corrective Action (RCCA) activities.

Store every aspect of every audit – answers to checklist questions, discussions, all RCCA information, and supporting evidence – in a secure, globally accessible online database; and use the database to produce reports that provide comprehensive visibility into the most critical issues all subscribing members.

Audit Criteria continually improved by feedback from Task Group members (Industry).

Issued after final decision by Task Group based on Staff Engineer recommendation.
MedAccred as a Tool for Critical Process Oversight

**OEMs and CMs:**
- Establish requirements and effective flow-down
- Ensure oversight

**SUPPLIERS:**
- Maintain compliance to requirements

**MEDACCRED:**
- Qualified Suppliers List (QSL)
- Sub-tier suppliers

**MEDACCRED:**
- Provide audits to verify compliance to requirements
- Issue accreditation
MedAccred as a Tool for Critical Process Oversight

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• For devices to meet the industry and FDA requirements, OEMs must:
  o Define design specifications for the products to be manufactured
  o Understand which of the manufacturing processes used in making the device or its components are Critical to Quality (CTQ) and hence safety of the device
  o Define industry standards and OEM specific requirements for these critical processes
  o Communicate (i.e. Flow-Down) these requirements to all levels of the Critical Process Supply Chain
  o Understand who are the Contract Manufacturers, as well as sub-tier suppliers that are providing Critical Manufacturing Processes for the devices or their components
  o Define requirements for periodic oversight

MedAccred provides:
• structured flow down of customer requirements using the audit criteria
• enhanced supply chain visibility
• comprehensive periodic oversight of supplier critical processes manufacturing
MedAccred as a Tool for Critical Process Oversight

**OEMs and CMs:**
- Establish requirements and effective flow-down
- Ensure oversight

**SUPPLIERS:**
- Maintain compliance to requirements

**MEDACCRRED:**
- Qualified Suppliers List (QSL)
  - Sub-tier suppliers

**MEDACCRRED:**
- Provide audits to verify compliance to requirements
- Issue accreditation
Critical Process Providers (Suppliers) are responsible for ensuring they are compliant with all requirements (Industry Standards, OEM specifications, etc.) as flowed down by the OEM.

MedAccred provides a mechanism for suppliers to demonstrate:

- compliance with all critical process requirements
- they have the necessary processing capabilities and controls to ensure compliance

**Flow Down:**
A systematic approach that ensures OEM specifications and expectations of quality are effectively communicated to critical manufacturing process providers for devices and device components at all tiers of the supply chain.
MedAccred as a Tool for Critical Process Oversight

OEMs and CMs:
- Establish requirements and effective flow-down
- Ensure oversight

SUPPLIERS:
- Maintain compliance to requirements

MEDACRED:
- Qualified Suppliers List (QSL)
- Sub-tier suppliers

MEDACRED:
- Provide audits to verify compliance to requirements
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The MedAccred Audit verifies the Suppliers have the process capability, necessary equipment, controls, qualified personnel, sub-tier controls, etc. and the ability to follow the process requirements as defined by the OEM and/or industry specifications.

Critical Process Task Groups, made up of Industry Representatives, create industry agreed audit criteria which drive supplier process compliance to customer requirements.

Auditors review OEM requirements and ensure the supplier is in compliance

Subscribing OEMs can maintain oversight and ensure effective flow-down of their requirements by participating in the Critical Process Task Groups and the audit process.
MedAccred as a Tool for Critical Process Oversight

**OEMs and CMs:**
- Establish requirements and effective flow-down
- Ensure oversight

**SUPPLIERS:**
- Maintain compliance to requirements

**MEDACCREDS:**
- Qualified Suppliers List (QSL)
  - Sub-tier suppliers

**MEDACCREDS:**
- Provide audits to verify compliance to requirements
- Issue accreditation
MedAccred: Provides Oversight To Verify Compliance To Requirements

• For those Suppliers that outsource a critical manufacturing process, the MedAccred QSL allows them selected accredited sub-tier suppliers

• The MedAccred QSL (Qualified Supplier List):
  o A publicly available list of accredited MedAccred Suppliers to specific Critical Process technologies
  o Display of all Audits/Certificates for a supplier
What are the Benefits to Industry?

- Promotes a philosophy of continuous improvement and a culture of patient safety and product quality for all participants
- Enhances compliance and quality management system effectiveness throughout the industry
- Promotes best practices to assure patient safety and quality
- Provides opportunity for collaboration between suppliers and OEMs
- Improves visibility of industry requirements to sub-tier suppliers
- Promotes least burdensome approach by reducing redundant process audits by multiple customers
- Provides real-time and consistent visibility of supply chain quality (QSL)
What are the Benefits to OEMs and CMs?

- Establish stringent **industry consensus audit criteria** based on industry and specific OEM requirements that ensure quality and compliance of devices and services.
- Provides **greater visibility of the supply chain** to all levels and sub-tiers that provide critical processes, consistent with regulatory requirements (e.g. Quality System regulation (21CFR Part 820), ISO 13485, MDD, IMDRF).
- Identify and **reduce risk** of exposure to lower-quality suppliers and improve product quality so as to reduce product recalls.
- Provides **early warning notification** to OEMs of potential supply chain quality issues.
- Program **frees up OEM resources** to focus on supplier development opportunities and/or problem area resolution.
More Benefits to OEMs and CMs

- **Implements flow down** of OEM requirements to sub-tier suppliers
- Makes the supplier selection process more efficient
- **Provides global** supply chain visibility through a web based system to support and improve efficiency in industry managed auditing and accreditation system (eAuditNet)
- Supports procurement to **identify accredited suppliers** (QML)
- Supports **supplier risk management strategies**
- Shared pool of trained, recognized and approved **subject matter experts** among OEMs
What are the Benefits to **Suppliers**?

- Provides **consistent/standardized** critical process audits accepted by the medical device industry **resulting in need for fewer redundant onsite audits by multiple OEMs and CMs**
- Enhances the **quality of the products and services** provided to customers
- Establishes **industry expectations** about quality and consistency
- Can use accreditation to **increase client-base** and opportunities across the medical device industry
- Enhances the supplier’s **compliance** status
Benefits of Early Adoption for Suppliers

• Opportunity to positively promote themselves as forward thinking leaders in the marketplace
  • PRI supports publicity with a supplier communications pack
• Setting themselves apart from competitors
  • Objective evidence of their commitment to quality
• Way of positioning themselves to win new business
  • Exposure to potential customers through program participation
  • Differentiating themselves on more than just pricing
Critical Manufacturing Processes Covered by MedAccred

Active

- Cable & Wire Harness
- Heat Treating
- MedAccred Quality Systems
- Plastics
- Printed Circuit Board Assemblies
- Sterilization
- Welding

Future (potential development)*

- Batteries
- Casting / Forging
- Chemical Processing
- Cleaning
- Coatings
- Electronic Displays
- Fluidics
- Machining
- Material Testing
- Laboratories
- Measurement / Inspection
- NDT
- Optics
- Packaging
- Power Sources
- Raw Materials
- Reagents
- Software

*Future Critical Process Areas of Interest with Industry and FDA Input and Trending
For Example, What is the Heat Treating Task Group Working On?

### Active
- Cable & Wire Harness
- **Heat Treating**
- MedAccred Quality Systems
- Plastics
- Printed Circuit Board Assemblies
- Sterilization
- Welding

### Future (potential development)*
- Batteries
- Casting / Forging
- Chemical Processing
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- Software

*Future Critical Process Areas of Interest with Industry and FDA Input and Trending*
Heat Treating Task Group
Chair: Bruce Dall, Sr. Materials Analysis Engineer, Stryker

AUDIT CRITERIA DEVELOPED:
• Core – Pyrometry (applicable to all sub-processes)
• Aluminum
• Room Temperature Testing
• Metallography and/or Microindentation Hardness
• Hardness and/or Conductivity Testing

• Developing additional audit criteria for Brazing

AUDIT STATUS:
• 1st MedAccred Heat Treating accreditations issued to Solar Atmospheres in March 2015

OTHER INFORMATION:
• Task Group supporting FDA review of AMS2750 standard for potential recognition – opportunity to establish an industry consensus standard
• 9 SME Auditors approved to conduct audits

PARTICIPATING COMPANIES
• Applied Thermal Technologies
• DePuy Synthes
• GE Healthcare
• Harterei Gerster
• Lake City Heat Treating
• Paulo Products
• Solar Atmospheres
• Stryker
**What about Sterilization?**

### Active
- Cable & Wire Harness
- Heat Treating
- MedAccred Quality Systems
- Plastics
- Printed Circuit Board Assemblies
- Sterilization
- Welding

### Future (potential development) *
- Batteries
- Casting / Forging
- Chemical Processing
- Cleaning
- Coatings
- Electronic Displays
- Fluidics
- Machining
- Material Testing
- Laboratories
- Measurement / Inspection
- NDT
- Optics
- Packaging
- Power Sources
- Raw Materials
- Reagents
- Software

*Future Critical Process Areas of Interest with Industry and FDA Input and Trending*
AUDIT CRITERIA DEVELOPED:
• Core (applicable to all sub-processes)
• Ethylene Oxide
• Radiation (Gamma and Electron Beam)

AUDIT STATUS:
• Pilot audit scheduled for August 2015, Coast Rica
Process Validation and Quality Systems

Process Validation

• Process Validation audit criteria are being developed for each critical process area

• Audit criteria follow GHTF guidance and industry best practices.

Quality Systems

• Auditees are required to have a valid QMS certificate as a pre-requisite for receiving a MedAccred audit

• QMS is covered at the critical process-level in each MedAccred audit criteria.
Audit Data Storage

• All MedAccred audits are electronically recorded in eAuditNet, an in-house, web based system

• All information for every audit conducted is held within in the system and accessible 24/7

• Access to audit data is restricted depending on participant status in the program

• eAuditNet will be validated to Medical Device Industry standards using FDA Guidance
# 2012-2015 Key Milestones

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| December 2012    | Initial Medical Device Industry Roundtable Meeting (5Dec12):  
|                  | - 19 industry stakeholders from 15 different OEMs and Suppliers present                           |
| March 2013       | Value Proposition document created and released to industry                                      |
| April 2013       | 1st Proof of concept audit (Welding) conducted                                                    |
| June 2013        | MedAccred Management Council (MMC) established with bi-weekly conference calls  
|                  | 5 Task Groups created (C&WH, HT, PCBA, STN, WLD)                                                 |
| September 2013   | Proof of concept audit (PCBA) conducted  
|                  | MedAccred website developed                                                                      |
| October 2013     | 2nd Proof of concept audit (Heat Treating) conducted                                               |
| December 2013    | Program presented to FDA CDRH Dept. (03Dec13)                                                     |
| January 2014     | Program presented to FDA Commissioners Level (27Jan14)                                             |
| March 2014       | 1st Subscriber to the MedAccred Program (Philips HealthTech)  
|                  | Program presented to AdvaMed                                                                     |
|                  | 3rd Proof of Concept Audit (C&WH) conducted                                                       |
| May 2014         | 2nd Subscriber to the MedAccred (DePuy Synthes (a Johnson & Johnson company))                   |
| June 2014        | 3rd Subscriber to the MedAccred (Stryker)                                                          |
| June 2014        | Presentation made to FDA Case for Quality Executive Forum                                         |
| November 2014    | Program presented to MDMA                                                                        |
| January 2015     | 1st MedAccred Heat Treat Audit conducted and accreditation issued in March 2015                 |
| February 2015    | Process Validation sub-team created                                                               |
| May 2015         | 1st Supplier Forum event held – Pittsburgh, PA                                                     |
What are Industry Stakeholders Saying?

“There are very few mandated technical standards in the medical device industry, so this program helps at the process level to have agreement among industry stakeholders, and it provides clarity to suppliers.”

Ravi Nabar, Head of Supplier Quality Assurance, Philips HealthTech

“The single biggest benefit to a supplier is that in order to answer the audit criteria, you will have to establish very detailed and well-thought out procedures so you know you will meet the requirements no matter when an auditor shows up.”

Ed Engelhard, Corporate Quality Manager, Solar Atmospheres

“[MedAccred] will help firms have better confidence about the consistency of products and provide them with a level of quality that they would expect”

Steve Niedelman, Lead Quality Systems & Compliance Consultant, King & Spalding LLP

Sources:
- The GMP Letter, July 2015, “Devicemakers Forge Program To Accredit Global Suppliers”
- The Silver Sheet, July 2013, “Nonprofit Groups Work to Bring Device Companies Together for Supplier Accreditation”
What is next for MedAccred?

- Continue to increase OEM and CM subscribing members
- Conduct additional Supplier Audits
- Continue dialogue with FDA CDRH and Commissioners Level
- Promote MedAccred to the wider Medical Devices industry
How Do I Get Involved?

MedAccred Management Council

• Teleconferences: Monthly
• Face-to-Face: Quarterly

Task Groups

• Teleconference: Bi-weekly/Monthly

Training Sessions

• Webinar / Classroom: Periodically (eAuditNet, Program Overview, Audit Preparation, etc.)

Contact MedAccred for more details
More Information:

**MedAccred Website:**
http://p-r-i.org/medaccred/

**eAuditNet - Online Audit Management System:**
www.eauditnet.com

**Contact PRI Staff:**
Connie Conboy
Director, Strategy and Business Development
cconboy@p-r-i.org
724 772 7153
PRI is a global, not-for-profit affiliate of SAE International with offices in Americas, Europe, Asia. PRI administers the MedAccred critical processes accreditation program on behalf of its Subscribing Members and industry, and is led by a Board of Directors with responsibility for strategic direction and financial stability.

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