MedAccred – Industry Managed Oversight of Medical Device Critical Processes
Agenda

- **Introduction** (Scott Dauphinee)
- **Discussion of MedAccred Process Validation and Case for Quality** (Ravi Nabar)
- **Overview of the MedAccred Program** (Connie Conboy)
- **Key elements of a MedAccred critical process audit** (Julia Markardt)
- **MedAccred for supply chain oversight** (Scott Dauphinee)
Presenters

Scott Dauphinee  
Director Supplier Quality  
Johnson & Johnson

Ravi Nabar  
Industry Expert

Connie Conboy  
Director of MedAccred  
Performance Review Institute

Julia Markardt  
Staff Engineer - Electronics  
Performance Review Institute
How did MedAccred Start?

- **2010**: Industry Roundtable, Chicago
- **2012**: DePuy Synthes – Johnson & Johnson, Cross industry benchmarking
- **2013**: First Meetings with FDA
- **2014**: FDA
  - First accreditation issued in US and globally
  - Johnson & Johnson
  - Philips
  - Stryker
  - First MedAccred OEM Subscribers
- **2015**: 1st Accreditation in Europe
  - Sinbon
  - 1st Accreditation in China
  - Flex
- **2016**: 1st Accreditation in Mexico
What is MedAccred?

**MedAccred** is an industry-managed supply chain oversight program for critical manufacturing processes that:

- reduces risk to patient safety
- assures quality products
- verifies compliance with requirements

**MedAccred Critical Process Accreditations** are issued by industry to suppliers.
MedAccred is a CtQ Production and Process Assessment...

...**NOT** a General Quality (QMS) audit.

"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 Regulatory Guidance

Supplier Quality

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

Support
- Critical to Quality
  - FOCUS: Derived from DFMEA/ PFMEA

Support
- FOCUS: Ensure compliance to critical manufacturing process requirements

Industry approach to Process Validation included in MedAccred audit criteria.
Leveraging 25+ Years of Aerospace Results

- 5,500+ audits per year
- 19 critical processes

* Zero escaping defects in Year 7
Companies Actively Participating in MedAccred

- Applied Thermal Technologies Inc.
- **Baxter**
- **Becton, Dickinson & Co.**
- BMP Medical
- Bodycote
- **Cordis (a Cardinal Health company)**
- Eltek
- **Flex**
- **GE Healthcare**
- Global Technologies
- GW Plastics
- Hansen/Balk
- Hilco Technologies
- **Johnson & Johnson**
- Kimball Electronics
- **Mack**
- **Medtronic**
- Metalworx Inc.
- Midwestern Thermal –Vac
- MTD Micro Molding
- **Oberg Medical**
- Paragon Medical
- Paulo Products
- **Philips**
- PTI Engineered Plastics
- **Sanmina**
- Sinbon
- Solar Atmospheres
- **Steris**
- Sunlite Plastics
- **Stryker**
- Wetsu Group
- Vesta
- Zeus

**Key:**
- OEM / Contract Manufacturer
- Supplier
What does MedAccred Do?

MedAccred verifies that an accredited supplier has the:

- critical process capability,
- necessary equipment,
- controls,
- qualified personnel,
- process validation,
- and sub-tier controls

as defined by industry standards, manufacturing best practices, and OEM requirements and verifies actual compliance.
How Does MedAccred Work?

Administered by the Performance Review Institute (PRI), a not-for-profit trade association, on behalf of leaders in the Medical Device Industry.
## MedAccred Critical Process Technologies

### Active*
- **Cable & Wire Harness**
- **Heat Treating**
  - Pyrometry
  - Metallography and Microindentation Hardness
  - Hardness & Conductivity Testing
- **Plastics – Extrusion**
  - Blown Film
  - Co-Extrusion
  - Film
  - Over-Jacketing
  - Ram Extrusion
  - Sheet
  - Tubing/Profile
- **Plastics - Injection Molding**
  - Compression Molding
  - Injection Blow Molding
  - Insert Molding
  - Micro Molding
  - Overmolding
  - Transfer Molding
- **Printed Board**
- **Printed Circuit Board Assemblies (PCBA)**
- **Sterilization**
  - Ethylene oxide
  - Radiation (Gamma & E-Beam)
- **Welding**
  - Fusion Welding
  - Laser Welding
  - Welding Operator Qualification
  - Resistance

### Future (potential development)
- Additive Manufacturing
- Assembly
- Batteries
- Casting / Forging
- Chemical Processing
- Cleaning
- Coatings
- Counterfeit Parts
- Electronic Displays
- Fluidics
- Machining
- Material Testing Laboratories
- Measurement / Inspection
- Non-destructive Testing
- Optics
- Packaging
  - Sterile Device Packaging
- Power Sources
- Raw Materials
- Reagents
- Software

*Developed with medical device industry and FDA input*
Highlights of One Critical Process Area: Printed Circuit Board Assemblies (PCBA)

**Active***
- Cable & Wire Harness
- Heat Treating
  - Pyrometry
  - Metallography and Microindentation Hardness Testing
- Plastics – Extrusion
  - Blown Film
  - Co-Extrusion
  - Pallet
  - Over-Jacketing
  - Ram Extrusion
  - Sheet
  - Tubing/Profile
- Plastics - Injection Molding
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  - Injection Blow Molding
  - Insert Molding
  - Micro Molding
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PCBA MedAccred Audit Criteria Includes Compliance to Standards

- **Printed Circuit Board Assemblies**
  - IPC-A-610 – Acceptability of Electronic Assemblies
  - J-STD-001 – Requirements for Soldered Electrical and Electronic Assemblies
    - J-STD-002 - 033
  - IPC-7711/7721 – Rework, Modification and Repair of Electronic Assemblies

- **Medical Industry**
  - QMS Certification such as ISO 13485, ISO 9001, etc.
  - 21 CFR part 820.181 Device Master Record
  - 21 CFR part 820.184 Device History Record
PCBA – Audit Criteria Compliance Ensures:

- **Product Quality**
  - Solder Purity – contaminated solder can cause poor electrical connection, solder joint failure and degradation
  - Hand Soldering Technique & Certification – wrong technique can cause solder joint failure and degradation

- **Consistency**
  - Process Validation
  - Time Temperature Profiles
  - Recipes
  - Detailed Work Instructions
  - Soldering Iron Tip Temperature
PCBA – Audit Criteria Compliance Ensures:

- **Safety**
  - Electrical Testing

- **Reliability**
  - Class 2 or Class 3?
  - Environmental Testing
  - Material Management – *Read the technical data sheet!*
  - Cleanliness testing
  - How long will a solder joint last?
MedAccred PCBA Top Non-conformances

- Solder Purity
- Environmental Controls
- ESD (Electrostatic Discharge)
- Moisture Control
- Cleanliness
  - FOD (Foreign Object Debris/Damage)
  - Flux Residue
- Shelf Life/Work and Pot Life
- Gold Embrittlement
- Recording Rework
  - Solderability
- Counterfeit Components
Additional MedAccred Audit Findings – Issues Addressed and Improved by Suppliers

Consistent Issues Across All Critical Process Areas:

- Failure of flowdown of requirements to sub-tier suppliers
- Misunderstanding Process Validation requirements

Plastics – Injection Molding

- A lack of understanding and use of Predictive Mold Maintenance
- Nonconformance with good clean room/white room procedures

Heat Treating:

- Issues related to Pyrometry that could impact the accuracy of the thermal process
- Calibration of instruments and System Accuracy Tests
# Current MedAccred Audit Activity

## Completed Audits

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## Scheduled & Scheduling Audits

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Typical Supplier Perspective

“…the MedAccred audit was the most difficult audit we have ever been through, but also the most valuable.

And…we have been through numerous ISO and most of the major medical OEM audits on a regular basis.”

- A major global medical device supplier
Advantages to OEMs

- **Improves consistency** across critical process supply chain
  - Utilizing expert industry-developed audit criteria
  - Employing expert auditors with extensive backgrounds in industry
  - Suppliers, CMs and OEMs actively participate in Task Groups to incorporate best practices and continually updating audit criteria
  - Leveraging expert team from multiple OEMs for oversight and review of every audit
    - Ensure audit findings are successfully addressed and closed
      - Suppliers cannot negotiate their way around addressing audit findings
    - Vote on final accreditation

- **Provides flexibility** to confidently identify and select new MedAccred accredited critical process suppliers for key products

- **Strengthens purchasing controls** for existing supply chain
Through MedAccred, the industry is…

Multiple Customer Requirements

…streamlining requirements through technical Task Groups,

Rigorous Industry Standards + Manufacturing Best Practices

OEM-specific Requirements
Through MedAccred, the industry is...

- Streamlining requirements through technical Task Groups.
- Conducting more rigorous critical process audits annually with experienced technical experts.

Image courtesy of MTD Micro Molding
Through MedAccred, the industry is…

- streamlining requirements through technical Task Groups,
- conducting more rigorous critical process audits annually with experienced technical experts,
- and reaching further down the supply chain.
In Summary
With MedAccred, you will see…

- Rigorous annual critical process audits by experienced technical experts
- Process requirements focused on established industry standards and manufacturing best practices
- Focus on alignment with FDA and regulatory requirements
- Enhanced quality of critical processes used in manufactured parts resulting in fewer defects and most importantly improved patient safety

Image courtesy of MTD Micro Molding
Learn More

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