MedAccred Electronics
Cable and Wire Harness

Critical manufacturing processes for the Medical Device Industry
Julia Markardt

- Performance Review Institute (PRI), Electronics Staff Engineer
- 40 years of experience in the electronics industry
- Extensive experience with NASA and US Military projects
- EPTAC, IPC Master Instructor (IPC MIT)
- Harris Corporation, Technical Trainer (IPC CIT)
- Eastern Florida State College, Adjunct Professor
  - Soldering and Advanced SMT
  - Space Tech Program
- Reliable Systems Services, Quality Manager/Configuration Manager
- ANSI/ASQC Q9003-1994 for DLA
William Brennan, GE Healthcare

- William has been with GEHC for 18 years as a Computed Tomography (CT) Development Engineer, Supplier Quality Engineer & currently the Principal Supplier Quality Engineer for Cables & Harnesses (C&H). William has been working with C&H for 15 years & is considered the Supplier Quality subject matter expert for GEHC since 2005.

- William is well versed with the C&H industry standard IPC/WHMA -A-620 and has both cable/connector design and assembly experience. William has performed over 25 C&H supplier audits for process capability/control & helped guide suppliers who have failed C&H audits to passing scores. Although William has not “seen it all”, he has definitely examined many cable failures over the past 10 years & has personal ownership of a C&H defect library which he uses when training GEHC employees in his C&H University “Lessons Learned” & “Best Practices” training classes.

- William owns the GEHC C&H standards & plans to deploy C&H drawing standard templates to all global GEHC sites by mid 2017. William has a Mechanical Engineering degree, is a Certified IPC/WHMA-A-620 Specialist, Six Sigma Greenbelt, & is the Co-Chair of the MedAccred C&H Task Group.
Paul Hugo is the Director of Quality for Global Technologies, a worldwide supplier of cable and wire assemblies based in Spring Lake, Michigan. Paul is a materials engineering graduate of Rensselaer Polytechnic Institute, where he also completed a master’s in materials science. He has achieved certification as a Certified Quality Manager (CQM) and a Certified Quality Engineer (CQE) through the American Society for Quality. Paul helped lead Global Technologies’ efforts to achieve Medaccred accreditation, and participated as a supplier representative on two audit criteria development task forces: Cable and Wire Harnesses and Process Validation. He is an avid swimmer who loves the early morning summer swims in Lake Michigan, he lives in Spring Lake with his wife Diana.
Agenda

- Critical Manufacturing Process
- Examples of Product Failure
- Critical Process Elements
- MedAccred ensures Quality, Consistency, Safety and Reliability
- Top Non-Conformances
- Typical Initial Root Cause Responses
- What is the Medical Device industry doing to improve Cable and Wire Harness Quality and Supply Chain Oversight?
Critical Manufacturing Process

- Best practices for ensuring
  - Quality
  - Consistency
  - Safety
  - Reliability
# Examples of FDA Product Failure Recalls - PBAs

<table>
<thead>
<tr>
<th>Product</th>
<th>Class</th>
<th>Reason</th>
<th>Impact</th>
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</thead>
<tbody>
<tr>
<td>Anesthesia Machine and Monitor</td>
<td>I</td>
<td>Unanticipated shut-down: A specific lot xxx machines control board wiring harness have a defect, which can cause the machine to unexpectedly shut down, terminating ventilation, anesthetic delivery, and potentially patient monitoring.</td>
<td>15 units recalled</td>
</tr>
<tr>
<td>Ultrasonic Instrument Cleaner</td>
<td>II</td>
<td>Smoke, sparking and fire hazard-Units manufactured between xxx and xxx are susceptible to water damage at the lid switch cable wiring harness, which may result in smoking, sparking, and fire.</td>
<td>353 units recalled</td>
</tr>
</tbody>
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Cable & Wire Harnessing - Critical Process Elements

- Process Validation
- Medical Record Keeping
- ESD (Electrostatic Discharge)
- Tools and Equipment
- Calibration
- Preventative Maintenance
- Facility Environmental Management
- Purchasing & Authentic Component Assurance
- Process Control
- Personnel Qualification
- Visual Acuity

- Magnification and Lighting
- Receipt, Inspection and Control of Incoming Material
- Rework
- Product Cleaning
- Wire Preparation and Stripping
- Solderability
- Gold Removal
- Wire Tinning
- Soldering
- Crimping
Cable & Wire Harnessing - Critical Process Elements

- Insulation Displacement Connection
- Ultrasonic Welding
- Connectorization
- Molding
- Potting
- Cable Assemblies / Wire Measurement
- Marking / Labeling
- Coaxial and Biaxial
- Wire Bundling and Securing
- Electrical Shielding
- Protective Coverings
- Finished Assembly
- Testing
- Storage, Handling and Packaging of Finished Product
Technical Standards Compliance is Critical

- **Workmanship Standard**
  - IPC/WHMA-A-620 Requirements and Acceptance for Cable and Wire Harness Assemblies
  - J-STD-001 Requirements for Soldered Electrical and Electronic Assemblies
  - ANSI/ESD S20.20 Protection for Electrical and Electronic Part, Assemblies and Equipment

- **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
  - Process Validation
MedAccred ensures:

- Quality
  - Soldering
  - Gold Removal
- Consistency
  - Process Validation
  - Soldering Iron Tip Temperature
  - Tool Calibration/Verification
  - Crimping
MedAccred ensures:

- Safety
  - Electrical Testing
  - Counterfeit Components
- Reliability
  - Class 2 or Class 3?
  - Mechanical Testing
  - Material Management – *Read the technical data sheet!*
Top Non-conformances

- Translation
- Process Validation
- ESD (Electrostatic Discharge)
- Preventative / Predictive Maintenance
- FOD (Foreign Object Debris/Damage)
- Counterfeit Components
- Uncertified Personnel
- Product Class not identified
- Recording Rework
- Purge Process
- Shelf Life/Work and Pot Life

- Solder Purity/Solder Bath Analysis
- Soldering Iron Tip Temperature
- Gold Removal
- Pull Test
Typical Initial Root Cause Responses

- Lack of understanding, lack of clarity
- Misunderstanding the requirement, unaware of requirement, or no customer requirement
  - No requirement for shelf life from the customer
- Lack of procedure, procedure was not well defined, or not in-depth
- Tooling specifications not clearly understood
- Misinterpretation of the standard
What is the Medical Device industry doing to improve CH Quality and Supply Chain Oversight?

CH Task Group

- Philips, Stryker, J&J, GE Healthcare, Baxter
- Open to Subject Matter Experts from OEMs, CMs and Suppliers
- Develop Audit Criteria
- Approve SME auditors
- Grant Supplier accreditations

MedAccred Accreditation is used by OEMs/CMs as a criteria to award new business and oversee their critical process supply chain quality.

Suppliers use MedAccred Accreditation to ensure final product quality and improved manufacturing operations.
Questions?

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