

# Electronics: Printed Boards and Printed Board Assemblies

Critical manufacturing processes for the Medical Device Industry



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Advancing Medical Device Quality Through Supply Chain Process Accreditation

# Julia Markardt

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- ▶ Performance Review Institute (PRI), 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



# Michael Brown, Stryker

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- Michael began his career with Celestica at their headquarters in Toronto, Ontario. Roles included PCBA Mechanical Test engineer (Vibration, thermal and shock environments) and Advanced Process Development Engineer for new processes (fine pitch, lead-free, PCBA stress/strain analysis). He joined Stryker as a Supplier Quality Engineer with Stryker Electronics (in-house PCBA manufacturer) and now is a Staff Audit Supplier Quality Engineer with a focus on PCBA supplier auditing and development. He is based in Redondo Beach, CA.
- Bachelor of Mechanical Engineering and Management - 2001
- MBA, Management of Innovation and New Technology - 2003
- McMaster University, Hamilton, ON Canada



# Agenda

- Critical Manufacturing Process
- Examples of Product Failure
- Technical Standards Compliance
- Top Non-Conformances
- Typical Initial Root Cause Responses
- Critical Process Elements
  - PBA
  - PB
- What is the Medical Device industry doing to improve PBA/PB Quality and Supply Chain Oversight?



# Critical Manufacturing Process

- Best practices for ensuring
  - Quality
  - Consistency
  - Safety
  - Reliability



# Examples of FDA Product Failure Recalls - PBAs

Product	Class	Reason	Impact
Bio-Console Extracorporeal Blood Pumping Console	II	Motor controller printed circuit boards with a capacitor installed in reverse can result in a shut down of the product pump	126 units recalled
Ventilator	II	An increased likelihood of failure of the CPU circuit board. This could result in a blank display or loss of mechanical ventilation.	46 units recalled





# Technical Standards Compliance is Critical

- ▶ Printed Boards
  - ▶ IPC-6010 series - Qualification and Performance Specifications
  - ▶ IPC-A-600 – Acceptability of Printed Boards
- ▶ Printed 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
  - ▶ IPC-TM-650 – Test Methods Manual
- ▶ 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



# Technical Standards 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





# Technical Standards Compliance ensures:

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- ▢ 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?

# Top Non-conformances

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- 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



# Typical Initial Root Cause Responses

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- Engineer did not read or fully understand the technical standard
  - Example: J-STD-033 requirements include:
    - Moisture Barrier Bag shall meet MIL -PRF-81705, Type I
    - Desiccant Material shall meet MIL -D-3464, Type II
    - Humidity Indicator Card (HIC) shall have 3 color spots of 5%, 10% and 60%
      - Operator did not know how to read HIC card
- Engineer wasn't aware that solder touch-up needed to be recorded
  - Example: J-STD-001 requirements include:
    - 13.1 Hardware defects shall (N2D3) be documented before rework. Rework for Class 2 should and for Class 3 shall be documented. The second application of a soldering iron during a hand soldering operation of a single connection is not considered rework.



# PBA Manufacturing - Critical Process Elements

- Process Validation
- Medical Record Keeping
- FOD
- ESD
- Calibration
- Preventative Maintenance
- Facility Environmental Management
- Purchasing & Authentic Component Assurance
- Process Control
- CAD/CAM Data
- Receipt, Inspection & Control of Incoming Material
- Storage & Handling of Received Materials
- Component Programming
- Electronic Component Preparation
- Stencil Printing
- Component Placement
- In-Process Placement Verification/Inspection
- Assembly Soldering Processes
- Secondary Assembly
- PCBA Cleaning Process and Control
- Coating and Encapsulation
- Adhesive Bonding
- Assembly Testing
- Final Acceptance Inspection
- Rework
- Storage, Handling & Packaging of Finished Goods



# PBA Manufacturing - Critical Process Elements

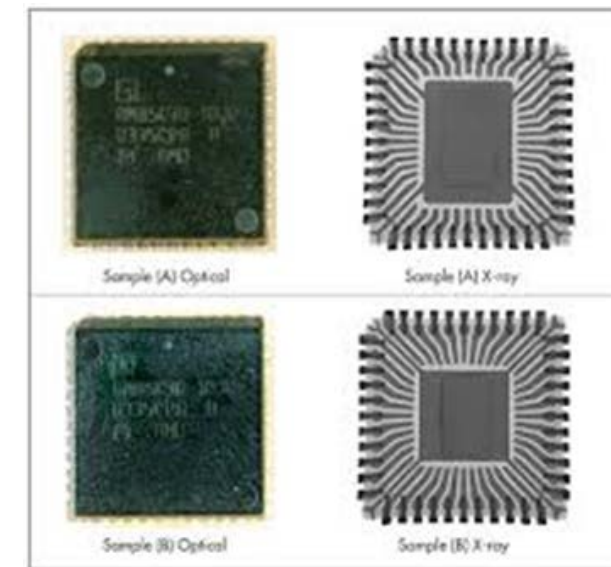
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# PBA Manufacturing - Critical Process Elements

- Purchasing & Authentic Component Assurance
- Receipt, Inspection & Control of Incoming Material



# PB Manufacturing - Critical Process Elements

- ▶ Process Validation
- ▶ Medical Record Keeping
- ▶ Process Control
- ▶ Engineering Source File Processing
- ▶ Material Control
- ▶ General
- ▶ Prepreg
- ▶ Imaging
- ▶ Photoprocess
- ▶ Develop-Etch-Strip (DES) and Strip-Etch-Strip (SES)
- ▶ Developing Photoimageable Resist
- ▶ Copper Etching of Inner Layers and Outer Layers
- ▶ Stripping of Resist Film and Etch-Resist Plating
- ▶ Etched Image Inspection (Manual or AOI)
- ▶ Permanent Solder Mask
- ▶ Solder Mask Application
- ▶ Solder Mask Exposing
- ▶ Solder Mask Develop and Cure
- ▶ Oxide Coating / Oxide Replacement Coating
- ▶ Material Lay-Up and Lamination
- ▶ Drilling
- ▶ Mechanical Drilling
- ▶ Laser Drilling – In House
- ▶ Laser Drilling – Out Sourced
- ▶ Post-Drill Cleaning and Etchback
- ▶ Copper Plating



# PB Manufacturing - Critical Process Elements cont.

- Electroless Copper/Direct Metallization
- Electroplated Copper
- Final Finishes
- Hot Air Solder Leveling (HASL)
- Fused Tin-Lead
- Electroless (Chemical)/Immersion Plating Final Finish
- Electroplated Final Finish
- Organic Solder Preservative (OSP)
- Wire Bondable Plating
- Legend and Marking
- Routing and Machining
- Electrical Test - Functional
- X-Ray Fluorescence (XRF)
- Microsection Sample Selection Preparation and Inspection
- Structural Integrity
- Materials Lab
- Chemistry Lab
- Monthly Quality Conformance Testing
- Final Validation
- Packaging



# What is the Medical Device industry doing to improve PBA/PB Quality and Supply Chain Oversight?

- ▶ Electronics PBA / PB Task Group
  - ▶ Philips, Stryker, J&J, GE Healthcare, Flex, Kimball, Sanmina, Eltek
  - ▶ 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.

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# Questions?

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