Advances in Medical Device Package Manufacturing

MEPTEC Symposium
October 23, 2014

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The Regulatory and Technology Challenges Associate With Medical Device Packaging

- Regulatory and Quality Demands
  - ISO 13485
  - 21 CFR Part 820
  - FDB (CA) Manufacturing License

- Documentation

- Product Architectures

- Technical Solutions – Stable and Automatable
Electronic “Medical” Devices Are Booming

We wear these ON our bodies

These go IN our bodies

Class I

FDA/FDB Involvement

Documentation Requirements

Class III
Medical Device Quality Management System (QMS)

- ISO Registration and CFR Requirements

- Extensive Documentation
  - Designs
  - Components & Materials
  - Equipment
  - Process
  - Lifetime Records

- Full & Regular Audits (ISO/FDA/FDB)
ISO 13485:2003 specifies the requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems.

As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements.
21 CFR Part 820
Defines Good Manufacturing Practices and Quality Control Requirements
# Equipment and Process Validation/Documentation

<table>
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<tr>
<th>Product Failure Mode Effects Analysis</th>
<th>pFMEA evaluates the manufacturing process to determine the likelihood of a process failure negatively effecting a clinical outcome to ensure adequate process quality controls are utilized.</th>
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<td><strong>pFMEA</strong></td>
<td><strong>Installation Qualification</strong></td>
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<td><strong>IQ</strong></td>
<td><strong>Operation Qualification</strong></td>
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<td><strong>OQ</strong></td>
<td><strong>Process Qualification</strong></td>
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Product Architecture Demands For In-Body & Implantable Devices

- Small Footprint – Nonintrusive
  - Chip-On-Board
  - Rigid – Flex Substrates
  - “3D” Stacked Components

- Integrated Optical Components
  - Precision Placement (+/- 5 microns) in 3 Axis
  - Particle Control

- Sterilizable - Hermetic
Endoscopes – Instructive Example

An Instrument Used To Examine The Interior Of The Human Body

There are many types, each named according to the organs or area they are used to examine. For example:

- Arthroscope – Joint examination
- Bronchoscope – Lungs and airways
- Cystoscope – Bladder
- Laparoscope – Abdominal organs
Typical Endoscope Design

- Replaced With Digital Camera
Next Generation Endoscope Design

Move Camera To The Tip Of The Endoscope

- Sharper Picture
- Simpler Optical Train
- Easier to Integrate
- Smaller, Easier to Handle
The Capsule Endoscope
Endoscope Cameras Require 3D Assembly

- 3D Assembly = Assembly of semiconductor components in a stacked configuration to pack more function in less space.

- This can be achieved by using mostly conventional processes.
  - Flip Chip, Waterfall bonding, or Combinations.
  - Flip Chip and On-Chip Thru Silicon Vias (TSVs).

- Conventional substrates may be used.
  - Rigid-Flex Assemblies.
  - Flex-Only Assemblies.
  - Ceramic – Used frequently for power dissipation & hermeticity.
3D Stacked Camera Assembly

**Features**

- Passive Alignment of Lens Assembly to the Package
- Alignment of the Imager Die to the Package: +/- 10 μ
- Z Axis Control for Optical Plane Alignment: +/- 15 μ
- Ceramic Substrate – Hermetic for Autoclave Sterilization
- Tight Dimensional Specs on All Package Components
- Microprocessor Flip Chip Attached, Imager Wire Bonded
Examples of Stacked Die with FC & WB
Conclusion

Medical Device manufacturing is characterized by:

- Tight regulatory oversight
- Lifetime BoM and Process documentation
- Demanding layout size control
- Mixed assembly processes (SMT, Die Processing, Optical Assembly)
- Development of stable, automated processes
- Longer time to market

**However**

Once a process has been fully developed and properly document it remains unchanged for the life of the product due to the costs associated with making any modifications.