TJ GREEN ASSOCIATES, LLC

739 Redfern Lane
Bethlehem, PA 18017 USA
www.tjgreenllc.com

Direct: 610-625-2158
Mobile: 610-730-3224
Email: tgreen@tjgreenllc.com

Packaging and Testing of Implanted Medical Devices (1 DAY)

Hermetic and non-hermetic packaging and testing of microelectronics, sensors, MEMS, hybrids and microwave components for use as implanted Class II/III devices in vivo is of critical importance. Cost, reliability, small form factors, biocompatibility and patient safety are driving concerns. This course begins with an overview of traditional hermetic packaging and testing approaches that have been in use for over forty years. Most pacemakers, IPGs, cochlear implants in use today follow a prescribed and proven path of hermetic sealing and testing to assure product reliability and patient safety, which includes hermeticity testing in accordance with MIL-STD-883 Test Method 1014.

Today however, the research is directed at development of a non-hermetic package that is at least as good as the proven path. Packages made from polymeric materials require a different approach from a manufacturing and testing standpoint. The problem is now one of moisture diffusion through the barrier and package interfaces. Candidate materials such as parylene, PDMS, various ALD and CVD organic and inorganic coatings, LCP, silicones etc. are reviewed and application processes discussed. How to test and evaluate "non-hermetic" packaging methods is a primary learning objective along with an understanding of the risks and consequences of failure.

This course is intended for process engineers, designers, quality engineers, and managers responsible for package seal, hermeticity testing and for those responsible for evaluating non-hermetic packages for medical implants.

COURSE OUTLINE

- **What is Hermeticity?**
- **Moisture Problems in Microelectronics**
  - Review of classic moisture related failure mechanisms

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- **Hermetic Seal Materials and Processes**

  - Seam welding, solder seal, laser welding aluminum and Al-Si alloys
  - On wafer MEMS seal processes

- **Review of Hermeticity Test Methods Based on Military/Industrial Standards**

  - Theory and technical basis of hermeticity testing
    - Air leak vs. measured helium leak rate
  - Helium based methods
  - Optical Leak Testing (OLT)

- **Theory and Technical Basis for RGA Testing**

  - Particle, moisture, and hydrogen getters in cavity packages
  - Moisture sensors

- **"Near- Hermetic Packaging" and Testing Issues**

  - Qualification of near hermetic packages for medical applications
  - Ficks law of moisture diffusion

- **Potting Compounds**

  - PDMS, PEEK

- **Thin Film/Vapor Deposited Coatings**

  - Parylene-C, ALD etc…

- **Thick Film, Spray, Dip, or Brush Applied Coatings**

  - Silicones –epoxies- bio-compatible organic coatings

- **Surfaces to Be Coated**

  - Preparation
  - Cleanliness evaluation, readiness for deposition

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- **Coating Material Evaluation and Effectiveness**

  - Test method 5011 for organic materials
  - Ampule test for outgassing properties
  - Coating integrity
    - Conformality
    - Chemical inertness/resistance
    - Permeability/diffusion properties
    - Pinholes/cracks
    - Adhesion

- **FDA Regulations for Class III Medical Implants**

  - Quality Systems Regulation (QSR) and Good Manufacturing Practices (GMP)
  - 21 CRF 820

- **Long-Term Testing and Associated Failure Analysis Methods and Techniques**

- **Course Summary**

- **Student Feedback and Course Critique**