Failure and Root Cause Analysis in Medical Electronics **½, 1, or 2 Day Course**

ABSTRACT
Medical electronics require extremely high reliability for a variety of reasons, the most important being the health and safety of the patient. Ensuring reliability requires multiple gates throughout the new product development process, including design reviews, supplier assurance, reliability prediction, and process control. However, the value of these processes often relies on a thorough and comprehensive understanding of root-causes that induced failure during test and in the field.

Using the case study approach proven to be effective by the Harvard Business School, this presentation will walk through a variety of case studies involving failures of medical electronics and similar devices. Within each case study, a description of the failure history, including design, manufacturing, failure mode, and failure site will be presented. The approach to performing failure analysis will then be discussed, with a particular emphasis on the appropriate tools and techniques and how they were selected. The case study example will then be completed with identification of root-cause and the corrective actions necessary to prevent a reoccurrence of the failure mechanism.

Attendees should leave this seminar with a base understanding of the logical and systematic process of root-cause analysis, an elevated awareness of potential risks in regards to their particular design, customer use environment, and risk level, and potential corrective actions they could implement today to reduce their company's exposure.

OUTLINE

- Introduction to Root Cause Analysis
  - Continuous Improvement & Problem Solving
  - What is Root Cause Analysis?
  - Failure Analysis: failure mode, failure site, failure mechanism, and root cause
- Approaches, Management, & Reporting Methods
  - 5 Why Approach
  - 8D (Eight Disciplines) Problem Solving
  - Shainin Red X® Statistical Problem Solving
  - Six Sigma (6σ)
  - Physics of Failure (PoF) / Reliability Physics
- Generic Failure Categories
  - Errors: Incorrect Operations & Variation Defects/Weaknesses
  - Overstress
  - Wearout/Changes (Damage Accumulation)
  - Temperature Issues
  - Vibration (Board or Components in Resonance)
  - Shock
  - Moisture/Contaminate Failures
- Finding Failure Modes
  - Product/Technology Life Cycle "S" Curve
  - Future Improvement
  - Collecting & Analyzing Data
  - Pareto Analysis
  - Other Data Sources
- Fault/Failure Investigation
  - Developing a Hypothesis
  - Investigation Tools
    - Ishikawa Cause & Effect Fishbone Diagrams
    - Fault Tree Analysis
    - Event/Issue Charting

            - No Trouble Found Issue
- Return Parts Analysis
    - Managing a Part Return Program
    - Return Policies
- Root Cause Failure Analysis Techniques
    - Visual Inspection
    - Stereomicroscopy
    - Optical Microscopy
    - Electrical Characterization
        - JTAG (Joint Task Action Group) Boundary Scan
        - Oscilloscope
    - Higher Risk Non-Destructive Evaluation
        - Thermal Imaging
        - Acoustic Microscopy
        - X-ray Microscopy
        - SQUID Microscopy
    - Surface Analysis
        - Electron Microscopy
        - Energy Dispersive X-ray Spectroscopy (Using SEM)
        - X-Ray Fluorescence Spectrometry
        - Fourier Transform Infrared Spectroscopy
        - Differential Scanning Calorimetry (DSC)
        - Thermo Mechanical Analysis (TMA)
        - Ion Chromatography
- Electrical Electronic: Failure Modes, Mechanisms, & Signatures
    - Printed Boards Substrate Materials
    - Printed Board Damage
        - Pad Cratering
        - Board Buckling
        - Cracks in Internal Conductors
        - Corrosion
        - Peeling of Surface Trace
        - Electrical Overstress
        - PTH Fatigue
        - PTH Plating Voids
        - PTH Etch Pits
        - PTH Overstress Crack/Via Wall
        - PTH Crack/Via Knee
        - PTH/Via Wall-Pad Separation
        - Conductive Anodic Filament Formation (CAF)
        - Fiber/Resin Interface Delamination
        - Hollow Fibers
        - Electrochemical Migration
        - Flex Crack
        - Solder Defects & Natural Wearout Aging
    - Wire Issues
- Developing/Implementing a Permanent Corrective Action Plan

Who Should Attend?
Recommended attendees include managers and technical personnel responsible for new product introduction (NPI), product design, component engineering, quality control, housing and packaging, accelerated testing, design verification and product qualification procedures, reliability assurance, and failure analysis.