This course covers current FDA regulatory compliance with respect to developing medical devices. Focus will be placed on relevant aspects of FDA regulation to V&V and Risk Analysis and the FDA's supplemental guidelines. An ISO perspective is offered to compliment the FDA view.

Among the topics to be discussed are: Context of V&V and Risk Analysis within the overall quality system and regulation, V&V and Risk analysis procedures, V&V methodologies, V&V strategies, types of risk analysis, risk mitigation, and methods to determine probability and severity for Risk analysis.
INSTRUCTOR CREDENTIALS

Jim Rosa provides quality engineering guidance to companies for the development, management, and operation of quality systems for devices. He has 40 years of experience leading R&D and quality functions within regulated industries. With roots in research and development and conversion to quality systems oversight later in his career, Jim provides a solid understanding and perspective from engineering and quality in bringing products to market in the medical device and IVD industries. The blend of working with research & development and quality system function, in the EU and US, in startups and large companies provides a unique insight into the practical application of design control for medical devices. Jim also has four patents related to medical device safety system implementations. Jim has worked for Gambro, Intel, Reglera, Dohmen and a number of start-ups such as CeMines (IVD) and FibroTx(IVD).

Jim’s recent focus has been on Systems & Software within the medical device market, driving strategy and implementation efforts for traditional electromechanical, mobile applications, wireless applications, infrastructure software devices, and software as a device. Additionally, Jim has taught Design Controls, V&V, and Risk Management at the University level. Mr. Rosa has earned degrees from Colorado State University (MBA) and the Radford University (BSCS).

WHO SHOULD ATTEND

This course will be most valuable to medical device industry engineers, engineering managers, regulatory affairs professionals, scientists, and quality engineers needing an understanding of Validation and Verification (V&V) per FDA’s 21 CFR Part 820.30 (f, g), ISO 13485-2003, and Risk Analysis Techniques consistent with ISO 14971-2007, as well as EN ISO 14971-2012.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPPIE room rate of $141/night if booked 3 weeks in advance)Club Quarters Hotels, Boston, MA (CPPIE room rate of $255/night if booked 4 weeks in advance).DoubleTree by Hilton London - Victoria (CPPIE room rate of £199.00/night if booked 4 weeks in advance)

FIRST DAY

Context for Validation, Verification, and Risk Analysis within the Medical Device Project
- Verification vs. Validation vs. Qualification
- Where do Validation, Verification, and Risk Analysis come from?
- FDA vs. ISO perspective
- FDA regulations (law)
- Related FDA guidelines
- Context from ISO 13485:2003 standard
- Context from ISO 62366 standard
- Related aspects of FDA regulations/ISO standard
  - Planning
  - Design Input, Output
  - Reviews
  - Record keeping
  - Documentation standards

Context within Procedure Based Quality System
- Purpose of quality system
- Need for Validation, Verification, and Risk Analysis Procedures
- Typical content for
  - Validation and Verification procedure
  - Risk Analysis Procedure

Development of Validation and Verification Plan
- Purpose of the Master Validation and Verification (MV&V) Plan
- Typical Contents of MV&V Plan
- Some typical medical device technologies
- V&V planning methodologies needed for various medical device technologies

Use of Validation and Verification Protocols
- Purpose of the Validation and Verification protocol template
- Sections of V&V protocol template
- Traceability considerations
- Style for test input, expected results, actual result, signatures
- How to determine expected results

Validation Methodologies
- What is the definition of Validation
- What are the different types of Validation
- What is difference between Design Validation and Process Validation?
- Where does IQ/OQ/PQ fit
- Using Process Validation model for SW development tools

SECOND DAY

Verification and Verification Strategies
- Start with requirement specifications as basis of what to apply V&V towards
- Determining test classes and test types
- Developing a matrix to provide overview – bring it back to V&V plan
- Special Cases
  - Reliability assessment
  - Designed experiments
  - HALT/HASS
  - Usability / Human Factors Engineering techniques
  - Test method validations

Methodologies to Analyze Risk
- Various tools and method that are used for purpose of risk determination
- Common design risk evaluation tools/methods
  - FMEA/FMEAs (Failure Modes and Effects Analysis/ Failure Modes and Effects and Criticality Analysis
  - FTA (Fault Tree Analysis)
  - Summary Risk Analysis
  - Risk/Safety Assurance Cases
- Other risk evaluation methods
  - Process FMEAs
  - PHA (Preliminary Hazard Analysis)
  - HACCP (Hazard Analysis and Critical Control Points)
  - HAZOP (Hazard and Operability Analysis)

Creation of Summary Risk Analysis
- Defining Hazards
- Typical Hazards for various types of medical devices
- Using a Risk Analysis template from Global Harmonization Task Force
- Severity Determination
- Probability Determination
- Risk Determination
- Risk Mitigation
- Residual Risk

References
- FDA Guidance
- ISO standards
- ISO guidance
- GHTF