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

Wen Schroeder is the founder and president of SEKI. With 20+ years of industrial experience, 30 US patents and author of numerous publications, Ms. Schroeder is an internationally recognized lecturer on medical devices, regulatory affairs, pharmaceuticals and cosmetic science.

Her lecture topics cover a wide range of areas including chemical management and biocide regulations, food, drug and cosmetic law. She is a key expert for numerous cross-governmental aid programs including the ASEAN-EU Programme, under the European Commission, for Regional Integration Support in cosmetic & pharmaceutical GMP and testing. Ms. Schroeder is scientific advisor to Taiwan External Trade Development Council and previously taught courses addressing cosmetics, food, OTC drugs, biocides and chemical management topics.

She served on the Personal Care Products Council and is active in the Society of Cosmetic Chemists and the Regulatory Affairs Professional Society.

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.

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 62304 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/FMECA (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

HOTEL INFORMATION

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