Process Validation for Medical Device Industry
Syllabus Rev.2

Day 1-
Validation life cycle

Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations
Introduction and requirements	• Regulatory Requirements • When is Process Validation required?
How to start Process Validation	• Process flow diagram, Risk Management • dFMEA X pFMEA
Master Validation Plan (MVP)	• Validation strategy and MVP structure
Installation Qualification (IQ)	• Requisites and Engineering support • IQ Practical example
Computer Software Validation (CSV)	• Regulatory Requirements overview • Software Categories and V shape model • Software validation life cycle overview
Session Wrap-Up	• Feedback • Reflection for next session

Day 2-
Validation life cycle

Module	Topics
Session Kick-Off	• Reflections from last session
Master Validation Plan (MVP) practice	• Review MVP template example
Operational Qualification – OQ	• Worst-Case determination • OQ Practical example
Performance Qualification – PQ	• Manual Assembly and Complex manufacturing processes and acceptance criteria • Sample size, Confidence, and reliability, Cpk • PV Protocols development
Soldering Process	• IPC-A-610 requirements overview
Re validation	• Maintaining the State of Validation and Guidelines for Re-Validation
Session Wrap-Up	• Feedback

Day 3-
Statistical Techniques to Support Validation Seminar

Module	Topics
Session Kick-Off	• Introduction • Course objectives and expectations • The statistical mindset
Location and Dispersion	• Data Type • Average and Standard Deviation • The knowledge of Variance
Regulations and Requirements	• FDA CFR Part 21 820.250 Statistical Techniques • ISO 13485:2016 - §7.3.6 Design and development verifications • Applicative examples
CPP/CQA	• How to find a CPP? • DOE complete example
Normal Distribution	• Histogram and the Standardized Z-distribution • Transformations • Oriented Examples
Intervals	• Confidence Interval • Tolerance Intervals
Sampling	• OC Curves • Confidence and Significance levels • Type I and Type II errors
Sample size Determination	• Continuous Data • Attribute Data
Process Capability	• *Cp* and *Cpk* • Regulatory Guidelines on Process Capability • Sample size for a minimum *Cpk*
Session Wrap-Up	• Feedback • Reflection for next session

Day 4- *Test Method Validation TMV* *Seminar- in Medical Device*	
Module	Topics
Session Kick-Off	• Reflections from last session
MSA Motivation	• Daily Life • Bulit-in manufacturing Variance • Types of study for MSA and TMV
Regulations	• FDA CFR Part 21 820.72 Inspection, measuring and test equipment • ISO 13485:2016 - §7.6 Control of Monitoring and Measuring Equipment
Metrology	• Introduction • Application fields • Traceability and Main components
Correction approach for Measuring error	• Static errors • Dynamic Errors • Accuracy X Precision
Type I study	• Definitions • Cg and Cgk • Examples
TMV Example	• How to Plan a TMV study • Cross X Nested approach definitions and NDC Concept • Formulae and Calculations
TMV Class exercise	• Measuring with active participation using templates • Analysis of data (Consistency and Bias) obtained from the exercise • Improvement recommendations • ANOVA approach for TMV
Attribute TMV	• Real life example • Accuracy, False Acceptance, False Rejection • Repeatability and Reproducibility Analysis • Kappa Statistics
Final Remarks	• Trouble-shooting for TMV • Common mistakes, when not to do TMV • How to improve Test Method Validation
Session Wrap-Up	• Open Questions • Feedback