Process Validation for the Medical Device Industry
Syllabus
September 2024

Day 1	
Module	Topics
Session Kick-Off	• Gstudy Introduction • Course objectives and expectation
Introduction to Process Validation	• Terms and Definitions (QMS/DHF/DMR/DHR) • Regulatory Requirements • When is Validation Required (FDA Decision Tree)
Assessment for Validation	• Risk Assessment principles • DFMEA • PFMEA
Validation Master Plan	• Contents • Templates • Justifications
Installation Qualifications	• Major IQ concerns • Examples and Case Study
Operational Qualifications	• Major OQ concerns • Control Boundaries and Worst-Case Determination • Case Study
CSV and TMV	• Who needs Test Method Validation? • VTMV and ATMV • Principles of Computer Software Validation
Performance Qualifications	• Major PQ Concerns (Component Production X Manual Assembly) • Examples • Case Study
PPQ and Re-validation	• Wʰat is Process Performance Qualification • When should Revalidations be performed? • Risk Assessment for Revalidation
Session Wrap-Up	• Feedback • Reflection for next session

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Day 2

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

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Day 3	
Module	
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 Questionnaire