

Process Validation for Medical Device Industry Syllabus Rev.2

Day 1- Validation life cycle

Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Introductions • Course objectives and expectations
Introduction and requirements	<ul style="list-style-type: none"> • Regulatory Requirements • When is Process Validation required?
How to start Process Validation	<ul style="list-style-type: none"> • Process flow diagram, Risk Management • dFMEA X pFMEA
Master Validation Plan (MVP)	<ul style="list-style-type: none"> • Validation strategy and MVP structure
Installation Qualification (IQ)	<ul style="list-style-type: none"> • Requisites and Engineering support • IQ Practical example
Computer Software Validation (CSV)	<ul style="list-style-type: none"> • Regulatory Requirements overview • Software Categories and V shape model • Software validation life cycle overview
Session Wrap-Up	<ul style="list-style-type: none"> • Feedback • Reflection for next session

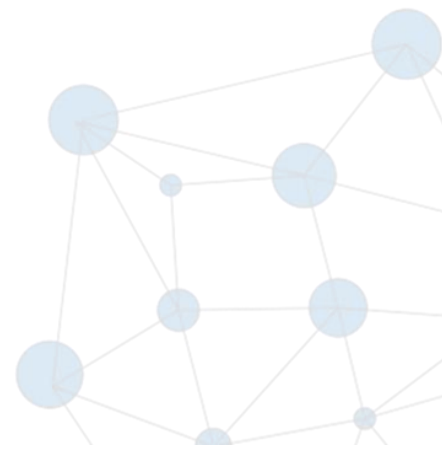
Day 2- Validation life cycle

Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Reflections from last session
Master Validation Plan (MVP) practice	<ul style="list-style-type: none"> • Review MVP template example
Operational Qualification – OQ	<ul style="list-style-type: none"> • Worst-Case determination • OQ Practical example
Performance Qualification – PQ	<ul style="list-style-type: none"> • Manual Assembly and Complex manufacturing processes and acceptance criteria • Sample size, Confidence, and reliability, Cpk • PV Protocols development
Soldering Process	<ul style="list-style-type: none"> • IPC-A-610 requirements overview
Re validation	<ul style="list-style-type: none"> • Maintaining the State of Validation and Guidelines for Re-Validation
Session Wrap-Up	<ul style="list-style-type: none"> • Feedback

Day 3-

Statistical Techniques to Support Validation Seminar

Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Introduction • Course objectives and expectations • The statistical mindset
Location and Dispersion	<ul style="list-style-type: none"> • Data Type • Average and Standard Deviation • The knowledge of Variance
Regulations and Requirements	<ul style="list-style-type: none"> • FDA CFR Part 21 820.250 Statistical Techniques • ISO 13485:2016 - §7.3.6 Design and development verifications • Applicative examples
CPP/CQA	<ul style="list-style-type: none"> • How to find a CPP? • DOE complete example
Normal Distribution	<ul style="list-style-type: none"> • Histogram and the Standardized Z-distribution • Transformations • Oriented Examples
Intervals	<ul style="list-style-type: none"> • Confidence Interval • Tolerance Intervals
Sampling	<ul style="list-style-type: none"> • OC Curves • Confidence and Significance levels • Type I and Type II errors
Sample size Determination	<ul style="list-style-type: none"> • Continuous Data • Attribute Data
Process Capability	<ul style="list-style-type: none"> • C_p and C_{pk} • Regulatory Guidelines on Process Capability • Sample size for a minimum C_{pk}
Session Wrap-Up	<ul style="list-style-type: none"> • Feedback • Reflection for next session



Day 4-
Test Method Validation TMV
Seminar- in Medical Device

Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Reflections from last session
MSA Motivation	<ul style="list-style-type: none"> • Daily Life • Built-in manufacturing Variance • Types of study for MSA and TMV
Regulations	<ul style="list-style-type: none"> • FDA CFR Part 21 820.72 Inspection, measuring and test equipment • ISO 13485:2016 - §7.6 Control of Monitoring and Measuring Equipment
Metrology	<ul style="list-style-type: none"> • Introduction • Application fields • Traceability and Main components
Correction approach for Measuring error	<ul style="list-style-type: none"> • Static errors • Dynamic Errors • Accuracy X Precision
Type I study	<ul style="list-style-type: none"> • Definitions • Cg and Cgk • Examples
TMV Example	<ul style="list-style-type: none"> • How to Plan a TMV study • Cross X Nested approach definitions and NDC Concept • Formulae and Calculations
TMV Class exercise	<ul style="list-style-type: none"> • Measuring with active participation using templates • Analysis of data (Consistency and Bias) obtained from the exercise • Improvement recommendations • ANOVA approach for TMV
Attribute TMV	<ul style="list-style-type: none"> • Real life example • Accuracy, False Acceptance, False Rejection • Repeatability and Reproducibility Analysis • Kappa Statistics
Final Remarks	<ul style="list-style-type: none"> • Trouble-shooting for TMV • Common mistakes, when not to do TMV • How to improve Test Method Validation
Session Wrap-Up	<ul style="list-style-type: none"> • Open Questions • Feedback

