



Validation and Six Sigma: How They Work Together to Improve Quality and Profitability

The key to a successful validation is a well thought out group of protocols that meet all regulatory requirements. This workshop is designed to teach the participants the requirements and standard practices for assembling, executing, and concluding validation protocols. Participants will come away with an understanding of the statistical tools needed to justify their protocols and to affect process improvement. They will learn how Six Sigma concepts can be used to facilitate compliance. The class will also focus on the roles of the individuals responsible for executing the protocols, and collecting and analyzing the data. Learning is reinforced by interactive exercises and learning games.



Target Audience: Medical Device, Pharmaceutical and Bio industry: Project managers, engineers, quality and production team members and business managers who have a basic understanding of validation concepts

Class Length: Two days

Maximum Class Size: 20

Course Prerequisites: Participants should have a working knowledge of cGMP's and basic validation concepts

Course Content: This course will include the following

- Review of regulatory requirements /expectations and industry standards for validation protocols
- Explanation of the pre-work that should occur prior to validation including documentation of process design
- The overlap between Design Validation and Process Validation
- Risk Management: how to demonstrate that your validation controls the risks that were revealed during risk assessment.
- Define, Measure, Analyze, Design, Verify (DMADV)
- The relationship between Design Control, Process Validation, and Six Sigma: similarities and differences
- Process characterization
- Review of the required elements of Installation Qualifications (IQ), Operational Qualifications (OQ), Performance Qualifications (PQ), and Validation Master Plans (VMP)





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- Discussion of the importance of multifunctional teams and the roles of the team members
- Design of actual protocols during the workshop. The problem solving sessions are based on real world scenarios that are modeled as closely as possible to the participants' manufacturing processes
- How much validation is enough?
- Hints to save time and money
- Explanation of how deviations should be handled during execution of protocols
- Discussion of the different tools available for data analysis
- Suggestions and guidelines for assembling a validation final report
- Review of the Quality Systems that should be in place to support a validated process
- The fact that every natural process has inherent variation
- Eliminating the Hidden Plant
- The Central Limit Theorem
- Define, Measure, Analyze, Improve, and Control (DMAIC)
- The 1.5 sigma empirical correction factor
- The need for statistics and validated measurement systems for the quality improvement process – Gauge R&R
- How to use control charts, run charts, histograms, pareto charts, and fishbone diagrams to monitor and improve processes
- Root Cause Analysis
- Analysis of variance
- How to use the C_{pk} index
- Process capability
- Tests for uncontrolled variation
- The evils of overadjustment during process control
- Lean validation

