Validation: a Practical Application of Qualification Principles

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. The class will focus on the roles of the individuals responsible for writing and executing the protocols and collecting and analyzing the data.

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

Class Length: One day

Maximum Class Size: 20

Course Prerequisites: Participants must 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
    - Process characterization
    - Inter-relationship with Quality by Design
- Discussion of the importance of multifunctional teams and the roles of the team members
- Review of the required elements of Installation Qualifications (IQ), Operational Qualifications (OQ), Performance Qualifications (PQ) and Validation Master Plans (VMP)
- How much validation is enough? how to determine how many samples to take
- 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
- Training requirements
- 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

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