Validation: Executive Briefing

The key to a successful validation is a well thought out group of protocols that meet all regulatory requirements. This class delineates the Quality Systems, procedures, and culture that must be in place in order to have a successful validation program. The participants will learn the requirements and standard practices for assembling, executing, and concluding validation protocols.

Target Audience: Pharmaceutical and Bio industry: Executives, Plant Managers, Quality Managers, Project managers, and business mangers who have a basic understanding of cGMP's and validation concepts

Class Length: 2 hours

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
- Review of the pre-work necessary to provide the basis for a successful validation
- Definition of the boundary between design phase and validation
- Examination of the required elements of Installation Qualifications (IQ), Operational Qualifications (OQ), Performance Qualifications (PQ) and Validation Master Plans (VMP)
- The importance of setting acceptance criteria that properly balance ease of validation with long term reliability
- Explanation of how deviations should be handled during execution of protocols
- Suggestions and guidelines for assembling a validation final report
- Summary of the Quality Systems that are necessary in order to maintain a validated process

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