



Analytical Method Validation

Course Objective: Upon completion of this course you will have a clear understanding of regulatory agency expectations and will have gained the background knowledge necessary to effectively place validation programs. You will have gained expertise in writing protocols and reports and acceptance limits for assay validation. You will have acquired insight into how to avoid conflict validation pitfalls and be able to quickly discriminate compliant from non-compliant validation activities. In addition, you will gain practical experience, during a validation workshop, in what you have learned.

Course Description: One of the most critical factors in developing pharmaceutical drug substances and drug products today is ensuring that the analytical methods that are used to analyze the products generate meaningful data. The FDA, USP, and the ICH have each recognized the importance of analytical method validation to the drug development process and have increased method validation requirements in recent years.

Both the theoretical basis and practical applications of the validation process will be discussed. Some of the more common mathematical and statistical treatments of validation data will be presented. Because of the tremendous effort that can be expended in conducting validation studies, efficiency of experimental design and documentation will be stressed throughout the discussions and case studies.

Course Outline:

- Method Validation Background
- ICH/USP Validation Requirements
- Acceptance Criteria
- Method Validation vs. Method Purpose
- Method Validation Overview
- Method Validation Process and Statistics
- BioAnalytical Method Validation
- Method Transfer Process
- Revalidation and Method Update
- Technology Changes

- Protocols /reports and Related Documents