



Assay Development and Method Validation

(16 hours)

Course Description:

This course is specifically designed to meet the analytical needs of people working within FDA regulated industries. This course is designed for those individuals directly working on assay development, test validation, variation assessment and measurement systems analysis (MSA). It is assumed that attendees come from a variety of backgrounds and disciplines and will be working on a variety of projects.

Audience:

Course is required for all employees who actively work on any aspect of assay, measurement, product and process development where the goal is to improve product and process measurement performance.

Prerequisites: Design of Experiments is a recommended prerequisite for this course.

Course Objectives:

Upon completion of the course the participants will be able to:

- Design experiments for assay characterization
- Design experiments for nonlinear modeling
- Design experiments for variation reduction
- Evaluate measurement errors and isolate sources of variation
- Determine methods to correct systematic errors in instruments and assay methods
- Determine inspection and test related errors

Course Outline:

Statistical foundations and Variation Assessment

Introduction to assay and test development
Review of basic statistics
Variation analysis methods

DOEs for Assay Development and Evaluation

Assay characterization experiments
DOE for variation reduction
DOE for robustness
DOE for nonlinear characterization

Chemical and Biological Assay Evaluation and Validation

Accuracy
Precision (Repeatability, Intermediate Precision, Reproducibility)
Detection limit
Quantitation limit
Suitability
Linearity



Range
Specificity
Robustness

MSA for Variables Data (Physical and Destructive)

MSA terms and definitions
GR&R procedure and analysis
Secondary breakdown of repeatability
Discrimination ratio
Bias
Linearity
MSA for destructive testing
MSA studies using fluids
Calibration, correlation and compensation

MSA for Attributes Data (Visual and Mechanical)

Operational definitions
Effectiveness
Probability of a false alarm
Probability of a miss
Bias
Escape rate
Statistical tests for attributes

Multifactor MSA Studies

Using POV for multiple factor gage studies