



Analytical Methods for Process Qualification and Validation

(8 Hours)

Course Outline:

I. Process Qualification

- Step 1. Determine the factors
- Step 2. Flowchart the process
- Step 3. Cause and effect diagram
- Step 4. Factor/response matrix
- Step 5. DOE
- Step 6. Exercise: Determine limits to be explored during qualification
- Step 7. Determine acceptance criteria
- Step 8. Basic statistics
- Step 9. Confidence intervals
- Step 10. Sample size selection
 - Variables
 - Attributes
- Step 11. Qualification runs
- Step 12. Reporting results
- Step 13. Excel spreadsheet

II. Process Validation

- Step 1. Measures of process capability
- Step 2. Percent defective and yield estimation
- Step 3. Use of the pre-control chart during validation runs
- Step 4. Excel spreadsheet