

Proposed Process Analytical Technology Curriculum
for FDA Inspectors and Reviewers

- 1) Basic Statistics
 - a. Nature of Randomness
 - b. Analysis of Variance
 - c. Permutation of Error
 - d. Figures of Merit: Precision, accuracy, limit of detection, dynamic range, sensitivity

- 2) Measurement Systems
 - a. Figures of Merit: Robustness (interferences), speed, hysteresis, maintenance, reliability, (self) diagnostics, etc.
 - b. Continuous vs discrete
 - c. Sensors: Temperature, pressure, flow, etc.
 - d. Physical properties: density, viscosity, particle size, rheology, etc.
 - e. Process Analysis:
 - i. Electrochemical
 - ii. Absorption spectrometry and optical sensors
 - iii. Advanced spectrometry
 - f. Sampling systems
 - g. Sensor placement

- 3) Data Analysis
 - a. Dimensionality
 - b. Correlation and Regression
 - c. Chemometrics
 - d. Pattern Recognition
 - e. Database design and mining

- 4) Process Control
 - a. Automation vs Statistical Control
 - b. Statistical Process Control
 - i. Statistical Sampling
 - ii. Attribute Charts
 - iii. Moving Range and Individuals Charts
 - iv. Components of Variation
 - v. Design of Experiments
 - vi. Process Capability
 - c. Batch Automation
 - i. Recipe management
 - ii. Within batch control
 - iii. Batch-to-batch control
 - iv. Characterization of batch trajectories and end points
 - v. Scheduling
 - d. Continuous Control

- i. Feedback
 - ii. Feed forward
 - iii. Cascade
- e. Model-based control
- f. Control Implementation
 - i. DCS
 - ii. PLC
 - iii. Database Historians

5) Pharmaceutical chemical processing fundamentals:

- a. Reaction
- b. Separation/Crystallization
- c. Mixing
- d. Storage
- e. Transport
- f. Grinding/Solids Handling
- g. Dissolution
- h. Packaging