



Process Analytical Technology (PAT)

Course Objective: The objective of this course is to provide a general understanding for the concepts and principles of product development and manufacturing (PAT principles) which when consistently applied will assist in the generation of products of predetermined quality and also set appropriate parameters for the continuous improvement of those products. Some of the expected benefits of a PAT approach to pharmaceutical manufacturing are:

- reduction of cycle times using on-, in-, or at-line measurements and controls
- prevention of reject product and waste
- real time product release
- increased use of automation
- facilitation of continuous processing using small-scale equipment, resulting in improved energy and material use and increased capacity

Course Description: Driven by a desire to improve overall efficiency of manufacturing while driving down cost and maintaining quality, the pharmaceutical industry and global regulatory agencies have been investigating innovative ways of improving manufacturing efficiency. The application of new measurement technologies, such as near infrared and laser sensing, have been explored as surrogates for the traditional “off-line” measurements which previously have been employed to characterize Pharmaceutical manufacturing processes and more specifically the products arising from those processes.

The Process Analytical Technology (PAT) approach to pharmaceutical development and manufacturing provides a sound scientific framework in which to develop and characterize processes by identifying the critical process variables, monitoring (in Real Time) their affect on the process, and developing predictive mathematical simulation models to fully characterize the process. With the attainment of this level of process understanding, testing of final product becomes a verification of specifications rather than the “pass-fail” exercise which exists today.

This course will introduce the concepts of Process Analytical Technology and serve as a foundation for its participants to become practitioners in this new pharmaceutical manufacturing paradigm.

Course Outline:

- History
- Definitions / Purpose
- Product Development
- Commercial Production
- Technology
- Case Studies / Work-shop
- Benefits / Costs
- PAT vs. cGMP Testing
- Limitations of current analytical methods
- Relative risks for in-process control and release when using regulated test methods
- Parametric Test Instruments
- Logical PAT selections: Spectrometric test instruments
- Adaptive-physics Instruments and Data
- Acoustic methods
- Thermal effusivity
- Chemometric tools for in-process testing
- PAT Method Validation:
 - Basic rules
 - Strictness
 - Parallel methods
 - Compliance
 - Preparation for inspection
- Practical PAT Program Design:
 - Validation and standardization plan
 - Preparing for inspection