



## Manufacturing Control in the Pharmaceutical Related Industries

**Course Objective:** To gain detailed knowledge on operating and regulatory issues that directly impact on the production of bulk chemicals to be incorporated into human and veterinary drug products. A good understanding of the requirements for active pharmaceutical ingredients manufacturing facilities, operating techniques, validation procedures, record keeping issues, quality control, and regulatory interfaces to foster successful manufacturing in this pervasively regulated industry will be gained as well.

**Course Description:** Manufacturing Controls are critical activity for cGMP compliance and meeting the operational/commercial demands, which required an approach that is current, complete, efficient and integrated into the overall quality program.

This course presents manufacturing concepts and their practical applications in the pharmaceutical and related industries. The focus of the course will be on manufacturing, packaging, QA/QC, material management and validation aspects of the manufacturing controls as required per cGMP. Special attention will be given to compliance elements for TPP (Therapeutic Products Program) and FDA regulatory requirements for manufacturing operations, including computer controlled materials management controls.

**Course Outline:**

- Facilities Control
- Utilities Control
- Equipment
- Personnel recruiting and performance appraisal
- Processing Step and Process Optimization
- Material Specifications
- Materials usage, shortages and changes
- Documentation Control
- In-process quality control
- Complaints trending
- Deviations and Out of Specifications
- Audits

- Change Controls
- Process Validation
- Technology Transfer