



## GMP Concepts and Applications

- Course Objective:** To learn the GMP concepts and key requirements for the proper implementation of a GMP program in the pharmaceutical or biotechnology facility. Attention is given to optimization of GMP and process requirements with proper design to achieve the ultimate goals of improving quality and profitability. Practical implementation of GMP concepts on critical aspects of the pharmaceutical and biotechnology operations will be addressed, as well as the latest updates on GMP and validation requirements.
- Course Description:** The course presents the cGMP concepts and their practical applications in the pharmaceutical industry. The presentation will focus on engineering, production, QC/QA and validation aspects of the GMP requirements. Opportunities for optimization of GMP and pharmaceutical processes are illustrated with practical design concepts and examples. This practical course is filled with recommendations that can be put into actions by engineering, production quality, validation and management personnel.
- Course Outline:**
- The Canadian GMP Compliance System
  - GMP Guidelines – current edition
  - GMP Concepts and Applications
  - Plant / Process Design
  - Process Analytical Technology (PAT)
  - Standard Operating Procedures (SOP)
  - Manufacturing Compliance
  - Validation
  - GMP Training
  - Laboratory Operations
  - Self-Inspections (Audits)
  - Inspections and Violations (Examples and Strategy)
  - Update on latest GMP and Validation Requirements