Good Manufacturing Practices and the Quality of Pharmaceutical Products

Session 1

GMP / FDA History Timeline

- How did FDA evolve?
  - Chronology of Drug Regulation in the United States
  - Why are there GMPs?
  - 21 CFR 210 and 211. What do they mean?
  - Definitions

Session 2

Implementation of GMPs in the Pharmaceutical Industry

- Raw material receipt into inventory
- Dispensing of raw materials
- Batch production
- Quality Control testing
- Quality Assurance Release

Session 3

Good Documentation Practices

- Raw Data Documentation
- 21 CFR Part 11
  - Electronic records
  - Electronic Signatures
  - Audit Trails
- GMP Review of raw data

Session 4

Currently Available Compliance Resources

- FDA Guidance Documents
- ICH Guidance Documents
- Country Specific Compendia (USP, BP, EP, JP)