



Pharmaceutical Quality Assurance and Control

Course Objective: To have an understanding of current QA/QC topics, which are of key importance for QA and/or QC management and personnel to consider.

Course Description: This course provides an understanding of the basic principles and practice of the QA and QC function, covering their role during product design, production, storage and distribution. The role of QA/QC during production will be addressed in particular detail, consisting of reviews of broad current quality issues including FDA activities, and the QA/QC aspects of a number of specific issues including: laboratory controls, validation, labels and labeling, water systems, change control, electronic records and signatures, deviations and discrepancies, OOS, FDA inspections, audits, vendor and contract supplier qualification, annual product reviews, and training. The QA/QC aspects of stability program operation and documentation will be presented as well.

Course Outline:

- Quality Function
- QA/QC's Role in Production
- Laboratory Controls
- Label and Labeling Control
- QA/QC Aspects of Water
- Change Control
- Deviation/Discrepancy Handling
- Electronic Records and Signatures
- FDA Inspections and Their Impact on QA/QC
- Internal and Supplier Audits
- Training Programs and Their Impact on QA/QC
- Vendors and Contract Suppliers
- Annual Product Reviews
- QA/QC Aspects of Stability Programs
- QA/QC Aspects of Documentation