



Natural Health Product (NHP) - Audit Programs, Annual Review and CAPA

Course Objective: To have an understanding of the necessary techniques to plan, organize and conduct audits, write reports and follow up on corrective actions, covering compliance with GMP (Good Manufacturing Practices) and GLP (Good Laboratory Practices). Also to gain the knowledge on importance of Change Control and APR (Annual Product Reviews) in satisfying FDA and ICH requirements and firm's quality objectives. The factors involved in the design, organization, implementation and operation of Change Control and APR systems will be presented as well.

Course Description: Government regulations have both explicit and implicit requirements for an internal audit function in the natural health product and related industries. Auditing is a powerful management tool in establishing how effectively a company controls the quality of its products and ensures compliance. Auditing techniques, which are applicable to any industry or function will be discussed. Specific examples will cover auditing of certain aspects of operations for compliance with NHP-GMP and GLP.

This course also addresses Change Control and Annual Product Reviews (APRs), two vital tools in the management of quality.

Course Outline:

- Quality Audits
- Auditing Aspects of Pre-Clinical Operations for Compliance with GLP
- Auditing Aspects of Plant Operations for Compliance with NHP-GMP
- Auditing Suppliers and Contractual Work
- Interviewing/Data Analysis/Report Writing
- Auditing/Inspections
- Validation and Audit of Pharmaceutical Computerized Systems
- Introduction and Overview of Change Control
- Relationship between the Change Control and Deviation Systems
- Change Control and Revalidation
- SOP for Change Control
- Introduction and Overview of Annual Product Reviews (APRs)
- Reviewing Investigation Reports
- Reviewing Recalls, Product Complaints and Returned Goods

- APR Format