



Conducting Effective Audits

An effective audit starts with a good plan. Participants will leave the seminar with an understanding of the importance of using a structured approach for audits. Participants will learn the important techniques for conducting both internal and external audits. The training materials include a generic checklist which can be used as-is or modified to suit individual needs. VCI's experienced facilitators will show you how to quickly assess an organization's performance in the limited time available in an audit.



The scope of the seminar includes:

- Buildings, facilities, equipment, laboratories, and processes
- Standard Operating Procedures
- Training
- Documentation
- Personnel observation

Who Should Attend: Individuals in the Medical Device, Pharmaceutical, Food, or Bio industry who conduct audits or manage auditors. Anyone who expects to **be** audited in the near future.

Class Length: One day

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The importance of using a structured approach.
- The Regulatory Requirements and Draft Guidelines.
- The importance of an open, honest and self correcting culture.
- How to know where to drill down: what you should do on the initial tour. The significance of employee restrooms and gearboxes.
- Auditing techniques for laboratories and production areas.
- How to analyze and review:
 - Quality Systems.
 - Out of Specification Results, CAPA systems, and Deviation reports.
 - Customer complaint files.
 - Standard Operational Procedures and batch records.
 - Raw material and finished product releases.
- How to audit vendors and suppliers.
- How the auditor can avoid creating the impression of being the police, and why this is crucial to conducting a good audit.

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