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# Auditing for Compliance

## ***Purpose***

To apply an auditing model that applies to a wide-variety of situations.

***Objectives*** At the completion of the class, students will be able to:

1. State the regulatory requirements for audits.
2. Identify common reactions to the audit process.
3. Manage adverse reactions to audits.
4. Plan an efficient and thorough audit.
5. Apply the Quality System inspection approach for audit planning.
6. Review relevant regulations applicable to the audit area.
7. Gather evidence of compliance/noncompliance.
8. Report results to affect change and build relationships.
9. Manage the corrective action and preventive action process

## ***Prerequisite***

Attendees need a very solid understanding of CGMPs is required for this class.

## ***Who should attend this class?***

Anyone who is about to conduct their first audit should obtain this solid understanding of the goals and objectives of auditing.

## ***About the class***

1. Students should be prepared to develop an audit plan. The plan can be for an internal department, supplier, contract manufacturer or contract laboratory.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 8 hours.

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## Course Content

### Introduction

1. CGMP Requirements
2. Definitions

### Managing Audits

1. Auditor's role
2. Auditee's concerns
3. Auditor concerns
4. Barriers to an effective audit
5. Audit master plan
6. Audit frequency
7. Communication and the audit

### Pre-audit Questionnaire

1. Purpose
2. Designing
3. Barrier to use
4. Overcoming barriers
5. **Activity:** *Writing A Pre-audit Questionnaire*

### Audit Focus

1. Overview of the audit
2. Traditional approach
3. Quality systems approach
4. Problem-based audit
5. Process-based audit

6. Complaint-based approach
7. Quality system-based approach
8. Single issue-based approach
9. Flow charting the process
10. **Activity:** *Flow Charting Your Audit*

### Gathering Evidence

1. Sources
2. Benchmarks
3. Questions
4. Probing
5. **Activity:** *Data Gathering Plan*

### Ratings

1. Rating system options
2. Ratings versus narratives
3. **Activity:** *Creating An Evaluation System*

### Auditing Report

1. Content
2. Guidance

**This class is always customized to reflect the language and procedural requirements of the site. Class us to discuss the details in more detail.**