# 3 Hrs Live Webinar Internal Auditor training

**Date :** Sep 17, 2019 - 12:00 PM - 03:00 PM

**Event URL :** http://www.BostonEventsList.com/events/3-hrs-live-webinar-internal-auditor-training-aug-2019

**Organizer :** WCS

**Venue :** online

**Location :** WCS Consulting Inc.3190 Stirling Rd, Unit K4 ,Hollywood, FL 33021,
Hollywood, FL, US, ZIP: 33021
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**Overview**

Regulatory agencies require pharmaceutical and medical device companies to have a systematic approach to assessing the health of their quality system. It provides management with information about how effectively the company controls the quality of their processes and products.It provides management with information about how effectively the company controls the quality of their processes and products.

Today's pharmaceutical auditor needs auditing skills, technical skills and up to date knowledge of the latest regulatory requirements in order to make that assessment.

Whether you are just beginning in pharmaceutical auditing or need to strengthen your internal skills, this 3-hour online seminar gives you the ability to conduct effective and efficient internal audits.

This course is for those intending to acquire the knowledge and skills to conduct GMP Internal Audits as an Internal Auditor.

Course attendees will gain the skills to properly plan, conduct, report and follow up on audit findings in order to establish compliance or non-conformance to applicable regulatory requirements.

**Course Objectives**

- Help make you a better auditor by developing your auditing skills
- Enable you to conduct audits of any element of the pharmaceutical quality system

- Provide a foundation for continued professional development in auditing
- Understand the regulatory requirements governing Internal Audits
- Have knowledge about audit planning, conduct, report writing and follow-up
- Know the key skills and techniques for managing an audit
- Have developed the essential soft skills of a good auditor

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**Session Highlights**
**Topic 1: Regulatory Guidance Review**

- **Increased knowledge of cGMP concepts and regulatory requirements related to auditing**
  - **FDA (CFR)**
  - **EU (EudraLex)**
  - **ICH Q10**

**Topic 2: Auditing Techniques**

- Quality Management Systems and auditing
- **Understand the concepts behind compliance auditing**
- Types of audits and reasons for performing them
- Traits/Skills of a Good Auditor
- Identify the critical competencies needed to be a conscientious auditor
- Good auditing techniques
- **Potential Interview Problems**

**Topic 3: Conducting the Audit**

- Effective audit planning and preparation
- Review of documentation before the audit
- Common Items to look for in an Audit
- Classifying, Managing, Justifying your findings
- Prepare and conduct audits using an audit trail and checklists
- The opening meeting
- Conduct an audit using an audit trail and checklist
- Identify critical components for a good audit report
- The closing meeting
- Finding faults and identifying opportunities for improvement
- Non-conformity reporting and corrective actions
- Audit reports and post-audit activities

**Topic 4: Review Elements of a GMP Compliant Internal Program**

- Certify auditors
- SOP

- Schedule
- Audit template

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**Who will benefit**
Employees that participate in Manufacturing, Engineering, Validation, Quality Assurance, and Regulatory Affairs as part of their job function – includes employees in the following departments:

- Quality Assurance
- Regulatory Affairs
- Production
- Engineering & Validation
- Facilities / Maintenance

**Event Categories :**