

Webinar on

Auditing Basics And Fundamentals For Medical Devices And Drugs

• Areas Covered

- Background Information – why are audits necessary?*
- Auditing Basics, Audit scheduling*
- Traits/Skills of a Good Auditor*
Tools
Potential Interview Problems
- GMP Background Information for Auditors*
- Pre-Audit Information, Pre-audit preparation*
- Scheduling, Conducting the Audit*
- Common Items to look for in an Audit*
- Audit reporting and closeout, Unresolved issues*



This course provides an overview of the "audit life cycle", including audit planning, conducting fieldwork, interviews, walkthroughs and tests of controls, and audit reporting and follow-up.

PRESENTED BY:

Frank Pokrop has worked in the medical device arena for more than 20 years and he is employed at Sotera Wireless in San Diego as the Senior Director for Regulatory Affairs and Quality Assurance. His prior experience covers manufacturing quality assurance for large and small volume parenteral drugs.

On-Demand Webinar

Duration : 100 Minutes

Price: \$200

Webinar Description

Internal audits are not just an important requirement for effective corporate governance – they are intended to show compliance with various domestic and international laws and regulations. Audits are also a fundamental tool of risk management. The auditor assures alignment with prescribed practices and is at the front line in evaluating control systems, testing, measurement and more. Auditors assess the accuracy, timeliness, and reliability of information.

Learn how to perform these important duties and comply with the professional auditing standards. This course provides an overview of the "audit life cycle", including audit planning, conducting fieldwork, interviews, walkthroughs and tests of controls, and audit reporting and follow-up. Designed for internal auditors who are new or have limited experience in the audit profession, this short seminar will walk the participants through the basics of being an internal auditor.

FDA and other worldwide health authorities all require that quality system audits take place in one form or another. Audit effectiveness can be enhanced through training and the appropriate background and introduction and this course serves to help with that goal.



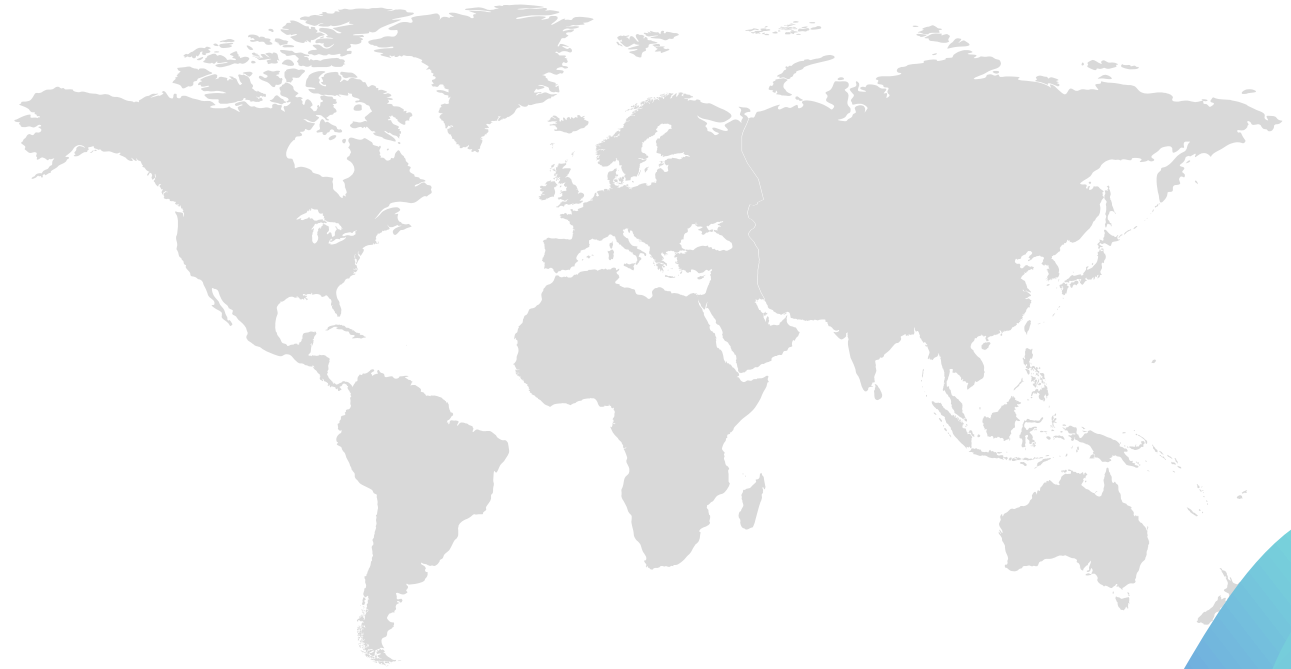
Who Should Attend ?

Managers of the audit function

Directors who are new to the audit function

*Individuals or departments with young, new or
inexperienced personnel assigned to auditing*

Personnel interested in auditing



Why Should Attend ?

Understand the quality system requirements and the role of auditing

Learn and review the basics of auditing

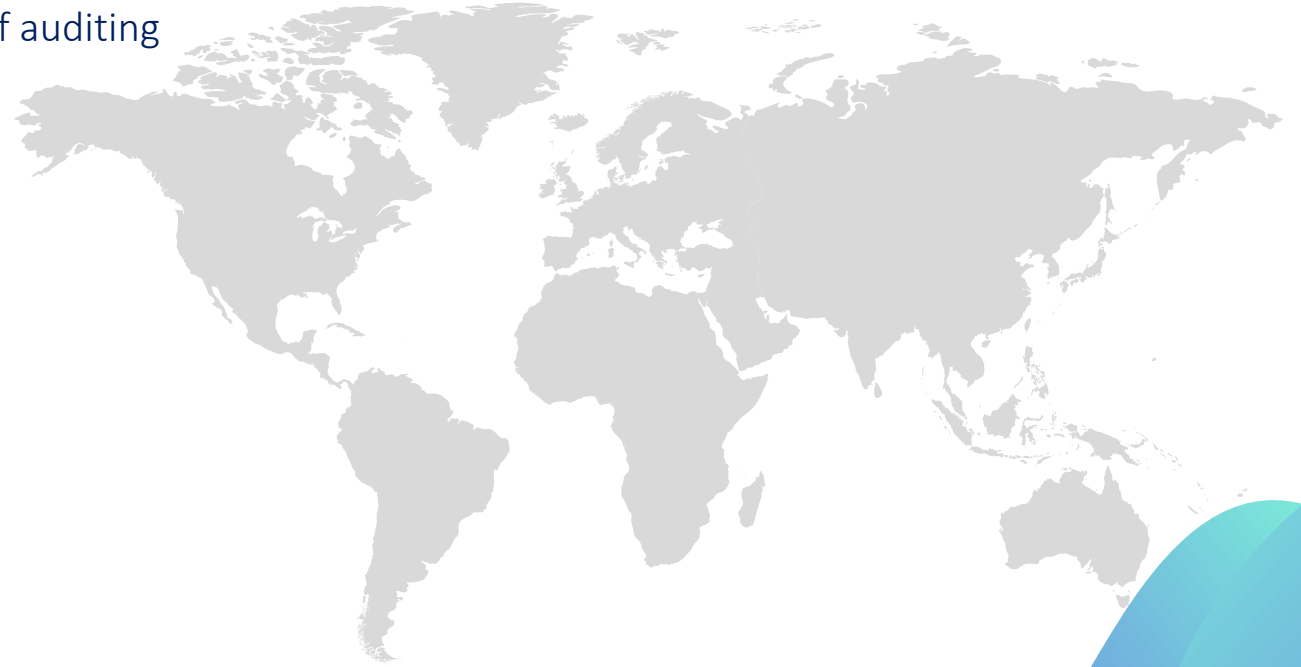
Recognize the required steps for a sound audit approach

Hear about the functions of hard and soft skills

Develop a consistent approach to the lifecycle of an audit

Learn about the characteristics of a good auditor

Discuss resources, standards and laws



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