

*Webinar on*

# **How to Prepare for and Conduct a Regulatory Audit**

*Date : July 21, 2021*

# Areas Covered

- *Preparing for a third-party audit or inspection*
  - *Assembly of an audit team*
  - *Prestaging of documents and records*
  - *Preparing “backroom”*
- *Conducting the audit*
  - *Required staff*
  - *Opening meeting*
  - *Tours*
  - *Notes and communication*
- *Responding to audit findings*
  - *Response team*
  - *How fast*
  - *Next steps*



This session will be highly interactive with audience members actively participating in an open discussion of their audit experience.

**PRESENTED BY:**

*Alan Golden - has over 30 years of experience in the medical device industry, both in basic research and in quality assurance. Alan spent 31 years at Abbott Laboratories. For the first 16 years as part of diagnostics R&D, he developed recombinant proteins used in diagnostics tests received three US patents and published numerous papers and abstracts.*

Date : July 21, 2021

Time : 01: 00 PM EST

Duration : 60 Minutes

Price: \$179

# Webinar Description

This session will be highly interactive with audience members actively participating in an open discussion of their audit experience. Through discussion and examples, participants will gain an understanding of how to prepare for an audit, strategies to conduct and support a successful audit, and ways to respond to audit observations. Special consideration will be given to virtual audits as a result of the Covid-19 Pandemic.

Successful audits by regulatory agencies are a critical part of getting products into the market in a regulated environment. In both the medical device and pharmaceutical industries, preparing for and conducting regulatory audits are critical to the introduction and maintenance of products on market.



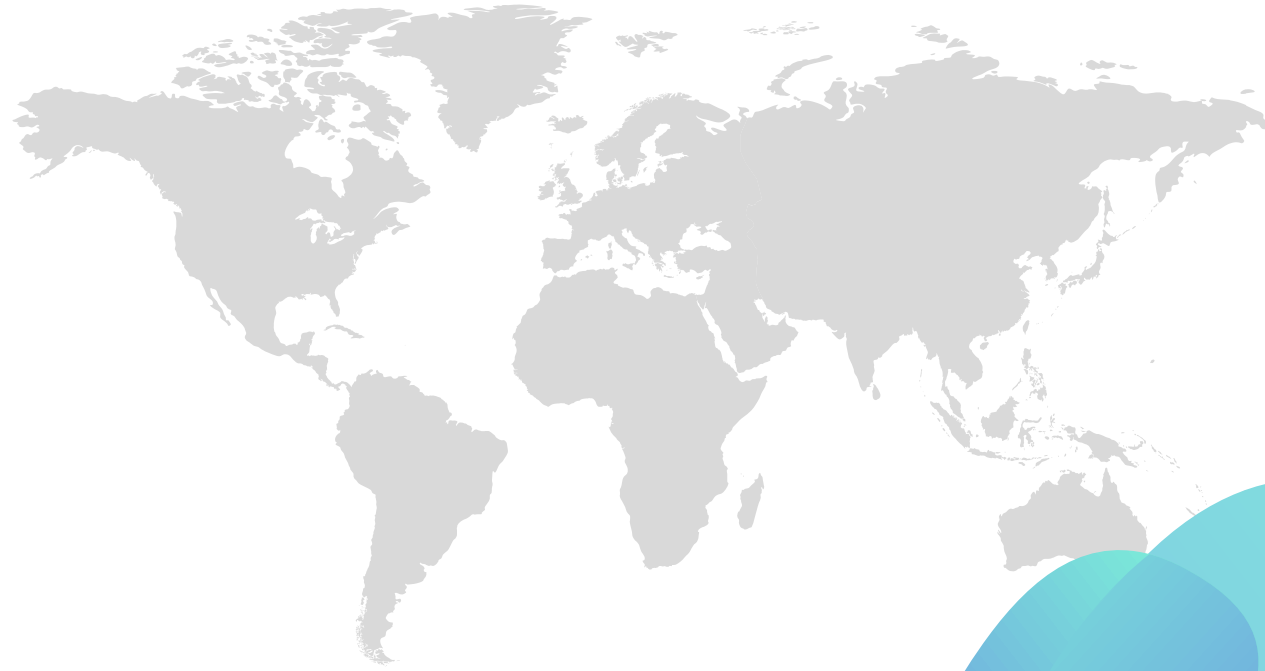
# Who Should Attend ?

*This session is geared toward Quality Assurance and Regulatory Affairs Professionals, however, anyone who will be supporting an audit such as R&D Scientists, Technical Support Scientists, Manufacturing and Production Personnel involved in audit support will benefit.*



# Why Should You Attend ?

*The successful outcome of a regulatory audit is highly dependent on preparation for and how the audit is conducted. Careful preparation, staffing, and managing an audit can mean the difference between a good outcome or a poor one.*



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