How to Prepare for and Conduct a Regulatory Audit

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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.

AREAS COVERED IN THIS WEBINAR

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

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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INSTRUCTOR PROFILE

ALAN GOLDEN

Alan 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. Alan then transitioned to a quality assurance role wherein both the Abbott Diagnostics and Abbott Molecular divisions, he was responsible for quality assurance for new product development, on-market product support and operations.

Alan's quality assurance experience extends from design control, change control, risk management, CAPA, process and test method validation, and statistics. He has been lecturing on these topics worldwide for over 10 years. Alan retired from Abbott in 2018 and now runs Design Quality Consultants, providing training, workshops, and seminars in many areas of quality assurance. Alan received his BS degree in Microbiology from the University of Michigan and his MS degree in Molecular Biology and Immunochemistry from the University of Illinois.

THIS WEBINAR IS AVAILABLE IN

LIVE ACCESS | DOWNLOADABLE LINK | PENDRIVE / USB | DVD

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