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Webinar on

Avoid 483 Observations and Warning Letters

Date : August 10, 2021

Areas Covered

- *Changing "targets" and Current regulatory "hot buttons"*
- *Avoid complacency from past "good" FDA (and notified-body/ISO) inspections/audits*
- *How to respond to the FDA 483s, 1st step, 2nd step, 3rd step to completion*
- *The desired results and how to achieve them*
- *Why do Companies Fail When They Are in Compliance*

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- *A risk-based phased approach, and the only FDA-acceptable meaning for “risk-based”*
- *The first review priority*
- *The first/key step when notified of an upcoming FDA inspection*
- *Documentation and What to Avoid*

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This webinar will provide valuable assistance to all regulated companies in evaluating their existing compliance and internal audit emphasis.

PRESENTED BY:

John E. Lincoln is Principal of J. E. Lincoln and Associates LLC, a consulting company with over 35 years of experience in U.S. FDA-regulated industries, 21 of which are as an independent consultant. John has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany, Sweden, China, and Taiwan.He periodically writes for the Journal of Validation Technology.

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Date : August 10, 2021

Time : 01 : 00 PM EST

Duration : 90 Minutes

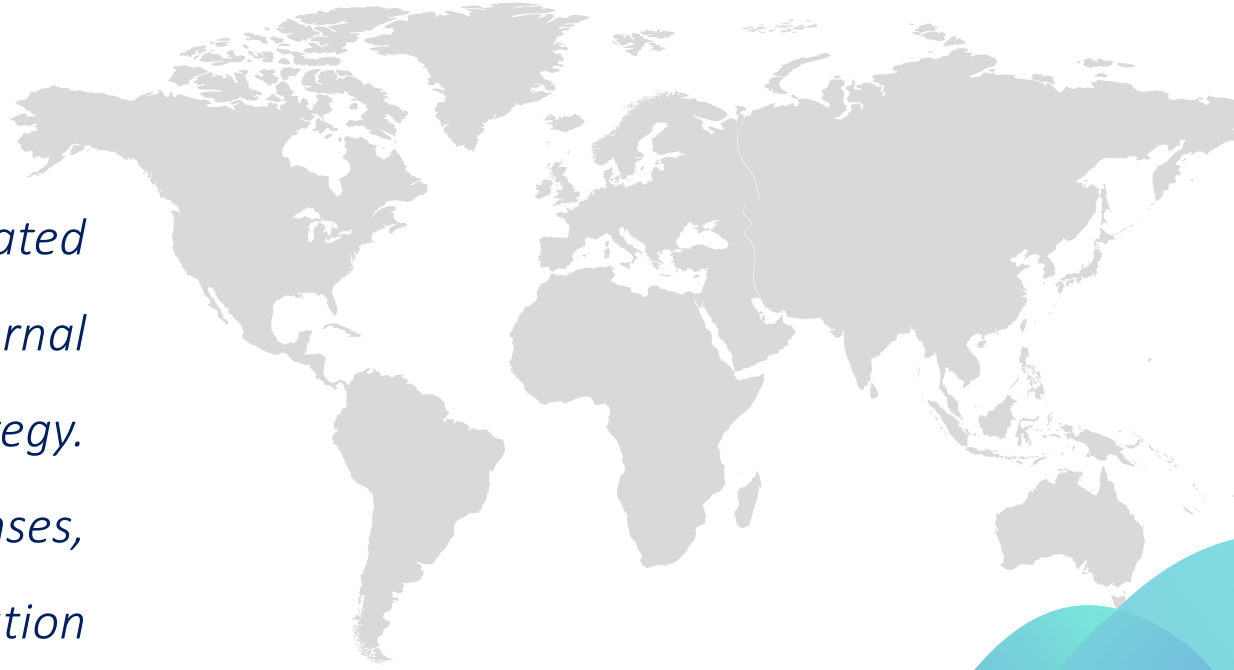
Price: $179

Webinar Description

U. S. FDA-regulated companies are responsible for understanding current Good Manufacturing Practices (CGMPs) as defined in the Code of Federal Regulations (21 CFR Part 111, 210/211, and 820), plus “current”. They are then required to translate those regulations into procedures and work instructions. Many companies who are successfully doing that are still failing audits, facing major recall, and multi-million dollar fines. What company failures contribute to this unnecessary result? What could / should be done differently? How does product hazard/risk management under ICH Q9 or ISO 14971 assist this process? And just what does the usually incorrectly defined phrase “risk-based” really mean, in the eyes of the FDA? How do companies address these issues now for inspections/audits that may be years in the future? Listen to an expert who wrote the definitive article on this subject in February 2002 and has benefited from resulting industry and FDA feedback and utilization to this day.

The company’s CGMP lapses have resulted in multi-million dollar fines, recalls, bad publicity, and lawsuits. Sadly most could have been easily prevented.

Who Should Attend ?



•*This webinar will provide valuable assistance to all regulated companies in evaluating their existing compliance and internal audit emphasis, and the propers phased response strategy. What does the FDA expect to see in the company responses, when, and what should not be provided. This information applies to personnel/companies in the Pharmaceutical, Medical Devices, Combination Products, Diagnostic, Dietary supplements, Human Tissue, and Biologics fields. The employees who will benefit include:*

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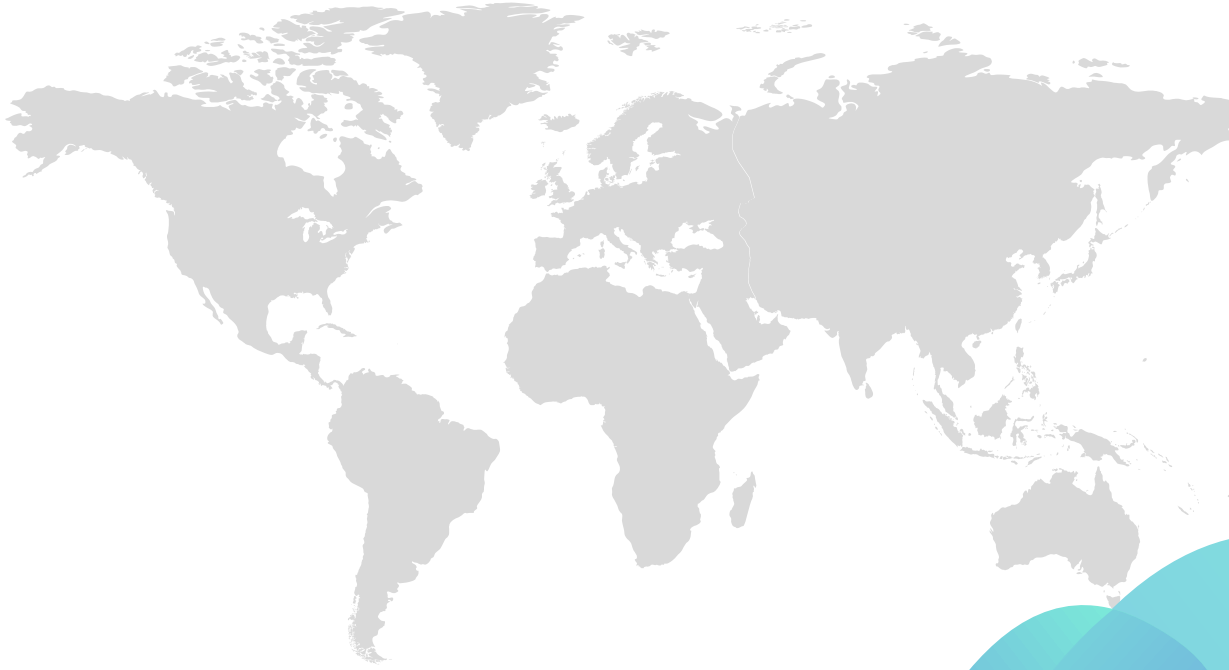
- *Sterility Engineers*
- *Design and Manufacturing Engineers*
- *Computer programmers and testers*
- *QA/QC/RA*
- *Marketing*
- *Management and Supervisory Personnel*
- *Operations*
- *R&D*



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Why Should You Attend ?

Many industry CGMP 483 observations shouldn't have been received at all. Most Warning Letters could have been easily prevented. Yet the last few years have seen several major "names" in drugs and devices stumble over cGMP issues, resulting in recalls, lawsuits, and even possible criminal prosecution. Recently one such repeated lapse has increased the public's fear of vaccines. What can companies do proactively to address these concerns and better ensure better regulatory compliance? What can they do to eliminate negative audit findings that should never have been written in the first place? If 483's are received, how can Warning Letters be avoided?

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-How can a company's positive actions be demonstrated/proven to the FDA to prevent their real achievements from being short-circuited? What can companies do in addressing these issues? Why is "entropy" a major player? How can a company "put an inspector's / auditor's mind at ease" before, during, and after a CGMP compliance inspection? How to address FDA District and Center concerns? Presented by one who first "wrote the book" on such avoidance techniques in an article published Feb 2002.

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