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Webinar on

Verification, Validation, Master Planning For U.S FDA And ISO 13485 Compliance

Areas Covered

- *Regulatory “Hot Buttons”*
- *V&V Background and Terms Defined*
- *The MVP / VMP*
- *Device / Product V&V, Drug / Process V&V*
- *Software/firmware V&V, QMS V&V*
- *Applicable guidance documents*
- *Suggested “Models”, Data Sources / Metrics*

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In this webinar will understand Why do companies need a Validation Master Plan?

PRESENTED BY:

John E. Lincoln is Principal of J. E. Lincoln and Associates LLC, a consulting company with over 35 years 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.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

How can companies address the U.S. FDA's tougher stance and product, process and QMS V&V? One major failing is the lack of sufficient or targeted risk-based V&V Master Planning. Why do companies need a Validation Master Plan? What is it? How is it structured? Supporting systems/documents? How should each individual V&V plan be structured? Clarification of validation terms. Device, product, process, equipment, QMS, software V&V. What are the key components in understandable language? How is it run? What are the "must have" elements from ISO 14971 and ICH Q9 for hazard analysis and product risk management? How can these be integrated into a company's QMS?

Who Should Attend ?

Senior management

Middle management

QA/RA

Operations

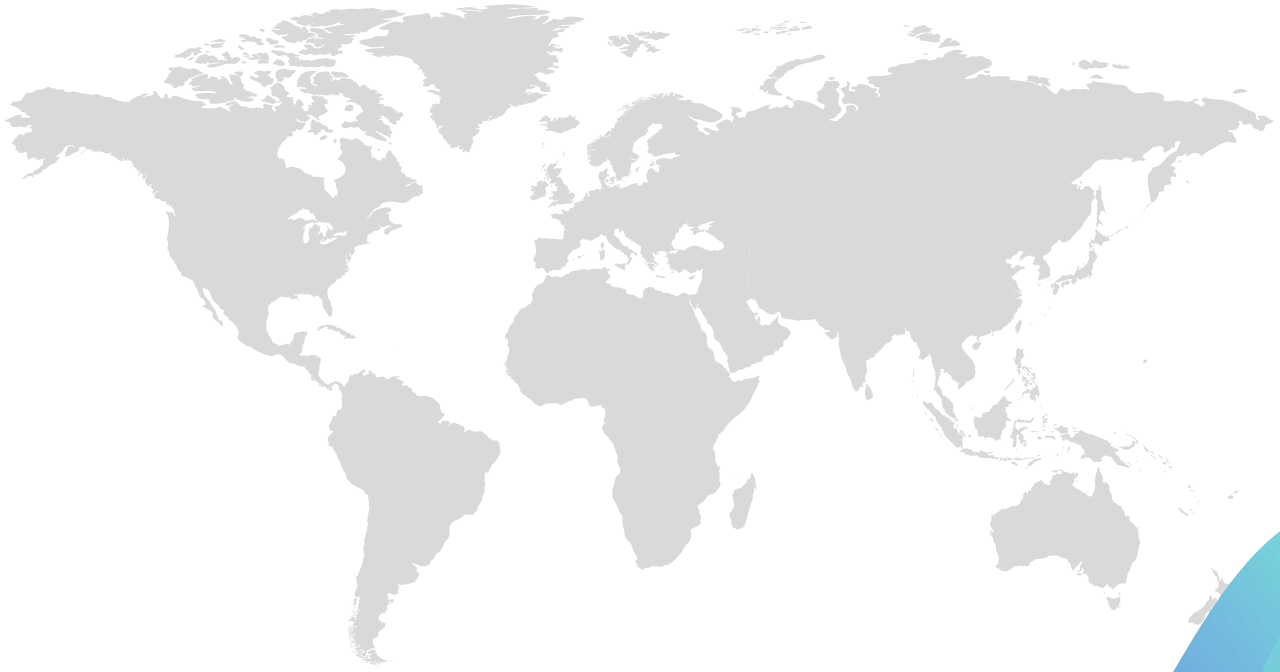
Production

Engineering

SW programming/engineering

Marketing

Consultants



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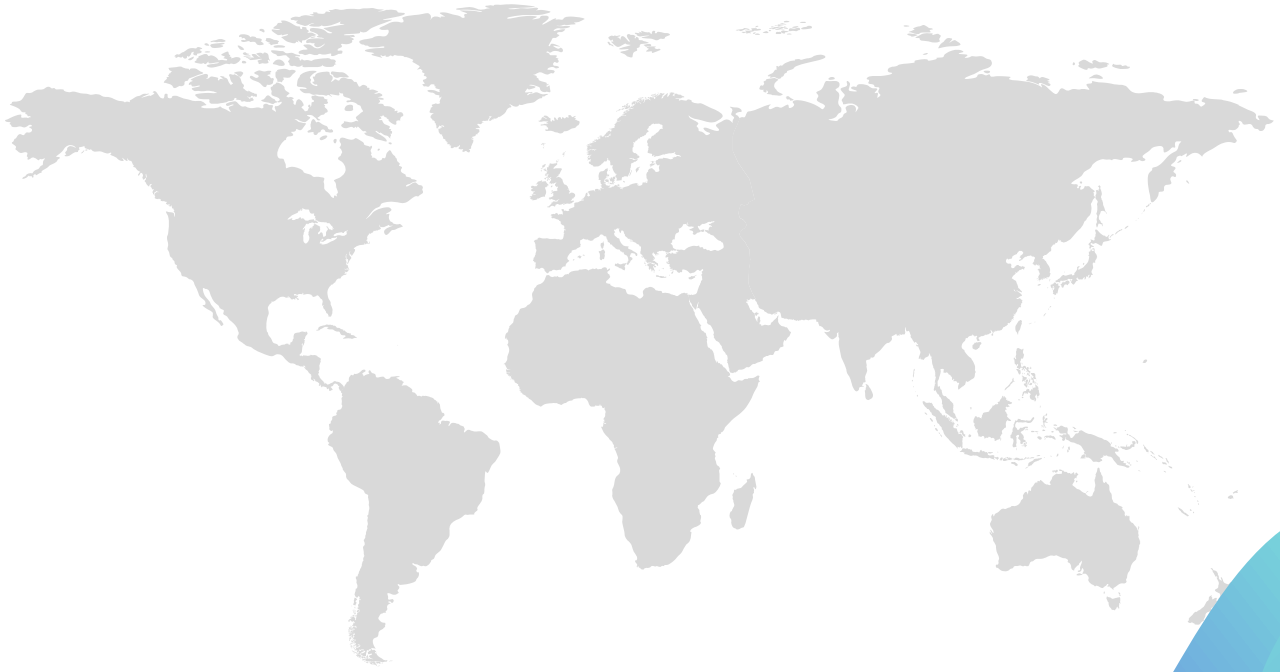
Why Should Attend ?

FDA Warning Letters and recent high-profile recalls indicate major cGMP deficiencies in big-name device and pharma companies. One major failing is lack of sufficient or targeted risk-based Verification and Validation planning and execution. Another is confusion over terminology. Why do companies need a Validation Master Plan? What is it? How is it structured? Supporting systems/documents? What are the "must have" elements from ISO 14971 and ICH Q9 for hazard analysis and product risk management? How can these be integrated into a company's QMS? How to meet the similar V&V requirements of ISO 13485. Eliminate the confusion over V&V terminology. Develop a repeatable and CGMP-compliant V&V system.



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