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Webinar on

Audit Trail Generation and Review

Learning Objectives

- *What is an Audit Trail*
- *21 CFR 11 / Annex 11 requirements for Audit Trails*
- *Why Audit Trails*
- *What are Audit Trail Features*
- *What are Audit Trail Contents*
- *What records need to have an Audit Trail*
- *When does Audit Trail begin*
- *What clock should be used for the timestamp*

- *How is Audit Trail versioned*
- *How is Audit Trail stored*
- *What if my system does not have an automated Audit Trail*
- *What about “hybrid” systems*
- *How to review audit trails*
  - *Risk-Based Approach*
  - *Best Practices*
- *Audit Trail and Data Integrity*

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One of the requirements for such compliance is the generation and review of audit trails. Thousands of audit trail records can be generated on a daily basis.

PRESENTED BY:

Angela Bazigos is the CEO of Touchstone Technologies Inc. She has 40 years of experience in the Life Sciences & Healthcare Industries. The experience combines Quality Assurance, Regulatory Compliance, Information Technology, Project Management, Clinical Lab Science, Microbiology, Food Safety, and Turnarounds.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

Computerized systems are used throughout the life sciences industry to support various regulated activities, which in turn generate many types of electronic records. These electronic records must be maintained according to regulatory requirements contained within FDA's 21 CFR Part 11 for US jurisdictions and Eudralex Volume 4 Annex 11 for EU jurisdictions.

One of the requirements for such compliance is the generation and review of audit trails. Thousands of audit trail records can be generated on a daily basis.

Who Should Attend ?

Quality Managers

Quality Engineers

Small business owners

GxP

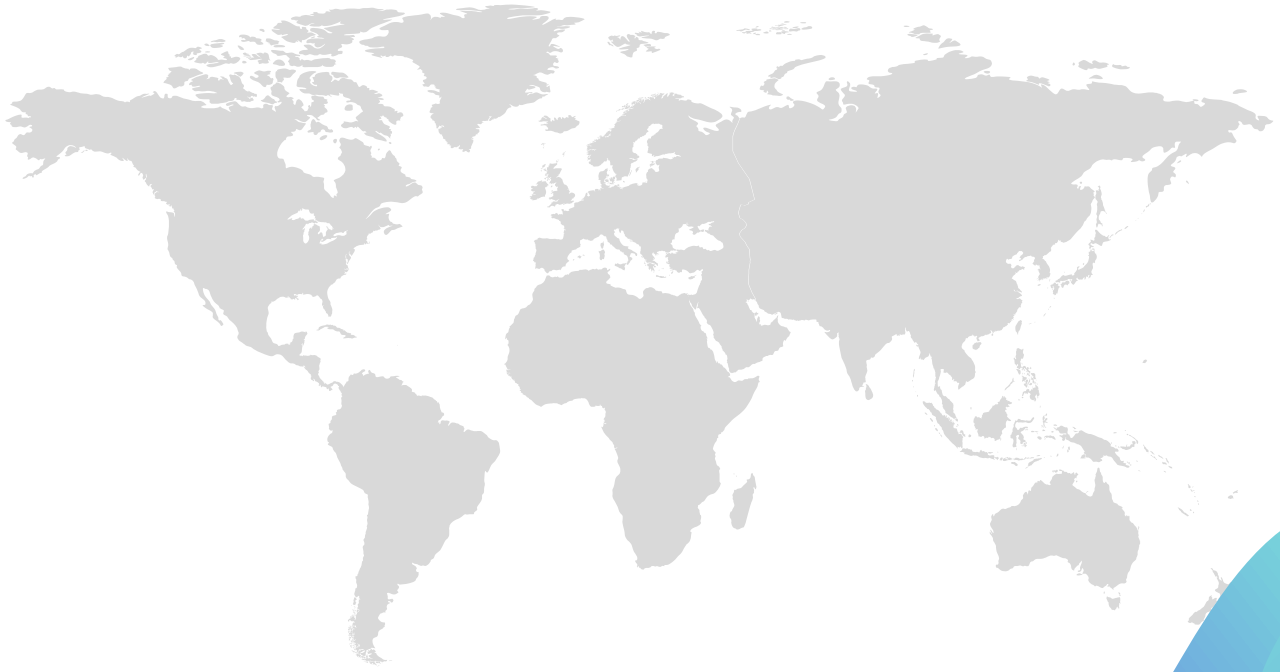
Consultants

Quality VPs

IT VPs

FDA investigators

Other regulatory agency investigators



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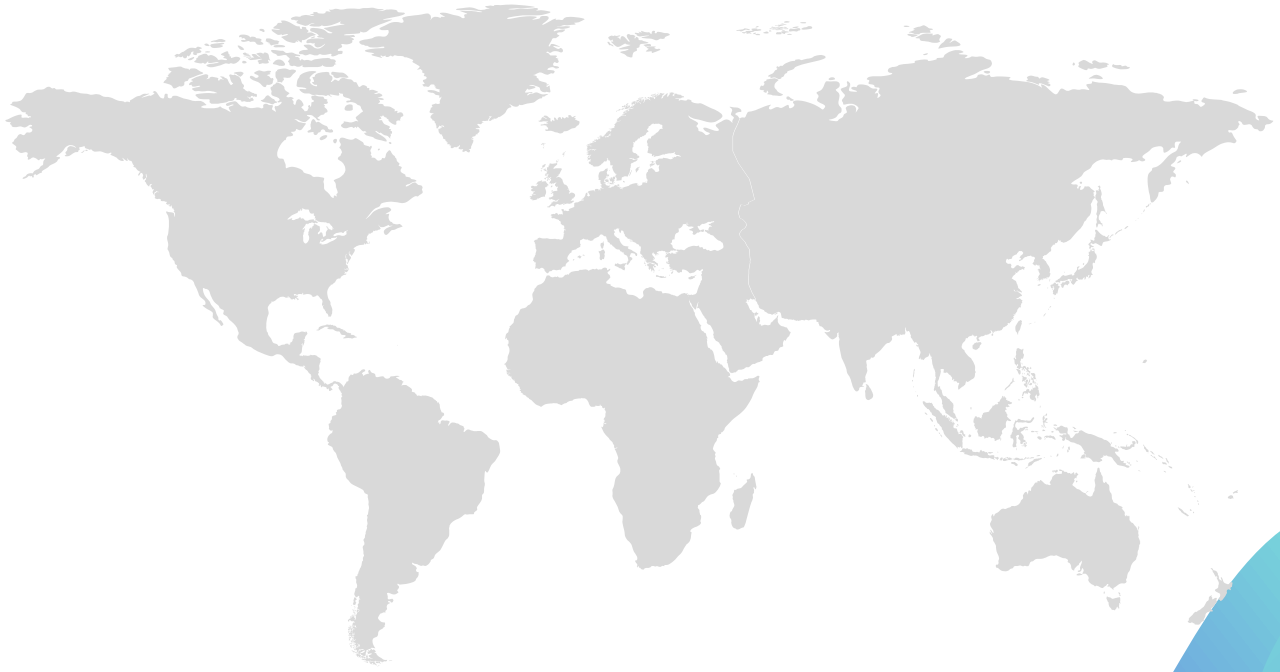
Why Should Attend ?

This webinar will demystify audit trails and describe the benefits of an audit trail for your company. Attendees will the tools required to generate compliant audit trails on a domestic and international basis and will answer the questions on how to handle systems without automated audit trails, in a compliant manner.

Additionally, attendees will learn how to review audit trails, using a risk-based approach to cull through the thousands of audit trail records that can be generated on a daily basis.



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