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Webinar on

Deviation Investigation Best Practices: Ensuring Correct Content and Conclusions

Learning Objectives

- *Discuss what to do when problems occur*
- *Outline the requirements of the Deviation and procedure including the deviation report*
- *Choose the most appropriate Root Cause Analysis methods for the situation*
- *Discuss how to conduct the deviation and the tools to be used in the process*

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Areas Covered

- *Review of FDA and Regulatory Requirements for Investigations*
- *What is the definition of a Deviation?*
- *Types of Deviations/Identification of Deviations*
- *Conducting the Investigation*
- *Interviews–dos and don’ts*
- *Source Documents/Evidence*
- *Determining Root Cause and Effective/Sustainable CAPA to avoid 483 observations*
- *Key Elements of the Investigation Report*

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Deviation investigations are a very common topic to be reviewed during FDA investigations.

PRESENTED BY:

Danielle DeLucy, MS, is the owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet regulatory compliance. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations.

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On-Demand Webinar

Duration : 60 Minutes

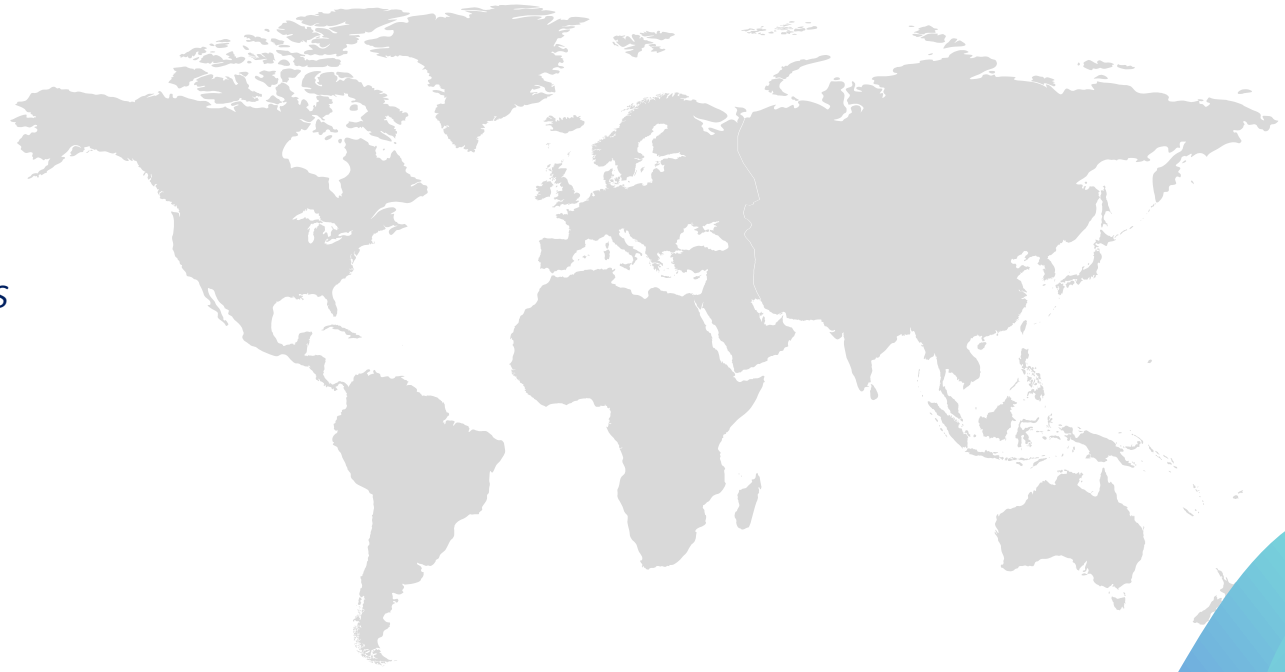
Price: $200

Webinar Description

Deviation investigations are a very common topic to be reviewed during FDA investigations. Ensuring the firm has robust and complete write-ups of these situations is key to a successful audit. Having inadequate investigations could potentially cause some severe issues for the company and may sometimes result in warning letters, consent decrees or recalls.

Who Should Attend ?

Site Quality Operations Managers
Quality Assurance personnel
Plant Managers and Supervisors
Manufacturing Superintendents and Managers
Regulatory Affairs Managers
QC Lab staff



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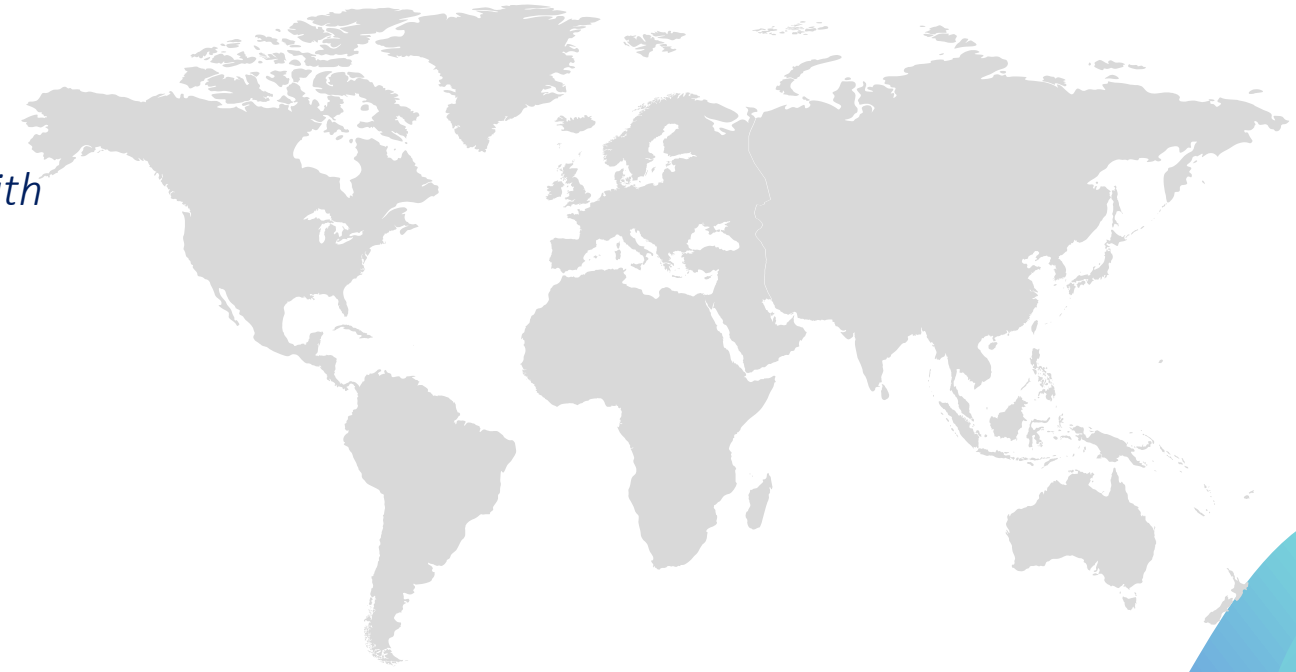
Why Should Attend ?

This webinar will help attendees understand the fundamental steps of a deviation investigation with a focus on using facts and objective evidence to arrive at root cause and CAPA. This webinar will focus on how to avoid the pitfalls that may occur during FDA inspections and help eliminate 483 observations. Learn how to identify and avoid potential pitfalls during deviation investigations.



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