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Webinar on

Best Practices For Investigating Deviations

Learning Objectives

- *Review of FDA and Regulatory*
- *What is the definition of a Deviation?*
- *Types of Deviations/Identification of Deviations*
- *Requirements for Investigations, Conducting the Investigation Interviews – do's 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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This webinar will help to understand the fundamental steps of a deviation investigation and objective evidence to arrive at root cause and CAPA.

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

One of the most common FDA 483 and Warning Letter citations continues to be inadequate investigations. The FDA uses the investigation reports and investigation trends to identify potential quality problems in all areas of the company. Ultimately, inadequate investigations can lead to 483 citations, Warning Letters, a release of the sub-standard product, or product recall. Furthermore, costly and time-consuming system remediation may be required. Having a procedure on Deviation Investigations is not enough. It is the content and conclusions of the investigations themselves that truly count. Doing a proper root cause analysis, gathering evidence and ensuring a sustainable corrective action is a key to a proper deviation investigation. This webinar will help attendees understand the fundamental investigation steps and skill sets. A key focus will be placed on identification and initial reporting of deviations, fact/evidence gathering, and arriving at the correct root cause and CAPA. The importance of investigation planning, critical thinking skills, and effective preventative action plans will also be discussed.

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.

Who Should Attend ?

Compliance auditors

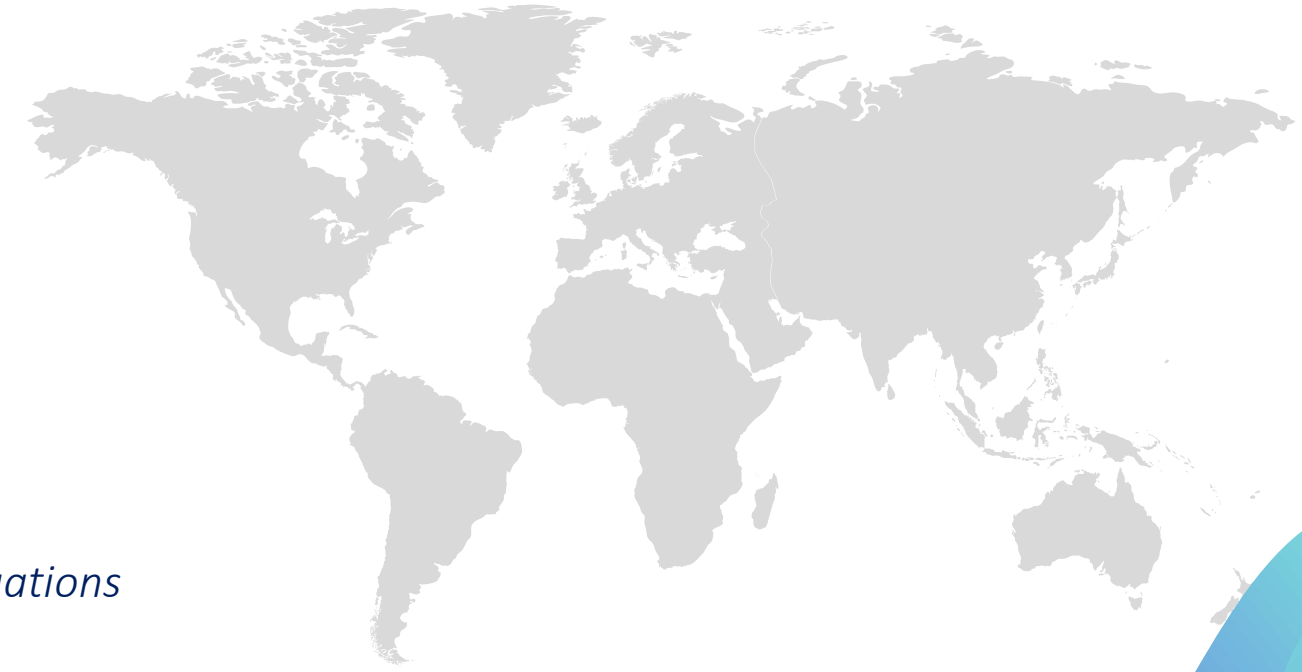
QC staff and management

Regulatory Affairs staff and management

QA staff and management

Reviewers and approvers of deviation investigations

Deviation investigators



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www.grceducators.com
support@grceducators.com
740 870 0321