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Webinar on

How to Write Effective 483 and Warning Letter Responses

Learning Objectives

Part 1 – Review regulatory policies and procedures in regard to FDA 483 observations or Warning Letters.

- *Understand the importance of responding to the observations*
- *Discuss timelines and potential regulatory outcomes of not submitting an appropriate response*
- *Understand who is the audience*
- *Understand what the regulatory agency is expecting in the response*

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Part 2 – Structure of the Response
What is Human Error

- *Review the components necessary to develop a thorough response*
- *Review response checklist*
- *Discuss recent Regulatory observations and review associated responses*

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Part 3 – Response Submission and Post Response Outcomes

- *Discuss the process for submitting the response to the regulatory agency*
- *Discuss when and how to provide follow-up updates to the regulatory agency post the initial response*
- *Discuss post response outcomes*

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This course will review the proper structure of the response to ensure the regulatory agency's expectations are met and the submission process is properly understood.

PRESENTED BY:

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation.

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On-Demand Webinar

Duration : 90 Minutes

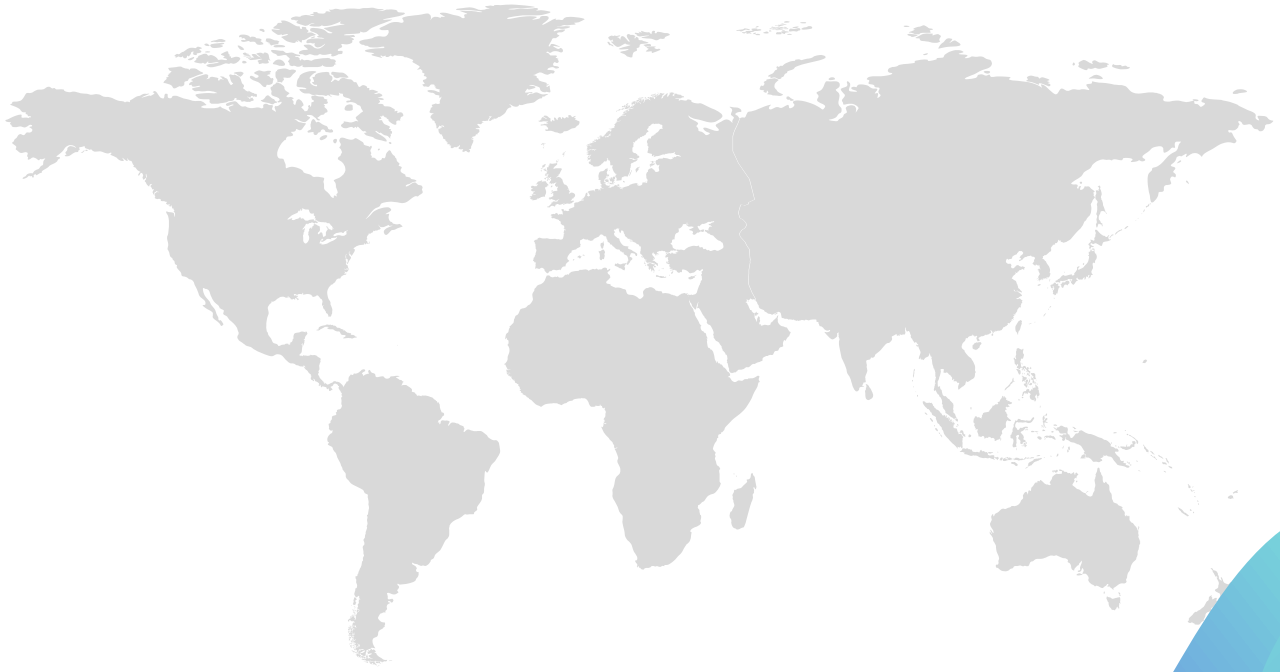
Price: $200

Webinar Description

The outcome of regulatory inspections is critical to an organization's success. If the outcome of the inspection results in FDA 483 observations or a warning letter, it is important to take the observations and subsequent responses very serious. This course will discuss the importance of developing and submitting a robust, timely response to FDA 483 observations or warning letters; as well as, educate the audience on the essential elements of a thorough response. Additionally, this course will review the proper structure of the response to ensure the regulatory agency's expectations are met and the submission process is properly understood.

Who Should Attend ?

Quality Assurance
Regulatory Affairs
Operations Managers



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