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*Webinar on*

# How to Write Effective 483 and Warning Letter Responses

*Date : July 21, 2021*

# Areas Covered

***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*

***Part 2 – Structure of the Response***

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

## *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 discuss the importance of developing and submitting a robust, timely response to FDA 483 observations or warning letters.

**PRESENTED BY:**

*Kelly Thomas - Vice President - Americas Quality Operations at Stallergenes Greer and 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 etc.*

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Date : July 21, 2021

Time : 01 : 00 PM EST

Duration : 90 Minutes

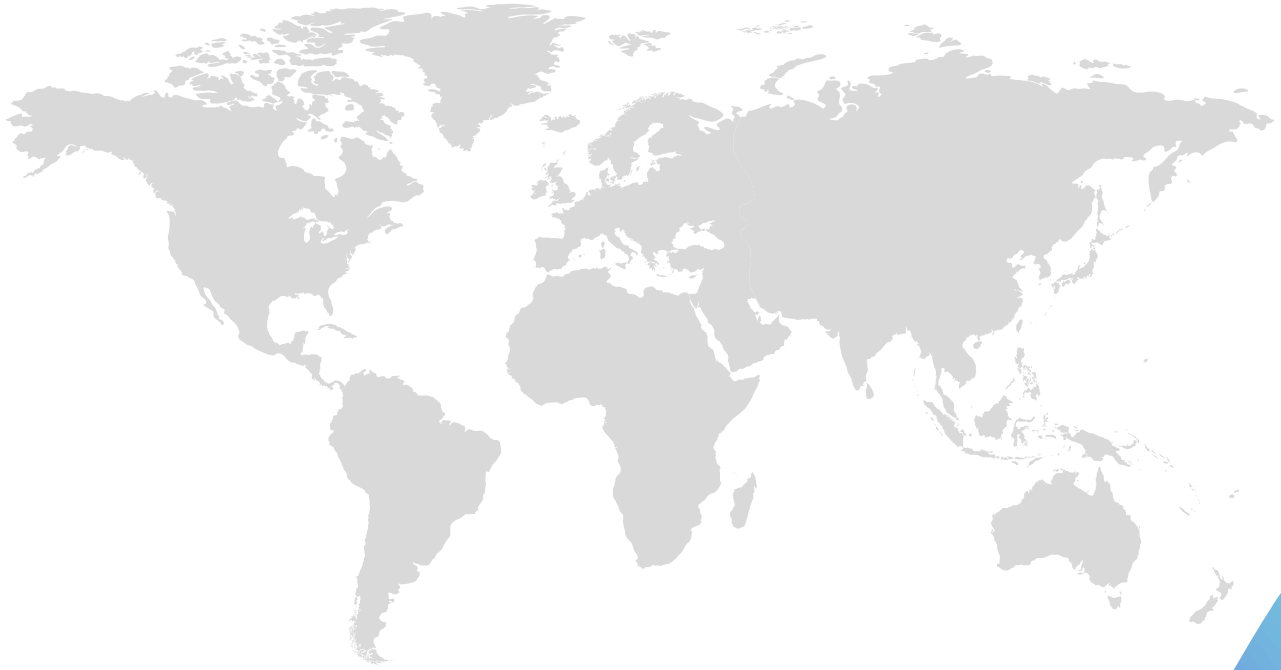
Price: $179

# 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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