

How to Write Effective 483 and Warning Letter Responses

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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 seriously. 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.

AREAS COVERED IN THIS WEBINAR

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

INSTRUCTOR PROFILE

KELLY THOMAS

Ms. 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, CSV and 21 CFR Part 11, test method validation, equipment/automated processes, and cleaning validation.



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