Webinar on

Analytical Method Validation and Transfer

Learning Objectives

- *Regulatory Requirements/Guidance on Analytical Method Validation*
- *Analytical Method Pre-Validation – Stage 1*
- *Analytical Method Validation Characteristics – Stage 2*
- *Test Method Validation Protocol*
- *Test Method Validation Report*
- *Regulatory Concerns About Test Method Validations*

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This course will provide a thorough review of regulatory guidelines on method validation and transfer.

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

This course provides guidance on how to perform QC analytical test method validations and transfers. One of the most critical factors in developing and marketing pharmaceutical drug substances and drug products is ensuring that the analytical methods used for analysis can generate valid data upon which business and regulatory decisions can be made. FDA, ICH, and USP have each recognized the importance of this relative to the drug development process and have each expanded method validation requirements in recent years. However, with only limited guidance, the industry has been left to interpret how to adequately comply with the regulations. This course provides a comprehensive overview of the international regulatory authority requirements and expectations for test method validation of these assays. This course will prepare attendees with the knowledge and tools to plan and execute test method validation packages for the NDA, BLA and MAA market application dossiers, covering in-process, release and stability assays commonly used by QC.

Whether involved in method development, method validation, method verification or method transfer, this course will provide a broad understanding and “hands-on” knowledge of the method validation process and the difficulties encountered in validating methods to comply with today’s upgraded FDA CDER requirements. Lectures will include some of the more common mathematical and statistical treatments of validation data. Because of the tremendous effort that can be expended in conducting validation studies, the efficiency of experimental design and documentation will be stressed throughout the discussions.

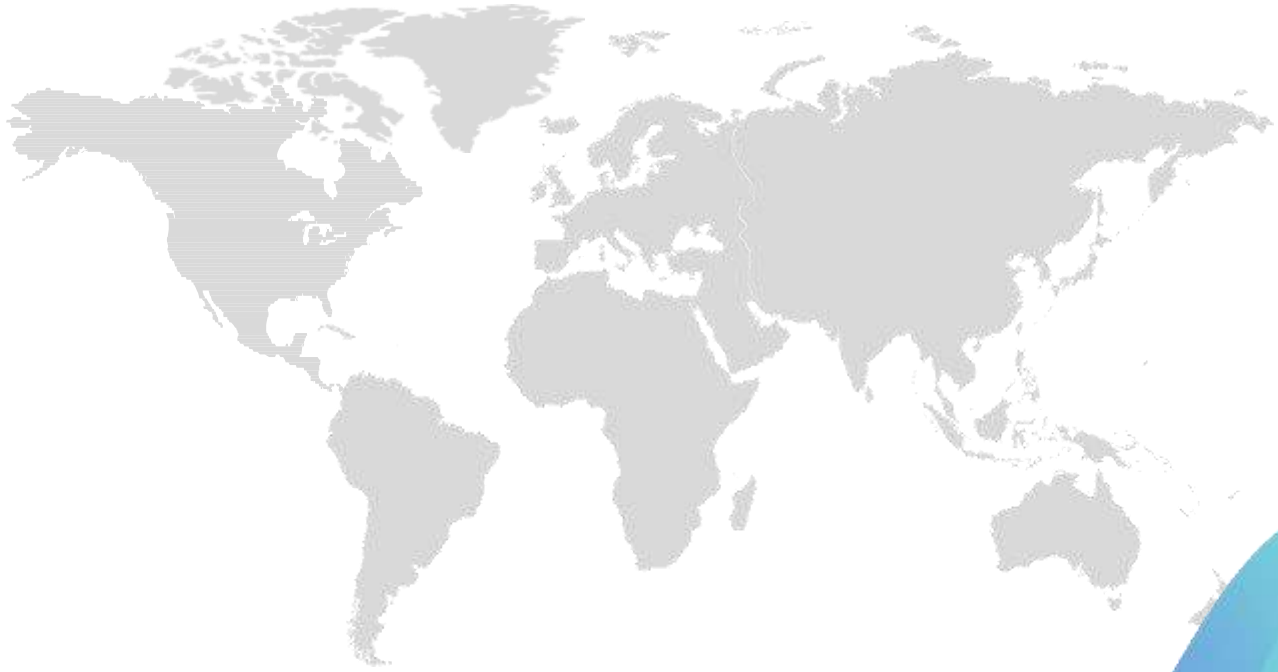
Methods utilized for the analysis of pharmaceuticals generate critical data in the determination of a product’s safety, identity, strength, purity, and quality. It is essential that the quality of the data is assured. Validation is required to demonstrate that these analytical methods are fit for their intended use. The validation data is also required by regulatory agencies for submissions.

This course will provide a thorough review of regulatory guidelines on method validation and transfer. Each element required to have a complete and thorough method validation will be discussed in detail to ensure course attendees have a clear understanding of each requirement.

A review of validation protocol requirements and selection of appropriate acceptance criteria will also occur during the webinar session; as well as, a discussion on how to select suitable statistical calculations for reporting and interpreting the data.

Who Should Attend ?

Analytical Development
Quality Assurance
Quality Control
Validation
Regulatory Affairs



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