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Webinar on

Analytical Method Validation And Transfer

Areas Covered

Topic 1: Regulatory Requirements/Guidance on Analytical Method Validation

- *Terminology defined: qualification, validation, revalidation, and verification*
- *FDA, EMA, ICH requirements and guidance*
- *Validation lifecycle for analytical methods*

Topic 2: Analytical Method Pre-Validation – Stage 1

- *Analytical Target Profile (ATP)*
- *ICH Q8, Q9, and Q10 adherence - Pre-Validation Requirements*
- *QC instrumentation qualification*
- *Training*
- *Critical assay reagent qualification*

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Topic 3: Analytical Method Validation Characteristics – Stage 2

- *Specificity, accuracy, precision, linearity, range*
- *LOD and LOQ*
- *Robustness and stability-indicating*
- *Value of system suitability controls*

Topic 4: Test Method Validation Protocol

- *Elements of a validation protocol*
- *Pre-planning and planning steps*
- *Identification and documentation of assay characteristics needing to be validated*
- *The critical importance of assigning pre-defined acceptance criteria*

Topic 5: Test Method Validation Report

- *Elements of the validation report*
- *Elements of the validation protocol and the associated final validation report*
- *Meeting the pre-defined acceptance criteria*
- *Handling deviations/OOS's, when (not if) they happen*

Topic 6: Regulatory Concerns About Test Method Validations

- *Validation issues identified during the review of the submitted market dossier*
- *Validation issues identified during regulatory inspections*
- *Test method validation "continuous improvement" – ICH Q10*

This course provides guidance on how to perform QC analytical test method validations and transfers.

PRESENTED BY:

John C Fetzer - John C. Fetzer has had over 30-year experience in laboratory compliance, including developing methods, writing SOPs, training, and auditing. He has served on the editorial advisory boards of the Journal of Chromatography, Analytical Chemistry, and Analytical and Bioanalytical Chemistry.

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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.

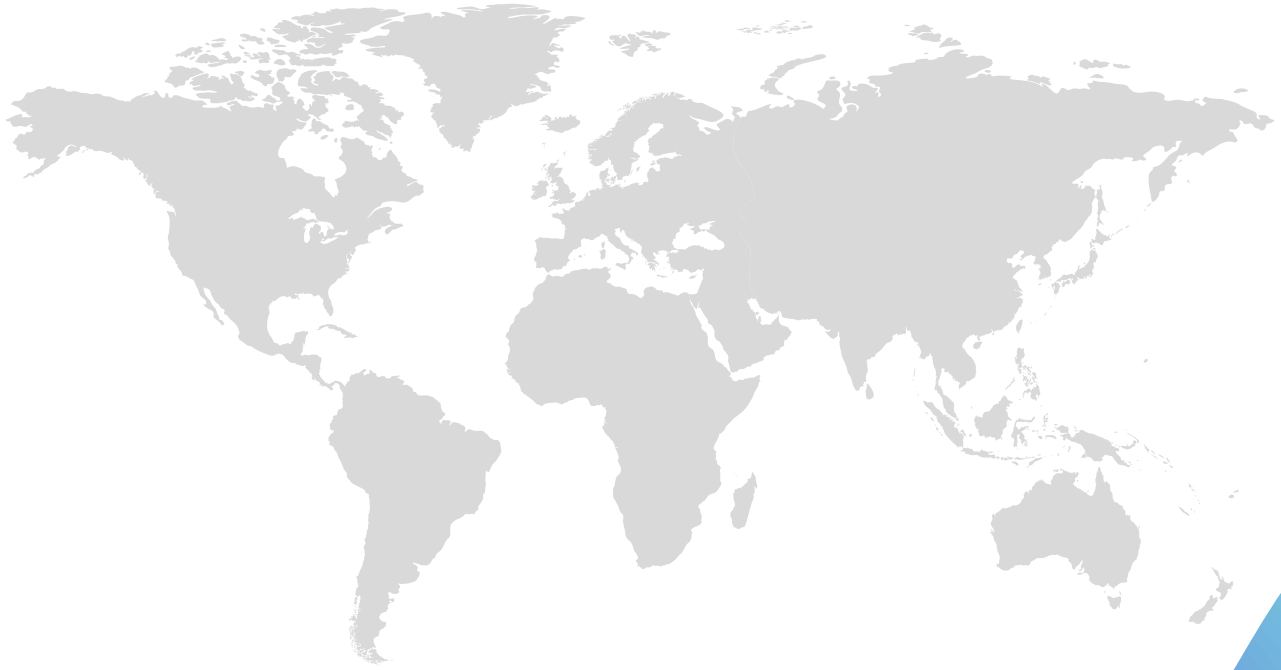
Whether involved in method development, method validation, method verification, or method transfer, this course will provide a broad

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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