Webinar on

Test Method Validation – The Lifecycle Approach

Learning Objectives

- *The USP Stimulus article: Lifecycle Management of Analytical Procedures: Method Development, Procedure Performance Qualification, and Procedure Performance Verification*
- *The three stages of test method validation:*
  - *Test Method Procedure Design (developmentand understanding)*
  - *Test Method Procedure Performance Qualification*
  - *Continued Test Method Procedure Performance Verification*

- *Analytical Target Profile*
- *Test Method uncertainties*
- *The Test Method Types*
- *Test Method characteristics*
  - *Specificity*
  - *Accuracy*
  - *Precision*
  - *Linearity*
  - *Range*
  - *Limit of detection*
  - *Limit of quantitation*

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The discussion will conclude with a review of the test method characteristics of accuracy, precision, linearity, range, specificity, limit of detection and limit of quantitation and the application of these characteristics through the test method life cycle.

PRESENTED BY:

John G. (Jerry) Lanese is an independent consultant with a focus on Quality Systems and the components of an effective Quality System. He has managed Analytical Research, Quality Control, and Quality Assurance functions.In 1994 Dr.Lanese formed his own company, The Lanese Group, and since that time he has been a consultant in the area of laboratory c controls, quality systems, and cGMP compliance and has consulted with small and large medical device and pharmaceutical companies, including companies under FDA Consent Decree, API and excipient manufacturers, electronic firms and other manufacturing organizations.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This webinar will help personnel in the Analytical Method Development Laboratory, Quality Control Laboratory and Quality Assurance understand the evolving expectations for analytical method validation. The paradigm that test method validation is one experiment performed just before method transfer must be replaced with a proactive, lifecycle approach that includes the three stages of Analytical Method Procedure Design (development and understanding), Analytical Method Procedure Performance Qualification and Continued Analytical Method Procedure Performance Verification. Consistent with this approach, It is important that the organization and the analyst understand the uncertainties of the test method, and therefore, the reported results.

Since the requirement for test method validation appeared in the GMPs in 1978 the industry has considered that test method validation is a one-time event in the life of a test method. This concept was supported by interpretations of USP <1225> Validation of Compendial Methods first published in the 1980s and ICH Q2(R1), Validation of Analytical Procedures: Text and Methodology, which was finalized in 2005. The pharmaceutical industry, as all industries, is now taking a more proactive view of all processes and has adopted a lifecycle approach to process understanding and validation. The FDA issued a guidance on process validation, Process Validation: General Principles and Practices, in 2011 which advocated a lifecycle approach to process validation.

The lifecycle concept was applied to analytical methods in a recent USP stimulus article and there is now a move to apply the lifecycle approach to test methods. The life-cycle approach will put more emphasis on a clear definition of the intended use of a test method and the uncertainties associated with a test method.

In this webinar, we will discuss the lifecycle approach to analytical method validation. and how it might impact the practice of method validation from the decision to develop a test method through to the discontinuation of the use of the method for the testing of a commercial product.

This ninety-minute webinar will begin with a review of the USP Stimulus Article, Lifecycle Management of Analytical Procedures: Method Development, Procedure Performance Qualification, and Procedure Performance Verification along with the FDA 2011 Process Validation Guidance and a discussion of how these apply to and impact test method validation. Key elements of the discussion will be the three stages of test method validation, the importance of the Analytical Target Profile and an understanding of measurement uncertainty. The discussion will conclude with a review of the test method characteristics of accuracy, precision, linearity, range, specificity, limit of detection and limit of quantitation and the application of these characteristics through the test method life cycle.

Analytical Method Validation should be approached with a clear understanding of the intended use of the method and an understanding of the application of the Analytical Target Profile through the lifecycle of the method. The approach to Analytical Method Validation should be consistent with the concepts discussed in recent stimulus papers and articles published in the USP.

Who Should Attend ?

Personnel who have responsibilities in laboratory operations, including Directors, Managers, Supervisors and line personnel

QA, Quality Control and Method Development Directors, Managers and those involved with the development, transfer, and use of test methods

Personnel in analytical method development

Quality Control Laboratory personnel

Validation specialists

These individuals should attend because the regulatory and industry concept of what should be included in test method validation is rapidly evolving to keep pace with the implementation of Quality System concepts in the pharmaceutical industry.

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