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Common Problems and Mistakes in Method Validation in Drug Development Process

Instructor: Gwendolyn Wise-Blackman

Date: Wednesday, 12 July 2017 | Time: 10:00 AM PDT, 1:00 PM EDT | Duration: 60 Minutes

Validation of test methods is a critical requirement for the drug development process. Testing of drug substance and drug product for quality requires validated methods. In addition, testing samples for PK/PD studies requires methods that are consistent, robust, rugged, sensitive, and specific in a variety of matrices. Collecting sufficient data prior to validation that can reliably support acceptance require is a frequent issue. Setting appropriate acceptance criteria based on data from final development and qualification is important for assay performance in the validation. This webinar will address issues that arise during development and validation that lead to failure and rework. The webinar also includes approaches to validation that can prevent failure and increase successful completion of validation.

Objectives of the Presentation

- Why method development is critical for a good method validation
- Importance of understanding trends and outliers
- Appropriate handling and setting of specifications for reagents and samples
- Importance of pre-validation (qualification) data
- Implementing good training procedures
- Defining the validation process
- Learning from failures

Why Should you Attend

Validation rework is costly and impacts timelines negatively. Properly preparing for validation contributes to successful, on time completion of method validations. This webinar provides information that will assist attendees with identifying and correcting common issues that may arise during validation of methods required in drug development. Issues revolving around lack of supporting data for validation acceptance criteria, lack of analyst training, and not testing specific parameters during development will be addressed. Attendees should gain knowledge to help resolve potential issues that may arise during validation.

Areas Covered

- Defining the method selected for development
- Certifying the reference standard
- Setting appropriate limits for reagents
- Reagent supply and sample handling
- Testing robustness/ruggedness/selectivity/specificity prior to validation
- Analyst training
- Peer review of the test method
- Validation protocol and templates

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- Preplanning
- Documentation of deviations and failures

Who will Benefit

Pharmaceuticals, biopharmaceuticals and dietary supplements professionals including:

- Method development scientists
- Method validation scientists
- Quality control professionals
- Quality assurance professionals
- Manufacturing professionals
- Laboratory managers
- Auditors
- Research and development
- Regulatory Affairs professionals

Topic Background

Test methods must be validated prior to use during critical phases of drug development. Validation failures are a common problem that increases cost of drug development and delays product timelines. Some of the common problems that negatively impact the quality of validations may be avoided with proper planning and assessment of development data. This webinar provides insight into scenarios that may become problems during method validation and addresses procedures designed to overcome the challenges.

Webinar Cost :-

$250.00 Live Session | **$375.00 Recorded Session** | **$500.00 Training CD** | **$1250.00 Corporate Live Session**

$500.00 Live Session + Recorded Session | **$625.00 Live Session + Training CD**

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Instructor Profile:

Gwendolyn Wise-Blackman is a successful scientist/manager with increasing accountability for scientific expertise and budget in the pharmaceutical industry, including managing multiple projects. She has working knowledge of FDA/ICH GLP and GMP guidelines and has proven experience with cell-based potency assays, Cell-based neutralization assays, PK and immunogenicity ELISA used to support bioprocess techniques for large molecule therapeutics. Ms. Wise-Blackman also holds Research & Development expertise in High Throughput Screening, 7-transmembrane receptor binding assays, cell-based assays, cell culture, and ELISA. Ms. Wise-Blackman is gifted with excellent presentation skills as evidenced by numerous scientific speaking engagements and working knowledge of PMP principles. She was an invited lecturer for IBC and IVT conferences, 1999-2008.