COBBLESTONE

COURSE ID 2567

REVISED!

Basic Requirement of the Bacterial Endotoxin Testing (BET) or LAL Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Advantages and Disadvantages of Each Method
- How to Forecast a Potential Failure of a Product's LAL Test Results
- Testing Materials and Reagent Qualification

about the course

cGMP drug products rely on the bacterial endotoxin test as a critical release test for products based on the route of administration of the drug product. Having a good concept of this critical release assay, its application and importance to the manufacture of cGMP product is valuable to avoid costly errors, batch disposal, expensive failure investigations and delays in the release of products that some manufacturers have undergone.

This 90-minute accredited training will discuss the requirements of current USP <85> Bacterial Endotoxin Test (BET) European Pharmacopoeia (Chapter 2.6.14) and the Japanese Pharmacopoeia (General Tests, No. 4.01). It will address the different LAL testing methodologies and how to choose the best test method applicable to the product type. This seminar will outline the importance, regulatory and testing requirements of products for compliance by applying the sequential steps in testing the product to rule out the presence of endotoxins.

This webinar will provide a great resource to companies in the Pharmaceutical, Biotechnology and Medical Device Industries that manufacture cGMP products requiring bacterial endotoxin release assay.

who should attend

This training applies to personnel/companies in the Pharmaceutical, Biotechnology and Medical Device Industries. The employees who will benefit most include:

• Quality Control Analyst and Management	• Senior Management
• Manufacturing Associates and Management	• Quality Assurance Analyst and Management

Those familiar with the Bacterial Endotoxin Testing (LAL), Product Validation and Suitability Tests may wish to recommend this webinar to anyone in their company that has questions about this subject

learning objectives

Upon completion of this course, you will be able to:

- Describe the steps involved in the performance of the different types of endotoxin test, when to use what method, the sensitivity of each chosen method
- List the advantages and disadvantages of each method and how to identify, investigate and resolve false positive or negative results
- Explain how the production and process controls of a manufacturing facility affect the product endotoxin levels
- Determine or evaluate the state of control of a cleanroom and utility systems using the manufactured product's bacterial endotoxin (LAL) test results
- Use product bioburden test data to forecast a potential failure of a product's LAL test result

course outline

Review of Learning Objectives
Module 1

- Introduction to current USP <85> Bacterial Endotoxin Test
- Types of Bacterial Endotoxin Test Methodologies
    - Rabbit Pyrogen, Gel Clot, Chromogenic, Turbidimetric Methodology
- Advantages and Disadvantages of Each Methodology and Choosing the Appropriate Method

Module 2

- Initiating a Bacterial Endotoxin Test-Initial Consideration
    - Initial Product Evaluation; Materials and Regents Evaluation
- LAL Testing Materials and Reagent Qualification
    - Receipt, Handling, Storage and Qualification of Materials and Reagents
- Products Receipt, Handling and Storage
- Product Processing

Module 3

- Handling, Investigating and Resolving Failure and Out of Specification (OOS) Results
- Relationship of Endotoxin Test (LAL) with other Production and Process Controls
    - Impact from Lack of Control of Product
- Bioburden and from the Cleanroom Environment; Impact from Personnel, Inadequate Disinfection Practices,

- Inadequate Sterilization or Depyrogenation Process

Question and Answer Session

Assessment Opportunity

course instructor

Charity Ogunsanya has more than 30 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and has a Masters degree from the Advanced Academic Master's Biotechnology Program at the Johns Hopkins University with concentration in Biotechnology/Biodefense. She is the CEO/ Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org