

Fundamentals of LAL Gel-Clot (BET) Procedure
Practical Course for Good Gel-Clot LAL-Endotoxin Testing
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Core Competency Training

Version: 1.0.1

Duration: 30 minutes

Number of Chapters: 5

Number of Course Pages: (including test pages & title pages): 91

Number of Test Questions: 27

Course Description

Five (5) chapters with qualifying tests after each chapter cover the course content. Chapter 1 discusses why endotoxin testing is needed with a brief summary of the various LAL-endotoxin tests and the regulatory requirements. Chapter 2 describes the utilization of Design Qualification for the selection and implementation of a suitable LAL-endotoxin test system. Chapter 3 provides a detailed procedure for executing the LAL-endotoxin gel-clot test. Chapter 4 focuses on the optimization of LAL-endotoxin gel-clot testing. Chapter 5 concludes by discussing the advantages of computer integrated LAL-endotoxin gel-clot testing.

Learning objectives

- Understand the need for LAL-endotoxin testing.
- Understand the regulatory requirements of LAL-endotoxin gel-clot testing.
- Understand the utilization of Design Qualification to select a suitable test system.
- Understand how to optimize gel-clot determination of LAL-endotoxin testing.

Intended Audience

Every employee who needs to design, implement, execute, and/or review Bacterial Endotoxin Testing (BET) by gel-clot.

Prerequisites

Trainees are required to possess a basic working knowledge of the computer, and possess basic competency in Good Manufacturing Practices.

Related courses

Introduction to LAL-endotoxin – This course provides a historical overview of the major milestones of LAL-endotoxin testing relative to the regulatory, technical, and human perspectives.

Fundamentals of LAL Quantitative (BET) Procedures */coming soon/* – This course provides sound foundation for Design Qualification-Installation Qualification-Operational Qualification-Performance Qualification (DQ-IQ-OQ-PQ) of Bacterial Endotoxin Testing by approved quantitative procedures.

Understanding the Uncertainty of Measurements of LAL-Endotoxin Testing */coming soon/* – This is an advanced course on the evaluation of the reliability of the LAL-Endotoxin tests systems relative to OOS, CAPA, & PAT.