

LAL Gel-Clot Basics

A Core Competency Course on the Theory & Practice of LAL Gel-Clot Testing Basics
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Core Competency Training

Version: 1.1

Duration: 35 minutes

Number of Chapters: 5

Number of Course Pages (including test & title pages): 85

Number of test questions: 27

Course Description

Five (5) chapters with qualifying tests after each chapter cover the course content. Chapter 1 provides an overview on the background LAL-endotoxin testing, including: why it is needed, units of measurement, basic principle of determination, the various techniques of analysis, and the regulatory requirements; Chapter 2 focuses on the Design Qualification (DQ) of the test system, including: standards, reagents, supplies, and equipment; Chapter 3 details the test protocol for LAL-endotoxin gel-clot testing; Chapter 4 deals with the analytical optimization of the gel-clot technique; Chapter 5 concludes with benefits of computer integrated gel-clot system and its application to Total Quality Control.

Learning Objectives

- Understand the need & fundamentals of LAL-endotoxin testing;
- Understand how to apply Design Qualification for LAL-endotoxin gel-clot testing.
- Understand the application of FDA & ICH protocols for LAL-endotoxin gel-clot testing.
- Understand the criteria of optimization to comply with regulatory & quality requirements at the most economical manner.
- Understand the benefits and advantageous of computer integrated gel-clot system for LAL-endotoxin determination.

Intended Audience

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

Prerequisites

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

Related Courses

Introduction of LAL & Endotoxin Basics – This course provides a historical overview on the importance of horseshoe crab to man, the risks associated with endotoxin, and the basic characteristics of LAL-endotoxin testing.

Fundamentals of LAL-Endotoxin Quantitative Testing – 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 techniques.

Understanding the Uncertainty of Measurement of LAL-Endotoxin Testing – This is an advanced course with examination for the evaluation of the reliability criteria of the LAL-endotoxin test systems relative to method validation, OOS, CAPA, & PAT