



CfPA

The Center for Professional Advancement

Accredited Technical Training Worldwide

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ON-DEMAND Online Training Course

Conducting Compliant Endotoxin Testing

Location: Your Computer

Offering # 0711-722

Priority Code: 520

WHO SHOULD ATTEND

This online training course will benefit professionals in the areas of pharmaceuticals, biotechnology, medical devices industries, sterile pharmaceutical compounding and cellular and tissue therapy. This training is applicable to:

- Microbiologists • Chemists, and Managers • Supervisors • Quality Assurance • Technicians concerned with endotoxin testing in Quality Control departments
- Regulatory Affairs • Research and Development

The course will benefit both the experienced manager and the novice technician who wishes to understand the overall regulatory context of the test.

LEARNING OBJECTIVES

Upon completion of this training, participants will be able to :

- Describe the elements of compliant endotoxin testing
- Conduct tests according to the USP Bacterial Endotoxins Test chapter
- Apply the GMP principles specified in the FDA Guideline on the Limulus Amebocyte Lysate (LAL) Test

COURSE DESCRIPTION

The essential elements of the bacterial endotoxins test are addressed in this 1½ hour course. Proper and appropriate inclusion of these elements in an LAL testing program will result in compliant testing. Performance of properly understood endotoxins tests benefits any company releasing products with endotoxin specifications and may avoid significant compliance problems.

Module 1:

General Principles and Introduction

- The five essentials of endotoxin testing
- The USP, EP and JP Harmonized Endotoxins Test Chapters
- Prerequisites for endotoxins tests:
 - Apparatus and Glassware
 - Standard Endotoxin stock solution and dilutions
 - Preparatory Testing
- Endotoxin Limits
- Maximum Valid Dilution (MVD)

Module 2:

USP Bacterial Endotoxins Test Requirements for Gel-clot and Photometric Techniques

- The Gel-clot method
 - Preparatory Testing
 - Gel-clot Limit Test
 - The Gel-clot Assay
- Photometric Techniques
 - Preparatory Testing
 - Gel-clot Limit Test
 - Test Procedure

Module 3:

Compliant LAL Tests and the FDA Guideline

- Technician and Laboratory Qualification
- Control Standard Endotoxin (CSE)
 - CSE potency determination
 - The USP position on CSEs
 - Certificates of Analysis (Potency)
- When to repeat validation
- Pooling Samples for Testing
- Out of Specification Results and Repeat Testing

COURSE DIRECTOR

Dr. Michael E. Dawson, Director of Regulatory Affairs for Associates of Cape Cod, Inc. (ACC)

ACCREDITATIONS



The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.



The Center for Professional Advancement (CfPA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Continuing Education Units (CEU) will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The CEU rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through interactive question and answer sessions. This offering is Program# 716-000-07-556-L04. If interested in ACPE credits, notify CfPA immediately upon completion of this course.

REGISTRATION

TUITION* – **Single Rate: U.S.\$99.00 per person** **Group Rate: U.S.\$99.00 per person****

Register at www.cfpa.com. Enter **Course Offering #0711-722** into **Quick Jump**. To register use **Priority Code: 520**.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from olinetraining@cfpa.com with your password to access the on-demand course. You will have two (2) business days to view the course. You MUST complete all polls and the course evaluation to receive your accreditation certificate for this course.

TERMS AND CONDITIONS

***Payment:** Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA's Customer Service for other payment options.

****Group Rate:** The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing. **Cancellations/No Show: "Live"** - Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. : **"On-Demand"** - No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant's cancellation.