



Complaint Systems-The Essential Requirements

Location: Your Computer

Offering # 0711-717

Priority Code: 520

WHO SHOULD ATTEND

This online training will benefit professionals in the following industries: Medical Device, Pharmaceutical, Human Tissue, Biotechnology. In departments such as: QA/QC/RA, Manufacturing/Operations, Research and Development, Legal

With job functions: Department Managers and Supervisors, QA/QC/RA Specialists and Engineers, Manufacturing and R&D Engineers, Chemists, Scientists, Formulators, Documentation Specialists, Auditors, Technicians

LEARNING OBJECTIVES

Participants of this course will learn key concepts essential for the deployment and smooth continuous operation of a Complaint System. Specifically, they will be able to explain:

- "Why" the Complaint System is critical to the effectiveness of your Quality System
- "What" is necessary for a Complaint System to be truly effective
- "What" FDA expects of your Complaint System
- "What" the Complaint "lifecycle" is
- "What" needs to be in your Complaint Standard Operating Procedure
- "How" to review Complaints to spot potential MDRs
- "How" to conduct effective Complaint Investigations
- "How" to document and close a Complaint.
- "When" a complaint investigation is not necessary
- "When" to take Corrective Action
- "When" to close a Complaint

COURSE DESCRIPTION

Complaint Systems have come under intense scrutiny by the FDA in recent years. This course will examine the current industry/FDA environment and will give you tools for survival; it will provide a step-by-step guide to the essential requirements of a Complaint System including setting-up, operating, and managing the system for today's FDA regulated industry environment. Further, this course provides "content understanding" so important when auditing Complaint Systems.

Module 1:

- Background-Regulatory Requirements
- Key Definitions: what is a complaint, anyway?
- What needs to be in my complaint procedure?

Module 2:

- Complaint Receipt
- Complaint Review: Is it an MDR?
- Complaint Investigations; so, why did it fail anyway?

Module 3:

- Do I need to take Corrective Action?
- Can I close this complaint already?
- What is Complaint Trending and why do I need to do it?
- Resources, Record-keeping, and other Essentials

COURSE DIRECTOR

Michael Patrick Barile, founder and Managing Partner of the consulting firm Barile & Associates.

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# 716-000-07-551-L04. If interested in ACPE credits, notify CfPA immediately upon completion of this course.

REGISTRATION

TUITION* - Single Rate: U.S. \$295.00 per person Group Rate: U.S. \$245.00 per person**

Register at www.cfpa.com. Enter Course Offering #0711-717 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.