



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide
PO Box 7077, East Brunswick NJ 08816
Phone 732-238-1600 • Fax 732-238-9113

ON-DEMAND Online Training Course

Introduction To Pharmaceutical cGMP

Location: Your Computer

Offering # 0812-702

Priority Code: 520

WHO SHOULD ATTEND

This course will be beneficial to professionals in the pharmaceutical industry especially:

- Employees who need basic cGMP training
- New Hires or Transfers from non cGMP areas
- Employees who have demonstrated a need for retraining

LEARNING OBJECTIVES

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

- Give a brief description of how the FDA & cGMP came to be and how they relate to job performance
- Describe the basics of and navigate through 21 CFR Part 210 & 211 to locate the sections of the cGMP and how each relate to an employee's position within their company
- Review the 7 key areas that are necessary for compliance to the cGMPs

COURSE DESCRIPTION

This 90-minute **accredited** training course introduces the employee to the cGMP environment. The attendee will gain understanding of the FDA, the Code of Federal Regulations, the reason for the unique laws governing pharmaceutical manufacturing and its role in the pharmaceutical arena.

Module 1:

- The need for the FDA and the cGMP's in our industry
- FDA enforcement
- The "Act"
- Introduction to 21 CFR, Parts 210 and 211
- Case study from the early cGMP history

Module 2:

- CFR 21, Part 210 Definitions
- The index to Part 211
- A brief overview of each section of 211 with examples of how they relate to job performance
- A case study of how a company uses cGMP's to gain instructions for improving their performance

Module 3:

- The 7 key areas that are necessary for compliance to the cGMPs
 - Follow good documentation
 - Keep it clean
 - Follow procedures
 - Don't make any unauthorized changes to anything
 - Avoid mix-ups
 - When in doubt, ask
 - The data, record and logs we create doing our job are critical; The most critical is the batch record

Question and Answer Session

COURSE DIRECTOR

William G. Marshall is President of William G. Marshall and Associates; Consultant to the worldwide drug and device industry as well as to the FDA and worldwide lecturer in GMP related issues.

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 0.15 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# 716-000-08-513-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 #0812-702** 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.

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 olinettraining@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.

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