

Introduction to cGMP System-Based Audits

Applicable to the Pharmaceutical, Medical Device and Related Industries

Location: Your Computer Offering # 0909-703 Priority Code: 520

This course presented by CfPA in conjunction with



and

PFQ

WHO SHOULD ATTEND

This **introductory** online presentation will benefit professionals in the pharmaceutical, medical device and related industries who are responsible for GMP compliance issues. The course will be of great interest to newly assigned auditors or those who expect to be involved in auditing in the near future. It can also be used as a refresher course for more experienced auditors.

The material presented will be very beneficial to professionals in the following areas:

- Management responsible for the audit function
- Regulatory
- Laboratory
- QA/QC
- Vendors and suppliers to these industries
- Production
- Packaging

LEARNING OBJECTIVES

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

- Outline the requirements for system-based audit programs as described in various regulatory bodies
- Develop a basic plan for initiating a system-based audit program
- Implement tools to confirm your company's compliance

COURSE DESCRIPTION

Auditing is a major management tool to ensure compliance with regulations and standards. The need for GMP system-based audits is a worldwide requirement at all stages, starting with active pharmaceutical ingredient (API), bulk pharmaceuticals, finished pharmaceuticals, medical device, biologics etc. This 90-minute **accredited** training course provides an introduction to the major regulations and standards requiring the existence of an audit function in companies. It details the beginning stages for setting up a system-based audit program and concludes with a few examples of check points during drug and device system-based audits.

Module 1: Requirements for system-based audit programs as identified in:

- QSR – Quality System Regulation for medical device
- FDA Guidance for Pharmaceutical Quality Systems
- Q7A – GMP for Active Pharmaceutical Ingredients
- ICH Q10 – Pharmaceutical Quality System
- Quality System Standards – ISO 9000 and 13485

Module 2: Getting started

- Audit classification
- Audit manual/procedures
- The audit cycle
- Audit master plan

Module 3: Is your company in compliance?

- Following the ten commandments of cGMP
- Check points during drug GMP system-based audits
- Check points during device GMP system-based audits
- Examples of Warning Letters

Question and Answer Session

TUITION AND 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 #0909-703** 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.

For more information see reverse side ➡



CfPA

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COURSE DIRECTOR

Renée B. Galkin is a quality management consultant with over twenty years experience in the pharmaceutical and medical device industries. Her areas of expertise include quality audits, quality programs, FDA regulatory compliance, GMP training, documentation systems management, strategic planning and organizational development.

Prior to starting her own consulting business, Ms. Galkin held managerial positions with two major companies – Wyeth Pharmaceuticals, Inc. and Science Management Corporation (a multinational consulting firm). Throughout her career she had both domestic and international assignments .

Ms. Galkin holds an MBA in Business Management from New York University, an MA in Education from Brown University and a Bachelor of Science in Biology from Northeastern University. She is a member of the American Society for Quality, the Parenteral Drug Association and the International Society for Pharmaceutical Engineering (ISPE). As a consultant, Ms. Galkin provides training, auditing and compliance advisory services to companies worldwide. She also directs several technical courses offered by **The Center for Professional Advancement (CfPA)**.

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.

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. **CfPA** courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company's training needs.

ABOUT WILEY-BLACKWELL

Wiley-Blackwell was formed in February 2007 as a result of the acquisition of Blackwell Publishing Ltd. by John Wiley & Sons, Inc., and its merger with Wiley's Scientific, Technical, and Medical business. Together, the companies have created a global publishing business with deep strength in every major academic and professional field. Wiley-Blackwell publishes approximately 1,400 scholarly peer-reviewed journals and an extensive collection of books with global appeal. For more information on Wiley-Blackwell, please visit www.blackwellpublishing.com or <http://interscience.wiley.com>.

COURSES OF INTEREST

- **An Overview of Documentation Requirements in FDA Regulated Industries –An Online Training Course**
course id# 2325
- **Applied cGMPs for Pharmaceutical and Allied Industries**
course id# 610
- **Auditing for cGMP Compliance**
course id# 1881
- **cGMP Auditing– Strategies for Compliance**
course id# 2012
- **Conducting Effective Quality Audits**
course id# 1681
- **Documentation Management and Control**
course id# 1866
- **Pharmaceutical Quality Assurance and Control**
course id# 224
- **Preparing for and Surviving an FDA Inspection**
course id# 187
- **Surviving an FDA Inspection – FDA Inspections of Non-U.S. Sites**
course id# 1880

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.