GMP Audits: Basic Tools and Techniques
Applicable to the Pharmaceutical, Medical Device, Cosmetic, Biotech and Related Industries
Course ID # 2819

who should attend
Newly assigned auditors or those who expect to be involved in auditing in the near future will find this introductory training very beneficial. It can also be of interest to those who need a refresher on this important subject matter. Professionals in the functions described below will also find the topic of interest:

Quality Assurance  Purchasing  Documentation Management  Quality Control  Production
Laboratory  Packaging  Regulatory Compliance  Vendors/suppliers

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

• Identify the requirements for a GMP audit function as described in various regulatory documents
• Define the steps to follow when setting up a GMP audit program
• Describe ways of auditing for GMP compliance in the Drug and Device industries

course description
This 90-minute, accredited, introductory online training covers the main steps to be taken when setting up and implementing a GMP audit program in the pharmaceutical, medical device and related industries. It outlines the requirements identified in FDA regulations, ICH guidances and ISO 13485-2016 standard regarding the need for an audit function. It covers various areas of concern including laboratory and manufacturing operations, risk management and data integrity issues.

For in-depth training on this topic, consider the CfPA 3-day, in-person training, Conducting Effective Quality Audits. To learn more, visit: www.cfpa.com and add ID# 1681 to the search bar.

Review of Learning Objectives
Module 1: Review of audit standards as required in
• 21 CFR Part 820 – QSR
• ICH – Q7 and Q10
• ISO 13485-2016
• FDA Guidance for Pharmaceutical Quality Systems

Module 2: Sequential steps to follow when setting up a GMP audit program
• Audit types
• Audit cycle/responsibilities
• Main areas of concern:
  – Data integrity, risk management

Module 3: The audit process
• What to look for in:
  – Drug GMP system based audits
  – Device GMP system based audits
  – Examples of non-compliance identified in
  – Warning Letters

Question and Answer Session

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.
course director

Renée B. Galkin is a quality management consultant with over 30 years experience in the pharmaceutical and device industries. Prior to starting her consulting business, Ms. Galkin was part of two major companies: Science Management Corporation – a multinational consulting firm and then Wyeth/Pfizer where she gained her pharmaceutical experience during her 20 year association. Throughout her career Ms. Galkin held both domestic and international assignments.

Ms. Galkin has an MBA in Business Management from New York University, an MA in Education and Science 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). She is also a Certified Quality Auditor.

As a consultant, Ms. Galkin has been providing training and consulting advice to pharmaceutical and medical device companies in the United States and Europe in areas related to consent decrees, pre-approval and regular FDA inspections, audit programs, quality systems requirements, documentation systems management, validation, supplier selection and management.

She also directs several technical courses offered by the Center for Professional Advancement. Participants at her courses enjoy and appreciate her interactive and personal teaching style which keeps the audience alert and constantly involved.

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 ID# 2819 into Search. To register click Register Now.

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.

accreditations/recertifications for this course

The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 11130 Sunrise Valley Drive, Suite 350, Reston, VA 20190. 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. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

courses of interest

• CGMPs for Pharmaceutical Life Cycle Management  course ID# 2474
• Conducting Effective Quality Audits  course ID# 1681
• Documentation Management and Control  course ID# 1866
• Effective Documentation Practices for GXP Compliance–An Online Course  course ID# 2818
• FDA Drug Approval, Regulation and Compliance  course ID# 587
• Managing FDA Inspections–An Online Course  course ID# 2704
• Preparing for and Surviving an FDA Inspection  course ID# 187
• Quality Management and Compliance in the Pharmaceutical and Related Industries  course ID# 224
• Setting Up and Implementing Supplier Audits–An Online Course  course ID# 2700
• Supplier Audits  course ID# 2435

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 onlinetraining@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.

For assistance contact Customer Service at 1/732-613-4500 or email us at: info@cfpa.com
For More Information or to Register Go to www.cfpa.com

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