

An Overview of Documentation Requirements in FDA Regulated Industries

Location: Your Computer Offering # 0908-703 Priority Code: 520

This course presented by CfPA in conjunction with



and

PFQ

WHO SHOULD ATTEND

This **overview** online presentation will benefit professionals in various functions in the pharmaceutical, medical device, biotech and related industries, who are responsible for the writing, implementation or management of various types of documents. These functions include:

- Pre-clinical operations
- Manufacturing processes
- Regulatory
- Clinical operations
- QA/QC
- Documentation writers/managers
- Laboratory operations
- Auditors

LEARNING OBJECTIVES

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

- Explain basic documentation requirements as presented in various regulatory bodies
- List examples of main documentation types in pre-clinical, clinical, manufacturing and laboratory operations
- Discuss the vital role record keeping plays within the FDA regulated industries
- Outline basic requirements of 21 CFR Part 11 and their impact upon documentation

COURSE DESCRIPTION

This 90-minute **accredited** online course presents an **overview** of the **main types** of documents required in FDA regulations and guidances, in ICH guidelines and in ISO 9000. Based on industry best practices, this presentation will discuss ways to classify documents and will clarify the distinction between controlled and non controlled documents. The transition from manual systems to electronic systems and the impact of 21 CFR Part 11 upon documentation will conclude the course. Please note that details about the management and control of documents, and documentation systems are discussed in other technical public courses offered by CfPA.

Module 1: Requirements for written documentation as identified in:

- 21 CFR Part 211–cGMP for Finished Pharmaceuticals
- Quality System Regulations–QSR
- 21 CFR Part 58–Good Laboratory Practice
- FDA Guidances
- ICH Q7–GMP for Active Pharmaceutical Ingredients
- Quality System Standards–ISO 9000

Module 2: Role of documentation and examples of main documentation types in:

- Pre-clinical operations
- Clinical operations
- Manufacturing processes
- Laboratory operations

Module 3: Impact of 21 CFR Part 11–Electronic Records and Signatures.

- Moving from a manual system to an electronic system
- Basic documentation requirements
- Need for validation
- Availability of documents during FDA inspections

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 #0908-703** 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 ➡



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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.

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COURSES OF INTEREST

- **Applied cGMPs for Pharmaceutical and Allied Industries**
course ID# 610
- **Auditing for cGMP Compliance**
course ID# 1881
- **Conducting Effective Quality Audits**
course ID# 1681
- **Documentation Management and Control**
course ID# 1866
- **Introduction to cGMP System-Based Audits–
An Online Course**
course ID# 2309
- **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:

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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.