

An Overview of Process Validation for the Pharmaceutical, Medical Device and Related Industries

Explaining Process Validation in Simple, Understandable, Pragmatic Terms

Location: Your Computer Offering # 0904-709 Priority Code: 520

WHO SHOULD ATTEND

This online training course is intended for managers, supervisors, engineers, chemists, scientists, technicians and formulators working within the Pharmaceutical, Medical Device and related industries. It will also be valuable to documentation specialists, auditors and those in regulatory affairs. Personnel from the following departments will find the course beneficial:

- Research and Development
- Manufacturing/Operations
- Finance
- QA/QC
- Quality Assurance and Control
- Facilities
- IT

This training will also benefit suppliers of equipment and services to these industries.

LEARNING OBJECTIVES

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

- Describe how to manage the validation process efficiently and pragmatically
- List simple metrics to use when auditing validation
- Summarize why and when a process must be validated
- Execute validation protocols and validation reports
- Explain what the regulatory agencies will look for
- Outline key concepts essential for the validation of processes
- Explain what process validation entails and how to prepare for it
- Explain how to maintain the desired, validated state

COURSE DESCRIPTION

In recent years, the FDA has placed intense focus on Process Validation. This 90-minute **accredited** training course will examine will examine how we have reached the present validation environment and will give you a means for survival. It will provide a step-by-step guide to planning and preparing for process validation, and includes a discussion of how to write validation protocols, handle deviations, report validation results and "maintain the validated state." The course provides a guide on how to manage the validation process efficiently and pragmatically. Further, this course provides "content understanding" so important for auditing validation activities as required in today's FDA regulated industry environment.

Module 1:

- How did we reach the present validation environment?
- Why do I need to validate processes?
- What is process validation?
- Does every process need to be validated?

Module 2:

- The Validation Master Plan
- Basics of validation
- URS, DQ, FAT, IQ, OQ, PQ: What are all these letters in the alphabet soup?
- Protocol basics and content

Module 3:

- Handling deviations
- Validation reports
- Proper validation timing
- Maintaining the validated state
- Auditing metrics for the validation system

Question and Answer Session

For more information see reverse side ➔



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COURSE DIRECTOR

William G. Marshall, President, William G. Marshall and Associates

William G. Marshall has over twenty years experience in the Pharmaceutical and Medical Device Manufacturing Environment. Mr. Marshall has held Director level and Chief Operating Officer positions with large multinational pharmaceutical corporations as well as start-up ventures. He has been the Director of a major reference laboratory, and has been active in clean room design and validation. In the last five years, he has acted as a third party in several consent decrees.

Mr. Marshall is currently a consultant to the worldwide drug and device industry as well as to the FDA. He lectures worldwide in GMP related issues including Clean Room Technology and Sterilization. In the past 18 months, he has been involved in 10 Pre-Approval Inspections that include the first aseptic processed injectables from India, the first ever drugs from Turkey, and APIs from China, that were all approved for introduction to the US market. He has a Master's Degree in Biology from Georgetown University, Washington, DC.

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 #0904-709** 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.

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.

For more information visit our website at www.cfpa.com

COURSES OF INTEREST

- **Applied cGMPs for Pharmaceutical and Allied Industries**
course id# 610
- **cGMP for Pharmaceutical Production Supervisors**
course id# 604
- **Introduction To Pharmaceutical cGMP–An Online Course**
course id# 2244
- **Pharmaceutical cGMP-Quality Systems–An Online Course**
course id# 2245
- **Process Validation for the Pharmaceutical and Medical Device Industries**
course id# 736

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 olinetraing@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.