Understanding the Process Validation Life Cycle

Wednesday, June 21, 2017  11:00 a.m.–12:30 p.m. (ET)
Course ID # 2759  Available On-Demand starting 6/22/17

who should attend

This online training will benefit professionals in the following industries: Pharmaceutical, Biotechnology, Medical Device, Chemical Processing, Food, Cosmetics, and Biologics

Potential job functions that would apply include: Engineers, Chemists, Scientists, Formulators, Documentation Specialists, Auditors, Managers, Technicians

In departments such as: Manufacturing, Operations, QA/QC, Engineering

learning objectives

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

• Define the stages of the Process Validation Life Cycle
• Discuss what data should be included in the protocols/reports
• Analyze recent regulatory citations on pertaining to Process Validation

course description

This 90-minute, accredited training is intended to help you better understand and get familiar with best practices for Process Validation applicable for the highly regulated biological / pharmaceutical industry. This course is further intended to discuss the life cycle of the Process Validation system. You will learn when a process should be validated, the basic components of a Process Validation (IQ, OQ, and PQ) and how to write protocols and reports.

review of learning objectives

Module 1: What is Process Validation?
• Regulatory Requirements
• Key Definitions
• The Stages of Process Validation

Module 2: Process Validation Implementation
• Installation Qualification
  – Drafting the Protocol, Data Gathering, Writing the Report
• Operational Qualification
  – Drafting the Protocol, Data Gathering, Writing the Report
• Performance Qualification
  – Drafting the Protocol, Data Gathering, Writing the Report

Module 3: Case Studies
• FDA 483 Citation Review
• Warning Letter Review

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 ID# 2759 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.

System Requirements: PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer
Danielle DeLucy, MS: Independent Consultant to the Biologics and Pharmaceutical Industries

Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Prior to this role, Ms. DeLucy has been in the industry for 15 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Ms. DeLucy began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Ms. DeLucy assists companies who are faced with warning letters, consent decrees and those wishing to improve compliance establish more robust quality systems so that the company can succeed.

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 350 short courses in 13 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 to fit you or your company’s training needs:

**In Person:** Away from responsibilities, participants are immersed without distraction
**Client Site:** Training at your site and at your convenience. For further information, please contact Client Site Programs: +1/732.238.1600, ext. 4547 or E-mail clientsite@cfpa.com
**Online:** A convenient and cost-effective way to experience our accredited training. For a list of upcoming courses visit www.cfpa.com/onlinetraining
**Virtual Attendee:** Ideal for those who need the training but cannot attend in person. For more information visit: www.cfpa.com/virtualattendee
**Virtual Recorded:** Watch the recorded version of the Live In Person course. For more information visit: www.cfpa.com/virtualattendee

### courses of interest

- **Analytical Methods Validation for FDA Compliance**
  - course ID# 1887
- **Design Control and Product Validation**
  - course ID# 1900
- **Effective QbD (Quality by Design): A Second Generation Approach**
  - course ID# 2525
- **Lyophilization Technology**
  - course ID# 279
- **Microbiology Current Practice: Drug and Devices**
  - course ID# 902
- **Packaging of Pharmaceuticals Essentials**
  - course ID# 42
- **Powders: Their Properties and Processing**
  - course ID# 117
- **Process Validation for Packaging of Pharmaceuticals and Medical Devices**
  - course ID# 1789
- **Quality Critical Cleaning and Cleaning Validation Processes**
  - course ID# 1867
- **Sterile Products: Formulation, Manufacture and Quality Assurance**
  - course ID# 435

### 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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CfPA/2017