Pharmaceutical Water System: Design, Testing and Data Management

Day: Thursday, April 23, 2015  Time: 11:00 a.m.–12:30 p.m. (ET)
Location: Your Computer  Offering # 1504-406 Priority Code: 520
(Available On-Demand starting 4/24/15)

WHO SHOULD ATTEND

This training will be beneficial to professionals in the Pharmaceutical, Cell Therapy, Diagnostics, Biologics, Biotechnology and Medical Device Industries. The employees who will benefit most include personnel and management within:

• Quality Control Analyst
• Manufacturing Associates
• Facility and Utility
• Quality Assurance Analyst
• Vendors and Suppliers of Pharmaceutical Water Systems and Peripherals

Site Directors, Operations Director and Senior Management will also find this training valuable.

LEARNING OBJECTIVES

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

• List the applicable regulations and types of pharmaceutical water systems
• Plan, define, design, and validate the various types of pharmaceutical water systems using a compliant validation protocol
• Define and describe the types of routine tests, testing frequencies and sampling procedures associated with Pharmaceutical Water systems
• Describe and define how to set the alert and action levels test specification for each type of test
• Perform routine recertification of water systems, re-testing and re-evaluation
• Perform test data management and trending

COURSE DESCRIPTION

This 90-minute accredited training will guide a drug product manufacturer with effectively designing, validating and maintaining a new or existing water system. The appropriate design planning considerations, validation, types of routine tests, testing frequencies, water system maintenance and how to set an acceptable alert and action levels will be reviewed. Water test result/data management and trending which will be a guide to a steady state of control of the different water systems will be presented. This will benefit the manufacturers by helping to avoid future costly pharmaceutical water systems failure, investigations or inability to validate or achieve passing test results from a new or existing water systems emanating from design-related issues.

Review of Learning Objectives

Module 1:
• Introduction to current USP <1213> Pharmaceutical Water System
• Scope of the Different Water Systems
• Planning the Design of a Water System
• Planning the Validation of a Water System

Module 2:
• Routine Testing Types Associated with Water Testing Systems
• Non-routine Water Testing Program
• Defining the Water Testing Specifications
• Standard/General Practices for the Collection of Water Samples – Testing Time Frame

Module 3:
• Water System Failures and Investigation
• Water System(s) re-certification procedure
• Water Testing Data Management and Trending
• Data Trending of Routine Water Testing

Question and Answer Session

For more information see reverse side
COURSE DIRECTOR

Charity Ogunsanya (CEO/Founder), Pharmabiodevice Consulting LLC

Charity Ogunsanya has more than 24 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology, Cell Therapy, Diagnostics, Drug and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control subject matter expert for multiple fortune 100 companies. She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and is currently in the Advanced Academic Master’s Biotechnology Program at the Johns Hopkins University with concentration in Biodefense. She is the CEO/Founder of Pharmabiodevice Consulting LLC. The consultancy provides Quality and Compliance consultancy/support to Biologics, Pharmaceuticals, Cell Therapy, Radiopharmaceuticals, Biotechnology and Medical Device Industries.

TUITION AND REGISTRATION

TUITION*:  Single Rate: U.S. $295.00 per person  Group Rate: U.S. $245.00 per person**


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

ACCREDITATIONS

The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500 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. 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 Learner’s Assessment.

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately four hundred and fifty short courses in 15 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

• CGMPs for Pharmaceutical Life Cycle Management course ID# 2474
• Clean Room Operation in a Nutshell–An Online Course course ID# 2662
• Environmental Monitoring Program Basics–An Online Course course ID# 2663
• Lyophilization Technology course ID# 279
• Preparing for and Surviving an FDA Inspection course ID# 187
• Sterile Products: Formulation, Manufacture and Quality Assurance course ID# 435
• IQ, OQ, PQ course ID# 1808

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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