WHO SHOULD ATTEND

This online training course is intended for managers, supervisors, engineers, chemists, scientists, technicians and formulators working within the Pharmaceutical, 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
- Facilities
- Audit
- Quality Assurance and Control
- Finance
- Training
- Manufacturing/Operations
- IT
- Technical Support

LEARNING OBJECTIVES

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

- Develop a procedure for where, when and how to conduct non-sterile product environmental monitoring
- Set monitoring action and alert limits
- Explain the strengths and weaknesses of a BMS (Building Management System)
- Avoid common pitfalls
- Conduct investigations
- Audit these systems

COURSE DESCRIPTION

Environmental Monitoring in Non-Sterile product manufacturing has become a current practice that encompasses temperature, relative humidity, non-viable (and in some cases, viable) particle counts, room classifications, pressure differentials and other environmental parameters. This 90-minute accredited training course will discuss monitoring procedures, frequencies, alert and action limits that are needed to assure compliance.

Module 1:
- What areas need monitoring in the non-sterile product manufacturing facility?
- Which parameters need to be monitored in the various areas?
- How is this monitoring typically carried out?

Module 2:
- What are typical monitoring frequencies?
- Setting alert and action limits
- Avoiding pressure differential pitfalls

Module 3:
- Understanding the impact of manufacturing personnel on the environment and the need for training
- Auditing the environmental program

Question and Answer Session

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.
**COURSE DIRECTOR**

William G. Marshall, President of William G. Marshall and Associates; Consultant to the worldwide drug and device industry as well as to the FDA and worldwide lecturer in GMP related issues.

William G. Marshall is President of William G. Marshall and Associates. He 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.

**ACCREDITATIONS**

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.

**WHO WE ARE**

Wiley-Blackwell was formed in February 2007 as a result of the acquisition of Blackwell Publishing Ltd. by John Wiley & Sons, Inc., and its merger with Wiley's Scientific, Technical, and Medical business. Together, the companies have created a global publishing business with deep strength in every major academic and professional field. Wiley-Blackwell publishes approximately 1,400 scholarly peer-reviewed journals and an extensive collection of books with global appeal. For more information on Wiley-Blackwell, please visit www.blackwellpublishing.com or http://interscience.wiley.com.

**COURSES OF INTEREST**

- **A Survey of Microbiology for the Pharmaceutical, Biotechnology, and Medical Device Industries – An Online Course**
  course ID# 2317
- **Data Integrity: The Proof’s in the Inputting– A FREE Online Course**
  course ID# 2343
- **Introduction To Pharmaceutical cGMP– An Online Course**
  course ID# 2244
- **Microbiological Control and Validation**
  course ID# 902
- **Pharmaceutical cGMP-Quality Systems– An Online Course**
  course ID# 2245
- **Pharmaceutical Process Validation Basics– An Online Course**
  course ID# 2327
- **Process Validation for the Pharmaceutical and Medical Device Industries**
  course ID# 736
- **Recognizing and Preventing Data Integrity Issues**
  course ID# 2349

**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.

**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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