

## Registration Form

Offering # **0810-204**

### Clean Room Technology

9-10 October 2008 • Amsterdam, The Netherlands

**Priority Code:** **520**

(Please use this code when registering)

Dr./Mr./Ms. \_\_\_\_\_  
Surname Given Name

Job Title \_\_\_\_\_

Company/Organization \_\_\_\_\_

Department/Mail Code \_\_\_\_\_

Mailing Address \_\_\_\_\_

Postal Code \_\_\_\_\_ City \_\_\_\_\_ Country \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail Address \_\_\_\_\_

How did you learn about this course?

Direct Mail  Colleague  Website  Other

### Tuition and Payment Methods

**Early Registration (Save \$200)** U.S. \$ **1640** / \$ **1560\***  
(Must register and pay by 14 August 2008) (Group Rate)

**Regular Registration** U.S. \$ **1840** / \$ **1760\***  
(Group Rate)

Tuition payable in US funds **net of all charges includes luncheon, breaks and course notes.**

Payment is due prior to course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee admittance.

\***Group Rate** is for two or more enrollments registering at the same time, from the same company, for the same course.

**Send Invoice** (POs must be received in advance of course)

Purchase Order # \_\_\_\_\_

**Check** (payable in U.S. funds to The Center for Professional Advancement)

**Bank Transfer** (Pay by Bank Transfer to Account No. 62.62.46.628 (USS) at ABN-AMRO Bank N.V., Postbus 2078, 1000 CB Amsterdam, The Netherlands. The course Offering # (above) and participant's name must be included on bank transfer.)

**Credit Card**

Visa  MasterCard  American Express  Discover

Card # \_\_\_\_\_ Exp. Date \_\_\_\_\_

Cardholder Name \_\_\_\_\_

Signature \_\_\_\_\_

ID 23

C8-049

### 3 Ways To Register

- Log on to [www.cfpa.com](http://www.cfpa.com)
- Fax to: +31.20.620.21.36
- Mail: **The Center for Professional Advancement (CfPA)**  
Oudezijds Voorburgwal 316A  
1012 GM Amsterdam, The Netherlands

### General Information

**Discounts/Rates:** Early registration discount requires payment at time of registration and before expiration or regular tuition will apply. Group Rate is for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

**Cancellations/Substitutions:** All cancellations are subject to a \$150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who do not attend the scheduled course and/or cancel less than two working days before the start date. Substitutions are permitted at any time. If for any reason, CfPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice.

**Confirmation Letters:** Before each course begins, all registrants will receive written confirmation including detailed information regarding course location. If confirmation is not received two weeks prior to the course please contact us.

For those requiring visas, confirmation letters will not be sent until payment is received.

Please note: **English** will be used in all lectures and course notes.

For our full terms and conditions, visit [www.cfpa.com](http://www.cfpa.com).

### 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.



**The Center for Professional Advancement (CfPA)** is accredited by the **Accreditation Council for Pharmacy Education** as a provider of continuing **Continuing Education Units (CEU)** will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The **CEU** rate is 0.1 **CEU** per contact hour; certificate will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a **Learning Assessment**. *This offering is Program# 716-000-07-152-L04*

### Who We Are

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 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.

### Courses of Interest

- **Control of Microbial Contamination in Manufacture of Sterile and Non-Sterile Products** – An Online Training Course course id# 2215 • **Critical Process Cleaning and Cleaning Validation** course id# 1867
- **Environmental Control and Monitoring** course id# 1937
- **Investigation of Microbial Contamination in Sterile and Non-Sterile Products** – An Online Training Course course id# 2216
- **Microbiological Control and Validation** course id# 902
- **Pharmaceutical Water and the International Regulatory Environment** – An Online Training Course course id# 2212
- **Pharmaceutical Water: Chemistry, System Design and Validation** – An Online Training Course course id# 2211
- **Sterilization in the Pharmaceutical Industry** course id# 2075
- **Sterilization Technologies and Process Validation** course id# 728

### The Center for Professional Advancement

#### Europe Office:

Oudezijds Voorburgwal 316A, 1012 GM Amsterdam, The Netherlands  
Phone: +31.20.638.28.06 • Fax: 31.20.620.21.36  
E-mail: [amsterdam@cfpa.com](mailto:amsterdam@cfpa.com)

#### U.S.A. Headquarters:

P.O. Box 7077, East Brunswick, NJ 08816-7077  
Phone: 732.238.1600 • Fax: 732.238.9113  
E-mail: [info@cfpa.com](mailto:info@cfpa.com)

[www.cfpa.com](http://www.cfpa.com)

**Register by 14 Aug and SAVE \$200**

**9–10 October 2008**  
**Amsterdam, The Netherlands**

# Clean Room Technology

For the Pharmaceutical and  
Medical Device Industries

### Course Topics Include:

- Design
- Upgrades
- Validation
- Troubleshooting
- Operation
- Monitoring
- Isolators and Barrier Technology
- Training
- cGMPs and Euro Regulations

Directed by:

**William G. Marshall**  
President  
William G. Marshall and Associates



**CfPA**  
The Center for Professional Advancement  
Accredited Technical Training Worldwide

[www.cfpa.com](http://www.cfpa.com)

## Who Should Attend

This course is intended for all personnel involved with the following areas of pharmaceutical and medical device sterile facilities:

- Design
- Construction
- Validation
- Operation
- Monitoring

Other personnel who will find this course of interest include:

- Design Engineers
- Contractors
- Equipment Manufacturers
- QA/QC
- Regulatory Affairs
- Production
- Maintenance

## Learning Objectives

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

- Develop programs for validation and monitoring of clean rooms
- Provide the necessary input for design and construction of clean rooms

Clean room supervisors, managers, and auditors will be better able to monitor the activities of the clean room worker.

## Course Description

This course reviews the current state of the technology associated with pharmaceutical, medical device, active pharmaceutical ingredient, medical component, R&D, and microbiological clean rooms. Regulations and guidelines for the U.S. and E.U. will be covered.

The course is conducted in an environment that encourages discussion, questions, input, and debate by the attendees. Case studies of actual rooms are presented. Attendees are invited to bring their own projects for discussion and review.

## Clean Room Technology

Offering# 0810-204

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### COURSE OUTLINE

#### first day

##### 08:00: Registration

##### 08:30–17:00:

##### Fundamentals of Airborne Contamination

- Small particle behavior
- Sources of contamination, variable and non-variable
- Monitoring for particles

##### Fundamentals of Air Filtration and Clean Room Design

- Selection, placement, installation and testing of HEPA filters
- Various options for room layout
- Material flow and personnel flow considerations
- Isolators
- Troubleshooting

##### Regulatory Requirements and Guidelines

- USFDA, U.S. Pharmacopoeia
- Fed. Std. 209, EN/ISO, European GMP

#### second day

##### 08:30–17:00: Equipment Issues

##### Personnel Issues

- Personnel behavior and training
- Gowning

##### Clean Room Maintenance, Cleaning and Disinfection

##### The Clean Room Validation Master Plan

##### Clean Room Monitoring

- Summary—10 common pitfalls in clean room construction and design

## Course Director

**William G. Marshall**, President of William G. Marshall and Associates, 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 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, and was a key member of the teaching team for the EU-PHARE funded Czech National Training Project on GMP and Quality Systems, for which **CfPA** was sole contractor. He has a Masters Degree in Biology from Georgetown University, Washington D.C.

## Course Location

This course will be held at the **Amsterdam Marriott Hotel**. The hotel is holding a limited block of rooms at a reduced rate for course participants. To obtain the preferred rate, you must inform the hotel that you are registering for this course. To ensure accommodations, reservations must be made at least four weeks prior to the course.

### Amsterdam Marriott Hotel

Stadhouderskade 12  
1054 ES Amsterdam, The Netherlands  
Phone: +31/20/607.55.08  
Fax: +31/20/607.55.12

*Acquire the skills to develop programs for validation and monitoring*

*Learn the input necessary for design and construction of clean rooms*

## Client Site

Training at your site and at your convenience. For further information, please contact **Client Site** Programs: Direct Dial (USA) +1/732.238.1600, ext. 4549; or fax +1/732.238.9113; or E-mail [clientsite@cfpa.com](mailto:clientsite@cfpa.com).

## Online Training Now Available

A NEW way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit [www.cfpa.com/online-training](http://www.cfpa.com/online-training).