

## Registration Form

Offering # **0812-205**

### Science and Risk Based Approach to Commissioning, Qualification and Validation

8–10 December 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. \$ **2345** / \$ **2235\***  
(Must register and pay by 13 October 2008) (Group Rate)

**Regular Registration** U.S. \$ **2545** / \$ **2435\***  
(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 \_\_\_\_\_

## 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 pharmacy education. **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; statement of credit 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# 716-000-07-115-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

- **ICH Q9: Managing Risk in Pharmaceutical Manufacturing**  
course id# 2158
- **ICH Q10: Pharmaceutical Quality System**  
course id# 2131
- **IQ/OQ/PQ**  
course id# 1808
- **Pharmaceutical Process Development**  
course id# 1358
- **Process Plant Start-Up**  
course id# 561
- **Validation of Computer Systems: Pharmaceutical Manufacturing**  
course id# 1526

## 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 13 Oct and **SAVE \$200**

**8–10 December 2008**  
**Amsterdam, The Netherlands**

## Science and Risk Based Approach to Commissioning, Qualification and Validation

Understand how ICH Q8, Q9, and Q10  
Influence the Qualification Process

Within the following manufacturing facilities:

- Medical Device
- Biopharmaceutical
- Pharmaceutical
- ASTM Standards

Directed by:

**Steven Wisniewski**  
Senior Associate and Director of Compliance  
Integrated Project Services (IPS)



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

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

## Who Should Attend

This **advanced** course is designed for individuals responsible for validation, commissioning, construction, or design who need a thorough understanding of the Validation and Commissioning Process for approved pharmaceutical/biopharmaceutical manufacturing facilities. The course will benefit individuals in:

- Engineering
- Production
- Regulatory Affairs
- Quality Control/Assurance
- Technical Services/Validation

Pharmaceutical Industry Service Providers will also find this course beneficial.

## Learning Objectives

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

- Effectively utilize Good Engineering Practice (GEP) to integrate commissioning into the validation process
- Apply a Risk Based approach to Impact Assessment and Critical Component Analysis
- Develop the rationale for Validation acceptance criteria
- Prepare Validation Master Plans and Commissioning Master Plans
- Understand how ICH Q8, Q9, and Q10 influence the Qualification process
- Apply the pending ASTM Standard for Qualification to projects

## Course Description

Because validation is the critical factor in achieving FDA approval of new and renovated facilities, it is essential that validated systems and equipment be commissioned using Good Engineering Practice (GEP) in a manner to facilitate the validation process.

This course will cover what has become the traditional approach to conduct Qualification and Validation, and will also show how that approach supports the new Regulatory Science and Risk Based Approach for the 21st Century. Current industry application of the impact assessment process for utility systems and equipment will be covered, and assessment results on Master Plans will be explained. The course demonstrates the importance of applying GEP in the preparation of design specifications, conducting design qualification, and correctly establishing contractor responsibilities for adherence to these specifications during construction and installation.

The course will show the relationship of all the steps in commissioning to the project life cycle. Necessary elements will be explored in detail to assure a successful integrated commissioning qualification effort. Examples will be used to provide guidance for development of sound commissioning and validation programs resulting in reduction of cost and time of 10-20%.

## Science and Risk Based Approach to Commissioning, Qualification and Validation

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### COURSE OUTLINE

#### first day

**08:00–08:30: Registration**

**08:30–09:15:**

**Validation/Commissioning Introduction**

**09:15–10:00:**

**Building Commissioning/Validation into the Concept/Design/Build Process**

**10:30–11:00:**

**Development of a Master Plan**

**11:00–12:00:**

**Protocol Development**

- Formats
- Requirements
- Development

**13:00–14:00:**

**Pharmaceutical Industry Guidance**

- Risk Based Approach for Impact Assessment

**14:00–15:00:**

**Installation Qualification Structure**

- IQ Content
- IQ Examples/Non-Conformances

**15:30–16:30:**

**Working with the FDA**

- Facility and Qualification Plan Review

**16:30–17:00:**

**Working with the FDA (continued)**

#### second day

**08:15–08:30:**

**Recap of First Day**

**08:30–09:15:**

**Workshop I – System Impact  
Workshop II – Critical Components**

**09:15–10:00:**

**Operational/Performance Qualification**

- OQ/PQ Format
- OQ/PQ Examples/Non-conformances

**10:30–12:00:**

**The Commissioning Steering Team**

**13:00–14:30:**

**Commissioning and Qualification**

- Integrating Commissioning into the Validation Process
- Factory Acceptance Testing
- Test and Balance Engineers
- Construction and As-Built Drawings

**15:00–15:45:**

**WFI System Commissioning and Validation**

**15:45–16:15:**

**Workshop III – Validation Execution Issues**

- Issue Identification
- Resolution Alternatives

**16:15–17:00:**

**Science and Risk Based Approach to C&Q**

- Introduction to Q8, Q9, and Q10

#### third day

**08:15–08:30:**

**Recap of Second Day**

**08:30–09:30:**

**International Standards**

- ASTM Standard for C&Q

**10:00–11:00:**

**Design Qualification**

**11:30–12:00:**

**Deviations**

**13:00–14:00:**

**Delays/Changes and Their Effect on Commissioning and Validation**

**14:00–15:00:**

**Supporting Quality Systems**

**15:30–16:00:**

**HVAC System Commissioning and Validation**

**16:00–17:00:**

**Group Questions and Discussion**

## Course Director

**Steven J. Wisniewski** is a Senior Associate and Director of Compliance for Integrated Project Services (IPS), a full service-engineering firm specializing in the delivery of technical complex projects, which offers complete design/build, commissioning, validation and FDA compliance services for the pharmaceutical, biotech, health care, and specialty manufacturing industries.

He offers more than 30 years experience in the pharmaceutical, biotech, and device industries. Prior to joining IPS, Mr. Wisniewski was Senior Consultant for Drug and Device Associates and has served in senior management roles at Sterling Winthrop and Bausch & Lomb. He has completed a wide variety of pharmaceutical manufacturing, filling and critical support operations to major R&D laboratories, facilities and upgrades. He served as a member of the ASTM Task Team that developed the International Consensus Standard for Verification (C&Q). Mr. Wisniewski holds a BSME from Rensselaer Polytechnic Institute, is a member of PDA and an active member of ISPE. He served on the ISPE Board of Directors beginning in 1982, served as Chairman of the Board in 1991, and currently serves as Chairman of the ISPE Community of Practice for Commissioning and Qualification and also serves on a Task Team in the process of revising the ISPE Baseline Guide for C&Q.

## Additional Faculty

**Aaron Weinstein** is the Validation Manager for the Compliance Services Group at Integrated Project Services' (IPS) PA office. He has over 7 years experience in validation within the pharmaceutical and biotech industries. Mr. Weinstein earned a BA in Interdisciplinary Studies from Touro College and is an active member of ISPE.

## Course Location

This course will be held at the **Renaissance Amsterdam Hotel**. Participants are responsible for making their own reservations. The Renaissance 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.

**Renaissance Amsterdam Hotel**  
Kattengat 1  
1012 SZ Amsterdam, The Netherlands  
Phone: +31/20/621.2223  
Fax: +31/20/627.5245  
www.renaissancehotels.com

## 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).

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