Registration Form

Course Offering # **1509-401**

IQ/OQ/PQ

September 22–23, 2015 • New Brunswick, NJ

Priority Code:
(Please use this code when registering) 520

Dr. Mr. Ms _____
First Name Last Name

Job Title _____

Company/Institution _____

Company Address _____

_____

City _____ State ____ Zip _____

Tel _____ Fax _____

E-mail Address _____
(Required in order to send confirmation material. CfPA does not rent or sell e-mail addresses)

Note: Please complete separate form for each registrant.

Tuition and Payment Methods

Early Bird (Save $200)
(Must register and pay by August 11, 2015) U.S.$ **1750 pp**

Regular Tuition U.S.$ **1950 pp**

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration.

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

Note: Payment is due 2 weeks prior to course or at time of registration.

❑ **Send Invoice/Bill Me** Purchase Order # (If Required) _____

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

❑ **Credit Card** ❑ Visa ❑ MasterCard ❑ American Express ❑ Discover

Card # _____ Exp. Date _____

Cardholder Name _____
(As appears on card)

Signature _____ Security code_____
(3 or 4 digit code)

Credit Card billing address (if different than above address)

_____

_____

ID 1808

3 Ways To Register

- Internet: **www.cfpa.com**
- Fax registration form to: **732.238.9113**
- Mail registration form to:

The Center for Professional Advancement (CfPA)
190 State Highway 18, Suite 203
East Brunswick, NJ 08816 USA

General Information

Payment: Tuition payable in US funds net of all charges. Payment is due 2 weeks prior to course or at time of registration. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Bird $200 Discount, payment is required at time of registration and/or BEFORE early registration discount expires or the regular tuition rate will apply. If choosing invoice/check/wire transfer, payment must be received prior to expiration of early registration discount or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group 10% Discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course offering.

Cancellations/Fees: ALL cancellations, must be in writing and are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund, less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit, less cancellation fee, that can be used towards a future course up to one year from the date of issuance. If you do not cancel and do not attend you are still responsible for full payment. All course cancellations must be in writing and e-mailed to: **info@cfpa.com**. 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.

Substitutions: Substitutions are permitted at any time and must be made in writing.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location – VIA EMAIL. We recommend that travel/hotel arrangements not be made until final confirmation package is received. If confirmation is not received two weeks prior to the course please contact Customer Service.

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.

Our full terms and conditions can be found on our website at www.cfpa.com

Courses of Interest

- **QRM Applications for Pharmaceutical Manufacturing Facilities**
  course id# 2616
- **ICH Q9: Managing Risk in Pharmaceutical Manufacturing**
  course id# 2158
- **Pharmaceutical Process Development**
  course id# 1358
- **Pharmaceutical Technology Transfer**
  course id# 2095
- **Process Validation for the Pharmaceutical and Medical Device Industry**
  course id# 736

Who We Are

The **Center for Professional Advancement (CfPA)** is the largest accredited technical training organization in the world with a curriculum of approximately 450 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.

Accreditations/Recertifications

The Center for Professional Advancement (CfPA) has been approved as an Authorized Provider by the **International Association for Continuing Education and Training (IACET),** 7918 Jones Branch Dr., Suite 300, McLean VA 22102. In obtaining this approval, **CfPA** has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. **CfPA** therefore authorized to offer IACET CEUs for itsprograms that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment.

The American Society for Quality (ASQ)
Recertification Opportunities
The following information was provided courtesy of ASQ, and is not meant as an endorsement of CfPA products. It serves only as an informational guide about the certifications offered by ASQ. Many CfPA courses offer training that may be helpful in obtaining required ASQ's recertification education units. To view a list of recommended courses that may be appropriate please visit www.cfpa.com
For more information about ASQ, contact them at: help@asq.org

The Center for Professional Advancement (CfPA) is a Regulatory Affairs Professionals Society (RAPS) RA Professional Development Portal provider. The Center for Professional Advancement (CfPA) is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. The Center for Professional Advancement (CfPA) has agreed to follow RAPS- established operational and educational criteria. This course has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

The Center for Professional Advancement
190 State Highway18, Suite 203, East Brunswick, NJ 08816
Phone: 732.238.1600 • Fax: 732.238.9113
E-mail: info@cfpa.com
www.cfpa.com

SAVE $200-Register & Pay by August 11

September 22–23, 2015
New Brunswick, NJ

This course has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

IQ/OQ/PQ

Preparing and Conducting Installation, Operational and Performance Qualifications

Course Topics Include:

- Protocol Responsibilities
- Writing Protocols
- Acceptance Criteria
- Qualification Reviews
- Validation Master Plan
- ICH Q9/ASTM Qualification Standards
- Risk Analysis Workshops
- Leveraging Commissioning Data for Compliance

Directed by:
Steven J. Wisniewski
Principal Compliance Consultant
Commissioning Agents, Inc. (CAI)

Maximize your learning! Attend this course and its companion
*See inside for details

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Who Should Attend

This **introductory/intermediate** course is designed for individuals who need a **basic**, but thorough understanding of the Qualification Process for equipment and systems in support of Process Validation for the manufacture of pharmaceutical sterile and oral solid finished dosage forms and bulk active ingredients through the use of IQ/OQ/PQ Protocols. The course will benefit individuals in:

- Engineering
- Technical Services/Validation
- Production
- Quality Control/Assurance
- R&D
- Regulatory Affairs
- University and allied health care professionals

Learning Objectives

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

- Prepare IQ/OQ/PQ Protocols and Verification Protocols
- Perform execution of approved protocols
- Write Protocol Summary Reports
- Prepare Validation Master Plans
- Apply a Risk Based approach for Impact/Risk Assessment
- Explain the ICH Q9/ASTM Standard for Verification
- Integrate an Integrated Commissioning Validation Approach
- Implement Quantity Systems to support validation

Course Description

The installation/operational/performance qualification/verification of equipment, systems, facilities and processes for pharmaceutical sterile, oral solid dosage, finished and bulk manufacturing operations are an essential part of the validation process. Equipment must be installed, operated and maintained within design specifications and facilities must be accepted as fit for use, while processes must be shown to be reliable, all of which to assure the consistent quality and integrity of the product. This course provides a basic and thorough understanding to preparing, executing, reviewing and approving protocols. A Risk Based approach to impact critically assessment is also provided along with an overview of ICH Q9 Quality Risk Management and ASTM E 2500 International Consensus Standard approaches now being applied by the Industry and Regulatory authorities to define Qualification (Verification) requirements.

Protocol examples/workshops will be utilized to enhance the learning, however this course will not provide a library of completed protocols.

IQ/OQ/PQ

Course Outline

September 22–23, 2015 • New Brunswick, NJ | Offering# 1509-401

First Day

8:00 a.m.:
Registration/Continental Breakfast

8:30–10:00 a.m.:
Review of Learning Objectives
Validation Overview

- History
- Definitions
- "V" Model

Regulatory Requirements

- FDA: CFR
- EMEA: Directives

10:30–12:00 noon:
Validation Master Plan

- Master Plan Purpose
- Master Plan Content

1:00–3:00 p.m.:
Why have Protocols?

- Protocol Format
  - Sections (Minimum Requirements)
  - Systems/Equipment to be Qualified
  - Responsibilities
  - General Requirements for Development
  - General Requirements for Execution

Integrating Commissioning & Validation

- Impact Analysis
  - Critical Components
  - Applying Good Engineering Practice

3:30–4:30 p.m.:
Installation Qualifications

- IQ Structure
- IQ Acceptance Criteria
- Execution Issue Examples

Second Day

8:00–10:00 a.m.:
Impact Analysis Workshop 1 & 2

10:30–12:00 noon:
Supporting Quality Systems

- Calibration Program
- Maintenance/preventive maintenance programs
  - Logs & equipment files
- Training
- Documentation Management
- Change Control

Protocol Execution

- Executing Protocols
- Preparing the Summary Report

Operational and Performance Qualifications

- PQ/OQ Structure
- PQ/OQ Acceptance Criteria
- Execution Issue Examples
- Preparing the PQ Validation Summary Report

1:00–3:00 p.m.:
Operational/Performance Qualifications (Continued)

Deviations and Reporting

- Deviation Types
- Deviation Corrections
- Deviation Investigation System

3:30–4:30 p.m.:
ASTM E 2500 Verification/Qualification Standard

- Relationship to ICH Q9
  - Standard Overview
- Status
- Qualification Impact

Assessment Opportunity

www.cfpa.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. 4547; or fax +1/732.238.9113; or **E-mail clientsite@cfpa.com.**

Online Training Now Available

A convenient and cost-effective 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.**

Course Director

Steven J. Wisniewski is Principal Compliance Consultant for Commissioning Agents, Inc. (CAI), provider of technical services for biotech and pharmaceutical manufacturers worldwide. Commissioning Agents focuses on the manufacturing process, with services including commissioning, validation, technology transfer, PAT, maintenance programs, SOPs, training and cGMP compliance.

Mr. Wisniewski offers more than 30 years experience in the pharmaceutical, biotech, and device industries. Prior to joining CAI he was Senior Associate and Director of Compliance for IPS. Mr. Wisniewski 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 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, and was chairman of the board in 1991. He served four terms as Chairman of the ISPE Community of Practice for Commissioning and Qualification, was a lead on the Task Team that drafted the new ISPE Guide in support of Risk-based Qualification and served on Task Team that just completed the ISPE Good Practice Guide to address transitional Science and Risk-based (ICH Q9) approaches for C&Q. He was on the Team that developed the ASTM E2500 Standard and has also served as course leader and/or presenter at multiple ISPE C&Q conferences and co-authored several C&Q related articles.

Course Location

This course will be held in **The Heldrich Hotel** located in **New Brunswick, New Jersey**. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance. For reservations call 866.609.4700 | Main Hotel Phone: 732.729.4670.

Maximize your learning!
Attend this course and its companion

***Companion Course: QRM Applications for Pharmaceutical Manufacturing Facilities** **September 24 , 2015**
New Brunswick, NJ • Course ID #2616

Quality Risk Management (QRM) is an expected element of a company's site quality system. This 1-day course will introduce the key principles of QRM across the product/system life cycle and within Quality Systems. Those attending this training will have a better understanding of how to apply Risk-Based approaches to IOQ and commissioning.