

# Implementing GEP (Good Engineering Practices) in the Pharmaceutical, Bio-Pharmaceutical, and Medical Device Industries



**Day:** March 24, 2009 **Time:** 11:00 a.m. - 12:30 p.m. (EST)

**Location:** Your Computer **Offering #** 0903-410 **Priority Code:** 520 (Available On-Demand starting 4/10/09)

This course presented by CfPA in conjunction with



and

**PFQ**

## WHO SHOULD ATTEND

This course is intended for Engineering Unit Managers and interdisciplinary Project Team Members who are responsible to deliver "Fit for Intended Use" cGMP manufacturing, R&D, and supporting facilities. The course is recommended for:

- Engineering Managers
- Project Managers
- Quality Unit Managers
- Commissioning & Qualification Project Team Leaders
- Engineering Design Service Providers
- Construction Managers
- Compliance Service Providers

## LEARNING OBJECTIVES

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

- Outline the methodologies required for the application of Good Engineering Practices to support Risk-Based approaches to successfully deliver compliant facilities.

## COURSE DESCRIPTION

This 90-minute accredited online course is aligned with current industry "Risk-Based" initiatives and guidance provided in ICH Q9, ASTM E2500, and ISPE Baseline & Good Practice Guides. This course will provide insight on critical project decision making and enable a project team to identify and document data during the application of GEPs during the design, specification, and verification phases of a project. Discussions will focus on identifying and implementing Engineering Quality Systems to assure efficiency and quality.

### Module 1:

- GEP Overview
- Engineering Quality Systems
- GMP and GEP

### Module 2:

- Design Review Process
- Change Management
- Risk Management

### Module 3:

- Applying GEP to the Verification (Commissioning & Qualification)
- Integrating the Project and Engineering Lifecycles
- Planning for Success

**Question and Answer Session**

## TUITION AND REGISTRATION

**Tuition- \$395.00 per person (USD)\* Group Discount Rates also available.**

**Register at [www.cfpa.com](http://www.cfpa.com).** Enter **Course Offering #0903-410** into **Quick Jump**. To register use **Priority Code: 520**.

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.

For more information see reverse side ⇨



**CfPA**

The Center for Professional Advancement  
Accredited Technical Training Worldwide

PO Box 7077, East Brunswick NJ 08816  
Phone 732-238-1600 • Fax 732-238-9113

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

---

## COURSE DIRECTOR

---

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

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 drafting the new ISPE Baseline Guide for Installation and Verification (C&Q).

### ADDITIONAL FACULTY:

**Chuck Stock**, Senior Vice President, IPS

**Vince Cebular**, Senior Director of Operations, Compliance Services, IPS

---

## 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.

---

## WHO WE ARE

---

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

---

## ABOUT WILEY-BLACKWELL

---

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](http://www.blackwellpublishing.com) or <http://interscience.wiley.com>.

---

## COURSES OF INTEREST

---

- **Applied cGMPs for Pharmaceutical and Allied Industries**  
course id# 610
- **Biopharmaceutical Process Systems**  
course id# 1116
- **Commissioning, Qualification and Validation**  
course id# 1954
- **Critical Process Cleaning and Cleaning Validation**  
course id# 1867
- **IQ, OQ, PQ**  
course id# 1808
- **Pharmaceutical Process Development**  
course id# 1358
- **Scale-Up and Post Approval Changes Guidelines (SUPAC & API Changes)**  
course id# 1948

---

## 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.

**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.