

**Pharmaceutical Engineering and Technology Series course...  
Writing and Managing Pharmaceutical SOPs in  
Compliance with cGMP**

**February 28–March 1, 2007  
Las Vegas, Nevada**

**Practical new course for  
persons involved in the  
preparation, implementation  
or management of individual  
SOPs or of the SOP system  
for GMP operations**

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**COLLEGE OF ENGINEERING ■ DEPARTMENT OF ENGINEERING PROFESSIONAL DEVELOPMENT**

**Pharmaceutical Engineering and Technology Series**

# **Writing and Managing Pharmaceutical SOPs in Compliance with cGMP**

**February 28–March 1, 2007  
Las Vegas, Nevada**

A practical new course to help you

- Realize the role of SOPs in documenting pharmaceutical GMP operations
- Understand regulatory agency and industry expectations
- Identify SOP needs and responsibilities for SOP preparation and approval
- Use appropriate formatting and writing techniques
- Analyze the adequacy of existing SOP systems
- Manage and use SOPs and the SOP system effectively and efficiently



# Writing and Managing Pharmaceutical SOPs in Compliance with cGMP

February 28–March 1, 2007 in Las Vegas Nevada

Save time and money!  
Inquire about our on-site courses.  
Call 800-462-0876 today!

## Know How to Implement and Use a Successful SOP Program

SOPs are the primary means used within the pharmaceutical and related industries to describe how operations are performed. They are a basic requirement of GMP regulations globally and are regarded by regulatory agencies globally as a rigid, legal written commitment. Thus SOPs are among the main documents scrutinized by the agencies during their GMP inspections.

This practical new course covers the various elements you must consider to ensure that your organization's individual SOPs and the SOP program for GMP operations are effective and efficient.

### Participants in Our Pharmaceutical Courses Say...

"Course very well organized. Interesting topics. Definitely recommend it to my colleagues."

"Excellent presentations, very experienced speakers."

"Learned a lot! Great opportunities to network."

"I was able to get answers to questions that have been brought up on the job regularly."

## Key Learning Objectives

Participate in this results-oriented course and learn about:

- The role of SOPs in GMP documentary systems
- Regulatory agency and industry expectations
- Determining what SOPs need to be written
- Analyzing existing SOPs to determine gaps and overlap in GMP coverage
- Needs for different types of SOPs
- Typical formats used
- Determining who should prepare, approve and authorize SOPs
- Understanding and describing operational flow
- Assessing what level of detail to address
- Writing accurately, clearly, unambiguously and succinctly
- Printing techniques that help make SOPs easy to read and understand
- Managing effectively and efficiently the SOP system: defining responsibilities, handling tracking and revisions, compiling the SOP on SOPs, and understanding SOP costs

## Who Will Benefit

This course will benefit all who are involved in the preparation, implementation or management of individual SOPs or of the SOP system for GMP operations. Typically it will assist personnel from all phases of production and quality operations and relevant personnel from R&D. These areas of responsibility include

- Quality assurance/quality control
- Regulatory affairs
- Purchasing
- Production (including manufacturing, packaging)
- Warehousing/distribution
- Maintenance/engineering
- Technical services
- Clinical supply management
- Senior management

## Bring Your Team

Gain maximum value for your organization by attending as a team. If you enroll two or more people, you will receive a substantial discount. Enroll online at <http://epd.engr.wisc.edu/webJ075> or call toll free 800-462-0876.

### For Related Course Descriptions

<http://epd.engr.wisc.edu/catalogs/pharmaceutical.lasso>

## Your Instructor

**Dr. Alan J. Smith** is a consultant specializing in pharmaceutical quality and technology. He was formerly the corporate director of quality affairs for the Whitehall Laboratories Division of American Home Products Corporation (now Wyeth) following a career with the Ayerst Division. He received his BSc and PhD degrees in chemistry from the University of London (UK) and studied business administration at the Wharton School of the University of Pennsylvania. His experience in both the chemical and pharmaceutical industries includes research, analytical methods development, stability programming, regulatory affairs, quality control and corporate quality assurance.

A member of the American Chemical Society and the American Society for Quality, Dr. Smith has served as chairman of numerous pharmaceutical conferences. He has been a member of several industrial association committees including the PMA (now PhRMA) Committee on Stability and Expiration Dating and the ASTM Committee on Quality Systems. He is also a member of the editorial advisory board of the journal, *Pharmaceutical Technology*. Dr. Smith received the 1998 WorldPharm Award for Service to the Pharmaceutical Industry. His consulting has included work with firms under consent decree.

# Writing and Managing Pharmaceutical SOPs in Compliance with cGMP

February 28–March 1, 2007 in Las Vegas Nevada

## Course Outline

### Wednesday, February 28

#### 8:00 Registration and Coffee

Tropicana Resort and Casino  
3801 Las Vegas Boulevard South  
Las Vegas, Nevada

#### 8:30 Welcome and Introduction

Michael F. Waxman PhD  
Professor and Program Director  
Department of Engineering  
Professional Development  
College of Engineering  
University of Wisconsin–Madison

#### 8:45 Introduction of Participants and Course Instructor

#### 9:00 Regulatory Aspects and General Role of SOPs

- FDA expectations and findings for SOPs and the SOP system
- Role of SOPs in GMP compliance
- Role of SOPs in the total documentary system

#### 10:15 Break

#### 10:30 Main Characteristics of SOPs

- Detailed characteristics of SOPs and the SOP system
- General controls required for documents including SOPs
- Understanding and describing operational flow
- Determining SOP needs and assigning preparers
- Needs for different types of SOPs
- Analyzing existing SOP systems for gaps and overlaps
- Workshop: classifying SOPs

#### 12:15 Lunch

#### 1:30 Formatting and Writing SOPs

- SOP formatting principles and templates
- Principles of readability
- Hints on how to write accurately, clearly, unambiguously and succinctly
- Assessing what level of detail should be addressed
- Techniques for text minimization

#### 3:00 Break

#### 3:15 Printing and Distribution

- Printing techniques that make SOPs easy to read and understand
- Elements of SOP distribution

#### 4:15 Interactive Question/Answer Session

#### 4:30 Adjourn for the Day

### Thursday, March 1

#### 8:30 SOP Examples and Critiquing Techniques

- Review of different examples of SOPs
- Critiquing SOPs
- Workshop: SOP critique

#### 10:15 Break

#### 10:30 Management of SOPs and the SOP System

- Defining roles and responsibilities
- Handling tracking and revisions
- Compiling the SOP on SOPs
- Assessing SOP effectiveness
- Performing periodic reviews
- SOPs as a training tool
- SOPs as an auditing tool
- Understanding and minimizing SOP costs

#### 12:15 Lunch

#### 1:30 Workshop: Organizing the SOP

#### 3:15 Break

#### 3:30 Final Question/Answer Session and Wrap-up

#### 4:00 Course Adjournment

## On-site Courses Save Time & Money!

Engineering Professional Development can offer many of our courses:

- At a location of your choice in North America
- At your convenience
- At reduced per-person cost
- Tailored to your needs

To inquire about courses that we can bring to your site, including optimal group size and costs, or to request an on-site course, call 800-462-0876 and ask for Corporate Education Director Carl Vieth (vieth@wisc.edu or 608-263-7424 direct).

Or see <http://epd.engr.wisc.edu/onsite>

## Related Courses

For details on the following courses, contact program director Michael Waxman at 800-462-0876 or waxman@engr.wisc.edu, or check our Web site at <http://epd.engr.wisc.edu/catalogs/pharmaceutical.lasso>

*Developing and Implementing Effective Pharmaceutical Stability Programs*  
February 26–27, 2007, Las Vegas, NV  
Course #J031

*Test Method Validation in Pharmaceutical and Biopharmaceutical Development and Production*  
March 5–7, 2007, Las Vegas, NV  
Course #J021

*Cleaning Validation Practices for Pharmaceutical and Biopharmaceutical Production*  
March 12–13, 2007, Las Vegas, NV  
Course #J022

*Tablet and Capsule Manufacturing: Introduction and Update for Competitive Organizations*  
March 19–21, 2007, Las Vegas, NV  
Course #J023

*Pharmaceutical Laboratory Controls for FDA Compliance*  
March 26–27, 2007, Las Vegas, NV  
Course #J032

*Pharmaceutical and Device Project Management*  
April 4–6, 2007, Las Vegas, NV  
Course #J024

*Best Practices in Biopharmaceutical Raw Materials Testing and Vendor Qualification*  
April 16–17, 2007, Las Vegas, NV  
Course #J025

## Four Easy Ways to Enroll

### Need to Know More?

Call toll free **800-462-0876** and ask for

**Program Director:**

Professor Michael F. Waxman  
waxman@engr.wisc.edu

**Program Associate:**

Diane Lange  
lange@engr.wisc.edu

Or e-mail **custserv@epd.engr.wisc.edu**

### General Information

**Fee Covers** Notebook, course materials, break refreshments, lunches and certificate. We do not publish proceedings, and due to copyright laws the course materials are not available after the course.

**Cancellation** If you cannot attend, please notify us by February 21, and we will refund your fee. Cancellations received after this date and no-shows are subject to a \$150 administrative fee. You may enroll a substitute at any time before the course starts.

**Location** The course will be held at The Tropicana Resort and Casino, 3801 Las Vegas Boulevard South, Las Vegas, Nevada. If you must be contacted during the course, phone messages may be left for you at 702-739-2222.

**Accommodations** A block of rooms for course participants has been reserved at The Tropicana Resort and Casino, the course site. To reserve your room (\$95/single and double, Monday-Thursday), call toll free 800-634-4000 or 702-739-2222 by Tuesday, January 30. Mention that you will be attending the UW-Madison course, *Writing and Managing Pharmaceutical SOPs in Compliance with cGMP*. The hotel's standard check-in time is 3:00 p.m., and the standard checkout time is 11:00 a.m.

**Earn Continuing Education Credit** By participating in this course, you will earn 1.2 Continuing Education Units (CEU).

*Good Manufacturing Practice for Regulated Consumer Products*  
April 23–24, 2007, Las Vegas, NV  
Course #J026

*Pharmaceutical Water Systems*  
April 25–27, 2007, Las Vegas, NV  
Course #J029

*Advanced Practices in Pharmaceutical Tablet and Capsule Technology*  
May 7–9, 2007, Las Vegas, NV  
Course #J027

*Auditing Suppliers to the Pharmaceutical Industry*  
May 10–11, 2007, Las Vegas, NV  
Course #J028

## Why Invest in Professional Training?

Whether acquiring continuing education hours or building the skills needed for a promotion, attendees in Engineering Professional Development courses have made lifelong learning a priority in their careers. Professional education benefits you and your employer by offering many opportunities to:

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- Expand your competencies to new areas
- Step back from your daily grind and refocus
- Connect with experts in the field
- Get fresh viewpoints on your challenges
- Re-energize and “recharge your batteries”
- Set yourself apart from competitors



**Phone:**  
**800-462-0876** or  
608-262-1299 (TDD 265-2370)



**Internet:**  
<http://epd.engr.wisc.edu/webJ075>

**Mail to:**

Engineering Registration, The Pyle Center  
702 Langdon Street, Dept. 106  
Madison, Wisconsin 53706



**Fax:**

**800-442-4214** or 608-265-3448



### Course Information

Please enroll me in **Writing and Managing Pharmaceutical SOPs in Compliance with cGMP Course #J075** February 28–March 1, 2007 in Las Vegas, Nevada Fee: \$2095

**Team Discount:** \$1995 each when two or more persons enroll from the same company.

I cannot attend at this time. Please send me brochures on future courses.

### Personal Information (Please print clearly.)

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Company \_\_\_\_\_

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City/State/Zip \_\_\_\_\_

Phone (\_\_\_\_) \_\_\_\_\_ Fax (\_\_\_\_) \_\_\_\_\_

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

### Additional Enrollees

Name \_\_\_\_\_

Title \_\_\_\_\_

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

Name \_\_\_\_\_

Title \_\_\_\_\_

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

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