NEW! Pharmacopoeias: A Global Perspective for Compendial Compliance

February 27-28, 2017 | New Brunswick, NJ

Course Topics Include:
- Focus on USP-NF, Ph. Eur., BP
- Consideration of JP and other National Pharmacopoeias
- Compendial development and revision process
- Compendial harmonization
- Compendial surveillance, advocacy and compliance

Course description

Compliance with compendial requirements is a legal and regulatory requirement in those countries in which the pharmacopoeia is applicable. There is currently a reasonably broad understanding regarding the applicability of USP-NF requirements in the US, Ph. Eur. and BP requirements in Europe, and JP requirements in Japan. However, there is less understanding of regulatory expectations regarding applicability of these same pharmacopoeias in other countries. Additionally, with increasing globalization in the bio/pharmaceutical industry, other pharmacopoeias are becoming more important, including those in Brazil, Russia, India, China and Korea. Further complicating the compliance picture is the interplay of compendial requirements and approved registrations for drug products.

This comprehensive 2-day course will provide an understanding, including practical examples of compliance with compendial requirements, as published by pharmacopoeias. The course includes an introduction to the pharmacopoeias, with an emphasis on the USP-NF, Ph. Eur. and BP. A global perspective is presented, with consideration also given to the pharmacopoeias in other important countries. Details of the content, organization and use of the pharmacopoeias are presented, along with regulatory considerations and applicability of compendial requirements. There is a detailed exploration of the development and revision processes for compendial standards, with real-life case studies offered. Efforts toward compendial harmonization are described, with information on the activities of the Pharmacopoeial Discussion Group (PDG) and prospective harmonization of drug substance/product monographs. The course concludes with an exploration of approaches to compendial surveillance, opportunities for advocacy, and ultimately – compliance with the requirements in the pharmacopoeias.

In addition to gaining in-depth knowledge of the pharmacopoeias, the course will assist the global bio/pharmaceutical industry, including innovator, generic, biotechnology and consumer-care companies, seeking greater understanding of compliance with USP-NF, Ph. Ph. Eur. or BP requirements, within and outside the US and EU borders. Information is also provided for companies to understand key elements of compliance with national pharmacopoeias in other countries.

SAVE $200-Register & Pay by January 16
who should attend

This course is intended for individuals who have the responsibility for ensuring compliance with requirements in the pharmacopoeias, and is applicable to the innovator, generic, biotechnology, consumer-care and related industries. This course will benefit individuals in:

- Compendial affairs
- Regulatory affairs/CMC
- Analytical chemistry/Process chemistry
- R&D/New products/Method development
- Quality assurance/Quality control
- Contract manufacturers/laboratories

learning objectives

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

- Demonstrate greater understanding of the pharmacopoeias, including USP-NF, Ph. Eur., BP, JP, as well as other national pharmacopoeias
- Describe the applicability of pharmacopoeias in the global bio/pharmaceutical industry
- Explain the content, organization and revision process of the pharmacopoeias, including monograph development
- Appreciate past and current efforts aimed at compendial harmonization
- Describe the processes for compendial surveillance and take advantage of opportunities for advocacy, which ultimately lead to compliance with requirements in the pharmacopoeias

course outline

First Day

8:00 a.m.: Registration/Continental Breakfast
Review of Learning Objectives
Pharmacopoeias: Introduction and History
- Purpose and Significance of Pharmacopoeias
- History: BP; USP-NF; Ph. Eur.
- Regulatory Guidance and Product Registrations
- Global Perspective: National Pharmacopoeias
- Introduction to Compendial Compliance
Focus on USP-NF, Ph. Eur., BP
- Content and Organization
- Monographs, General Chapters, Solutions, Reagents, General Notices
- Reference Standards
Consideration of National Pharmacopoeias
- WHO/International Pharmacopoeia (Ph. Int.)
- Japan (JP), India (IP), China (ChP), Korea (KP), Russia (Ph. Rus), Brazil (FBras)
- Other Pharmacopoeias: Languages; Translations

Second Day

Compendial Revision Process: USP-NF; Ph. Eur.; BP
- Pharmacopoeia Forum and New Editions/Supplements
- Publication Schedules
- Impact of Compendial Revisions
  - Case Study: New Monograph
- Revision Process: Other Pharmacopoeias

Compendial Harmonization
- Objectives and History of Harmonization
- PDG/ICH Q4/Q4A/Q4B
- Prospective Harmonization
- Good Pharmacopoeial Practices (WHO)

Monograph Development
- Timing (Initiation to Completion), Process Steps
  - Challenges/Case Studies: Impurities; Dissolution

General Chapter Development Process

Focus on Compendial Compliance
- Surveillance
- Advocacy
- Compliance
  - Specifications
  - Methods
  - Implementation

Conclusions, Discussion and Wrap-up

Assessment Opportunity

A one-half hour break at approximately 10:00 am and 2:30 pm and a one-hour lunch at noon are planned for each day.

course director

J. Mark Wiggins is a Director in Regulatory Policy and Compendial Affairs at Merck & Co., Inc., West Point, PA, U.S.A. (known as MSD outside the United States and Canada), with over 30 years’ experience in the pharmaceutical industry. His current responsibilities include preparing and submitting new and revised monographs to the pharmacopoeias for drug products, drug substances, and excipients, as well as reviewing and responding to proposed compendial changes published by pharmacopoeias around the world. Prior to his current position, Mr. Wiggins was responsible for testing and releasing excipients for use in formulation design, scale-up, and clinical supplies. He also has experience in the synthesis and characterization of active pharmaceutical ingredients for use in the treatment of HIV/AIDS, cancer, diabetes, hypercholesterolemia and depression.

Mr. Wiggins has been an active participant in compendial harmonization efforts, serving as PhRMA representative on the ICH Q4B Expert Working Group, and leading several face-to-face meetings with pharmacopoeias on the topic of harmonization. He is also an active contributor to several industry-based compendial discussion groups, and has chaired the US-based PhRMA compendial team, which has important connections with EFPIA, based in the EU. He has been an invited speaker in several international meetings, including presentations on compendial harmonization at the Ph. Eur. workshop on “Quality of Medicines in a Globalized World”, and more recently at meetings with the pharmacopoeias and regulators in the US, Europe, India, Japan, Korea, and China.

Mr. Wiggins has authored several papers covering each area of his career. Recent articles include introductions to the concepts of the “Ideal Pharmacopoeia” and “Compendial Globalization”, as well as the industry perspective on the pilot project to achieve “Prospective Harmonization” for API monographs. Mr. Wiggins holds degrees in Chemistry from Trinity University and the University of Wisconsin, both in the US.

For assistance contact Customer Service at 1/732-613-4500 or email us at: info@cfpa.com
For More Information or to Register Go to www.cfpa.com
This course will be held in the New Brunswick, New Jersey area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee. We recommend that travel/hotel arrangements not be made until final confirmation package is received.

- Easy access to Manhattan, Trenton, NJ and Philadelphia, all less than 40 minutes

**Accreditations/Recertifications for this course**

The Center for Professional Advancement (CfPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 12100 Sunset Hills Rd., Suite 130, Reston, VA 20190. 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 is therefore authorized to offer IACET CEUs for its programs 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. This course offers a total of 18 contact hours, or 1.8 CEUs.

**Who We Are—“Celebrating 50 Years”**

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 to fit you or your company's training needs:

- **In Person:** Away from responsibilities, participants are immersed without distraction
- **Client Site:** Training at your site and at your convenience. For further information, please contact Client Site Programs: +1/732.238.1600, ext. 4547 or E-mail clientsite@cfpa.com
- **Online:** A convenient and cost-effective way to experience our accredited training. For a list of upcoming courses visit www.cfpa.com/onlinetraining

**We Also Offer**

- **Client Site:** Training at your site and at your convenience. This course and any of our other courses are available to be customized and brought to your location. For more information visit www.cfpa.com/ClientSite
- **Online Training:** 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/onlinetraining.

**Virtual Attendee Training Option**

About the Virtual Attendee Training Option

Though attending in person at one of our courses is highly recommended, attending virtually is the next best thing when you can’t be there. We will provide you with access to the complete live in person course via an internet connection and phone/audio speakers. You will receive a hard copy of the course notes, follow the same course schedule as the live course and see the slide presentation and hear the audio, in addition you will have the ability to participate and ask questions through the online chat. For complete information and FAQs visit: www.cfpa.com/virtualattendee

**Tuition**

- **Early Bird—Save $200** (Must register and pay by January 16, 2017) $1970
- **Regular Tuition** $2170
- **Virtual Tuition** $1736

**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.

For assistance contact Customer Service at 1/732-613-4500 or email us at: info@cfpa.com

For More Information or to Register Go to www.cfpa.com
Pharmacopoeias: A Global Perspective for Compendial Compliance  
course id# 2728/course offering# 170227NJ2728

Instructions:
Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant.

☐ Check here if group discount applies (two or more enrollments for the same course, from the same company)

**Registrant Information**

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How did you hear about us?  
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☐ Send Invoice/Bill me (PO# if applicable ______________________)  
☐ Check: Payable in US funds to: The Center for Professional Advancement  
☐ (Pay by Bank Transfer to Account No. 2000012656408 (US$) ABA Routing No. 121000248, Swift Code WFBIUS6S at Wells Fargo, 420 Montgomery Street, San Francisco, CA, USA. The course Offering # (above) and participant’s name must be included on bank transfer.)

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**Terms and Conditions**

Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration or upon receipt of invoice. 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 tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. The Virtual Attendee Option does not qualify for Early Bird pricing. If choosing invoice/wire transfer, payment must be received prior to expiration of early registration tuition or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Please note: Group Rate Discount cannot be combined with any other discount. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: ALL cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 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 the full payment. 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 are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

Confirmation Letters: Before each course begins, all registrants will receive written Final 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 at info@cfpa.com.

Course photography / video: By registering and attending a CfPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CfPA using these photos and/or videos for marketing or any other CfPA Course and/or promotional purposes. You agree to release CfPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Please note: English will be used in all lectures and course notes. For questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com.