COBBLESTONE

COURSE ID 3046

NEW!

Pharmacopoeia Compliance: An Overview

How to Meet Legal, Regulatory, and Compendial Requirements

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Why pharmacopoeia compliance is necessary and why it is difficult
- A brief history of pharmacopoeias and harmonization efforts
- The revision process for global and national pharmacopoeias
- The associated surveillance process used to identify changes that impact a company
- A practical approach to compliance that addresses differences in limits and methods between a pharmacopoeia monograph and approved registrations

about the course

Compliance with requirements published by pharmacopoeias around the world is a legal and regulatory requirement in those countries and regions in which the pharmacopoeia is applicable. This fundamental – and often misunderstood – principle is an important consideration throughout the drug product life cycle across the bio/pharmaceutical industry. Ensuring pharmacopoeia compliance is often complex and the challenges are unique to any given company and its product portfolio.

This Free Webinar provides an overview of the interplay of pharmacopoeias and a company's quality assurance and regulatory affairs functional areas to assist in establishing effective processes, partnerships, and tools for pharmacopoeia compliance. This course can also help you determine whether additional customized training – which is available through Cobblestone – could enhance your understanding and improve the approaches taken by your company to maintain appropriate and timely compliance with pharmacopoeia requirements.

who should attend

This Free Webinar is intended for individuals who have the responsibility for ensuring compliance with requirements in the pharmacopoeias and is broadly applicable to the global bio/pharmaceutical industry, including innovator, generic, biotechnology, consumer-care, and related industries.

• Compendial affairs	• Analytical chemistry/Process chemistry
• Regulatory affairs/CMC	• 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 compendial requirements, as published by the pharmacopoeias, including USP-NF, Ph. Eur., and BP, as well as other national pharmacopoeias (e.g., JP, ChP).
- Demonstrate greater understanding of both the need and challenge of compliance with compendial requirements.

course outline

Review of Learning Objectives
This free webinar provides a brief introduction to pharmacopoeia compliance and will cover the following topics.
Why Pharmacopoeia Compliance Is Necessary

- Understanding the legal and regulatory basis for pharmacopoeia compliance in the United States, Europe, Japan, and other countries
- Understanding the purpose and content of pharmacopoeias
- Understanding the impact of pharmacopoeias throughout the drug product lifecycle

Why Pharmacopoeia Compliance Is Difficult

• Understanding the external and internal challenges that make pharmacopoeia compliance difficult, utilizing an end-to-end framework to explore the processes and activities

A Brief History of Pharmacopoeias: A Global Perspective

- Understanding the historical and global context for pharmacopoeias to gain perspective on the complexity and challenges of pharmacopoeia monitoring and compliance

An Overview of Pharmacopoeia Harmonization

- Understanding harmonization efforts already underway, including the Pharmacopoeial Discussion Group (PDG), International Council for Harmonization (ICH), WHO's Good Pharmacopoeial Practices (GPhP), and prospective harmonization of new monographs for APIs and products

The Pharmacopoeia Revision Process

- Understanding the revision processes used by pharmacopoeias, and their associated schedules for publication of proposed and official updates

The Industry Surveillance Process for Pharmacopoeia Revisions

- Examining the industry processes to monitor pharmacopoeia changes and achieve on-time compliance with updated requirements

A Practical Approach to Pharmacopoeia Compliance

- Exploring options to deal with differences in limits and methods between a pharmacopoeia monograph and approved registrations

course instructor

Mark Wiggins is Owner and Compendial Consultant with Global Pharmacopoeia Solutions LLC, which he formed after more than 30 years' experience in the pharmaceutical industry. He was previously Director of Compendial Affairs at Merck, with more than 15 years' experience submitting new and revised monographs to pharmacopoeias, as well as reviewing and responding to proposed compendial changes from around the world. He also has experience in the testing and release of excipients for use in formulation design, scale-up, and clinical supplies in support of new product R&D, and in the synthesis and characterization of active pharmaceutical ingredients for use in the treatment of HIV/AIDS, cancer, diabetes, hypercholesterolemia, and depression. Mark has been an active participant in pharmaceutical industry associations in the US and abroad and represented PhRMA on the ICH Q4B activities to harmonize general chapters in the pharmacopoeias. He has been an invited speaker at international meetings in the US, UK, Europe, India, Japan, Korea, and China, including the Ph. Eur. workshop "Quality of Medicines in a Globalized World." Mark holds a B.S. and M.S. degrees in Chemistry from Trinity University and the University of Wisconsin.

Joe Albanese is Owner and Managing Director of Albanese Consulting LLC, which he formed after more than 29 years' experience in the pharmaceutical industry. He recently retired from Janssen Pharmaceuticals (part of Johnson and Johnson) where he held positions in R&D, Supply Chain and Quality in both Small Molecule and Biotherapeutics development and manufacturing. As part of his duties, Joe was responsible for the compendial vigilance process for all Janssen products ensuring compliance with all major global and national pharmacopoeias. He actively served in industry working groups such as the PhRMA Limited Duration Key Issues Team for compendial issues with USP, the EFPIA Biotherapeutics subteam for the elaboration of biotherapeutic compendial standards and was a member of the USP General Notices Project Team. He is currently active in the industry trade organizations NJPQCA, Midwest Compendial Discussion group and PDA that influence global health and compendial authorities. Joe received a B.S. degree in Chemistry from Elizabethtown (PA) College and a Ph.D. degree in Chemistry from the University of Delaware.

Mark and Joe co-authored a comprehensive series of twelve articles on pharmacopoeia compliance that have been published as on-line regulatory sourcebooks for the journals Pharmaceutical Technology and BioPharm International, which serve as the foundation for this Free Webinar.

note

Additional detailed training is available for all of the topics listed above as well as the topics described below:

- Monograph Development: Why, When and How to Participate
- Pharmacopoeia Trends: Continuing Evolution and Future Directions
- Pharmacopoeia Compliance: Case Studies

If your company could benefit from more in-depth and targeted training and consultation – across all functional areas and at all levels - contact us for more information 732.613.4500