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COURSE ID 2795

Excipients: Compliance with Compendial and GMP Requirements

DIRECTED BY

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12 Hours

ACCREDITED COURSE

- Application of major pharmacopoeias to excipients; US (USP-NF), Europe (Ph. Eur.), Japan (JP, JPE, JPC, JSFA)
- Compendial revision and harmonization
- Complying with the pharmacopoeias of Brazil, Russia, India, China, Korea
- Meeting regulatory requirements of major global
- Markets; U.S., European Union, India, China
- Focus on compliance
- Excipient Good Manufacturing Practice standards
- Supplier qualification

about the course

Excipients are crucial in the manufacturing and formulation of bio/pharmaceuticals, enabling medicines to be delivered to patients in need. Compliance with appropriate quality and regulatory requirements is essential for companies that manufacture, distribute, and use excipients. The United States Pharmacopeia-National Formulary (USP-NF) requires that official substances be prepared according to recognized principles of good manufacturing practice and from ingredients complying with specifications to ensure that the resulting substances meet the requirements of the compendial monographs. However, there is often less understanding by excipient manufacturers related to confirming that the excipient meets the pharmacopeia monograph.

To address this issue, the International Pharmaceutical Excipients Council (IPEC) and Cobblestone have developed a comprehensive 12-hour accredited course. The training includes an introduction to pharmacopeias, with an emphasis on the USP-NF and Ph. Eur., and a global perspective that touches on other pharmacopeias. The course covers the content, organization, and use of the pharmacopeias, as well as regulatory considerations for excipients. It reviews practical examples of compliance with compendial requirements and explores the development and revision processes for compendial monographs with real-life case studies.

Co-sponsored by IPEC-Americas and Cobblestone; partners in training and education (T&E).

For information on pricing, terms/conditions, Team Training, and other courses, please visit **www.TrainwithCobblestone.com**

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The course also examines efforts toward compendial harmonization by IPEC, the Pharmacopeial Discussion Group (PDG), and the International Council for Harmonisation (ICH). Finally, the course explores approaches to compendial surveillance, opportunities for advocacy, and compliance with the requirements in pharmacopeias.

This course will assist the global bio/pharmaceutical industry, including innovator, generic, biotechnology, contract manufacturer, and consumer-care companies, in seeking a greater understanding of compliance requirements for excipient suppliers, particularly with the USP-NF and Ph. Eur.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

This course is intended for those responsible for ensuring compliance of excipients with the pharmacopeias and regulatory authorities and applies to pharmaceutical and excipient manufacturers and excipient distributors within the OTC, generic, innovator, biotechnology, consumer-care, and related industries. This course will benefit individuals in:

- Compendial Affairs
- Analytical Chemistry
- Product Development
- Quality Assurance/Quality Control
- Regulatory Affairs/CMC
- R&D
- Formulation/Method Development
- Product Management/Marketing

learning objectives

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

- Describe the content, organization, and revision process of the major pharmacopeias, including USP-NF, Europe (Ph.Eur.), Japan (JP), India (IP), and China (ChP)
- Identify the GMP quality system and compendial requirements for the manufacture of excipients
- Describe the regulatory expectations for approval of pharmaceutical excipient suppliers and the approval of incoming excipients
- Describe the role of pharmacopeias in the global bio/pharmaceutical and excipient industries
- Describe the processes for compendial surveillance and take advantage of opportunities for influencing monograph and other compliance requirements Identify the customer and regulatory expectations for non-monograph excipients

IPEC is the industry association that develops, implements, and promotes the global use of appropriate quality, safety, and functionality standards for pharmaceutical excipients and excipient delivery systems. IPEC-Americas, along with our counterparts around the world, serves as the primary international resource on excipients for its members, governments, and public audiences.

course outline

Review of Learning Objectives

Part 1: Introduction
- Introductions and review of learning objectives
- Course expectations
- Overview of course content
- Introduction to compendial and GMP requirements

Overview of USP-NF, Ph. Eur.
- Introduction / History
- General Notices
- General Chapters
- Monographs: USP vs. NF
- Europe: Ph. Eur.
- Case Study
- Other Pharmacopoeias
- Japan: JP, JPE, JPC, JSFA
- Other pharmacopoeias
  - Brazil, Russia, India, China, Korea
- Case Study
  - FCC

Part 2: Specific Compendial Requirements
- Residual Solvents <467>
- Elemental Impurities <232>, <233> / Heavy Metals <231>
- Method Transfer <1224>, Validation <1225>, Verification <1226>
- Supporting Documentation

Part 3: Regulatory Requirements/Compliance Expectations
Regulatory
- U.S. FDA
- EMA
- India
- China
- Latin America

Compliance
- Overview of excipient manufacture
- Role of the distributor
- Bio/Pharmaceutical Manufacturers
- Specifications for non-compendial excipients
- Case Study
- Multi-compendial requirements

Part 4: Quality Partnership
- Supplier Qualification
- Manufacturer audit
- Distributor audit
- Change Control and notification of significant change
- Pharmaceutical company Incoming Inspection and QC Approval
- Overview of IPEC guidelines Compendial Revision and Harmonization
- Revision process for new or revised monographs
- New / Revised General Chapters
- Harmonization: Pharmacopoeial Discussion Group (PDG)
- Harmonization ICH Q3C/Q3D and Q4/Q4A/Q4B
- Case Study

Focus on Compliance

- Compliance for Excipient Manufacturers and Suppliers
- Compliance for Bio/Pharmaceutical Manufacturers
- Setting up a compendial review process
- Putting it all Together
- Influence, Advocacy, IPEC

Question and Answer Session

Assessment Opportunity

co-course instructors

Irwin Silverstein has been a consultant to the pharmaceutical industry since 2000. His career included 17 years as the head of corporate quality for ISP, a specialty chemical manufacturer that produced excipients and Active Pharmaceutical Ingredients. Since leaving ISP, he has worked as a consultant and was the Chief Operating Officer of International Pharmaceutical Excipients Auditing (IPEA) from its incorporation until its sale in 2014. During this time, IPEA was accredited by ANSI for their Excipient GMP Conformance Certification Program. He has been a subcontractor to a consulting firm hired as an expert consultant by pharmaceutical firms in a consent decree with the FDA. Currently, he has continued to work with the International Pharmaceutical Excipients Council of the Americas (IPEC) since its founding in 1991 and has been involved in the development of excipient GMPs and related guidelines. He is on the NSF Standards Writing Committee that developed the NSF/IPEC/ANSI 363 Good Manufacturing Practices for Pharmaceutical Excipients ANSI standard. He is also the chair of the IPEC Learning Lab with responsibility for the development of synchronous and asynchronous learning including workshops, webinars, and eLearning.

Joe Albanese, Owner and Managing Director of Albanese Consulting LLC, which he formed after more than 29 years of 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, he 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 which influence global health and compendial authorities. He recently co-authored a comprehensive 12-part series of articles, with J. Mark Wiggins, on compendial compliance that were published in Pharmaceutical Technology and BioPharm International.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), www.iacet.org. In obtaining this approval, Cobblestone has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. Cobblestone is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in Cobblestone'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. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 12 contact hours, or 1.2 CEUs.

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.