who should attend

This accredited, 4-hour training course will be valuable to pharmaceutical companies and excipient makers/distributors – regulatory affairs professionals and other interested parties who want to know more about the similarities and differences between Active Pharmaceutical Ingredients (APIs) and excipients in regions outside the US. Although there are no prerequisites, participants should possess a general basic knowledge of pharmaceutical ingredients and industry terminology.

learning objectives

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

• Locate and identify resources (regulatory agencies, laws, regulations, guidance, etc.) within each region/country* to define what is needed
• Describe the process of determining what applies to API, and excipients for each region / country
• Describe the process of applying learnings above to your business/company
• Describe the process of addressing questions / challenges to regulations in a region / country

* Regions/countries discussed include Argentina, Brazil, Canada, China, the EU, India, Japan, Korea, Mexico, and Taiwan

course description

Regulations for Active Pharmaceutical Ingredients (APIs) and Excipient ingredients in drug products in some parts of the world are often not well known or can be confusing. Some countries do not differentiate the ingredients from the drug product (DP), others may have regulations specific to them.

This 4 hour, accredited webinar delivered over 2 days at 2 hours per day, will provide an overview of regulatory requirements and processes, and in some cases, the challenges they bring, for excipients and APIs in regions outside the US such as Canada, the EU, China, India, Japan, Latin America (Brazil, Argentina, Mexico), Korea and Taiwan.
Richard G. Einig, Ph.D., RAC, CQA; Pharmaceutical Quality Assurance Consultant; CfPA

Richard G. Einig is a consultant specializing in the pharmaceutical and veterinary medicine industries. His experience spans over twenty years in senior management of quality, regulatory, and development units of large international companies and start-up “biotechs”. He has worked internationally with innovator and generic dosage form companies, medical device manufacturers and research organizations. Dr. Einig participated in developing the PhRMA Bulk Pharmaceutical Committee’s Guidance on Production of Drug Substance, and is an invited speaker at domestic and international meetings on quality and processing of pharmaceutical products. Dr. Einig is a member of the American Chemical Society as well as a member and carries certifications from the American Society for Quality, the Regulatory Affairs Professional Society, and the Institute for Independent Business. He received undergraduate and graduate degrees in Chemistry from St. Louis University, MBA from Webster University, and Ph.D. from Missouri University.

Priscilla Zawislak; Global Regulatory Affairs Advocacy Manager; The Dow Chemical Company

Ms. Zawislak has over 30 years’ experience in Regulatory Affairs and Quality functions. Currently with The Dow Chemical Company, Ms. Zawislak is the Global Regulatory Affairs Advocacy Manager for Dow’s Food, Pharma and Medical Solutions business. Ms. Zawislak is the current Chair of IPEC-Americas and has been an active member of IPEC Americas committees since 2001 and is a member of the IPEC Americas Executive Committee. She is also the Vice-President of the IPEC Federation, a global organization consisting of regional IPECs in the US, Europe, Japan, China and India. Ms. Zawislak has also participated for over 10 years in the International Food Additives Council and OFCA, a trade association for cellulose derivatives. Ms. Zawislak earned her Bachelor degrees in Biological Sciences and Chemistry from the University of Delaware.

how to register

Tuition: $530 for 2 days, 2 hours each day.

To Register: Go to: http://ipecamericas.org. Click on Excipient Learning Lab—Webinars— APIs & Excipients – A Global Regulatory Overview

accreditations/recertifications for this course

The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 11130 Sunrise Valley Drive, Suite 350, Reston, VA 20190. 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. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

who we are—CfPA “Celebrating 50 Years”

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 350 short courses in 13 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

Virtual Attendee: Ideal for those who need the training but cannot attend in person. For more information visit: www.cfpa.com/virtualattendee

Virtual Recorded: Watch the recorded version of the Live In Person course. For more information visit: www.cfpa.com/virtualattendee

IPEC

IPEC is the industry association that develops, implements, and promotes 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.

courses of interest

Excipient GMP Compliance Workshop for Auditors and Auditees (IPEC workshop) | October 17-19, 2017 (see IPEC website for details)

CfPA Courses:

•  Best Practices for Manufacturing Active Pharmaceutical Ingredients course ID# 2742

•  CGMPs for Pharmaceutical Life Cycle Management course ID# 2474

•  FDA Drug Approval, Regulation and Compliance course ID# 587

•  Pharmaceutical Process Development course ID# 1358

•  Pharmaceutical Technology Transfer and Post-Approval Changes course ID# 2671

•  Pharmacopoeias: A Global Perspective for Compendial Compliance course ID# 2728

•  Quality Management and Compliance in the Pharmaceutical and Related Industries course ID# 224

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