Understanding Pharmacopoeias

Overview

This one-day training course provides a basic understanding of the various pharmacopoeias governing the international pharmaceutical industry. It will familiarize participants and provides a basic understanding of the how the United States, European, Japanese and Chinese Pharmacopoeia work and how to interpret their monographs. The course will also help attendees to understand the importance of ensuring compliance with pharmacopoeial requirements. The information provided is widely applicable to the global biotechnology and pharmaceutical industry that includes innovator, generic and over the counter healthcare manufacturers.

Who Should Attend

- QC Manager
- Laboratory supervisors
- QA Manager
- Validation/Qualification personnel
- Process Developers
- Regulatory Affairs
- R&D personnel

Learning Objectives

The participants

- Have understood concept of different pharmacopoeias
- Have understood differences, purpose and relationship of Monographs, General Notices, General Chapters and General Information
- Have understood the concept of reference standards and how to use them
- Apply lifecycle management for reference standards
- Introduce/improve compendial compliance program

Faculty

Janeen Skutnik-Wilkinson, *Senior Manager Quality/cGXP and Pharmacopoeial Affairs, Biogen*

Janeen has been in the pharmaceutical industry for nearly 20 years, with most of these positions being in a technical or regulatory support role. She has been very active on a number of pharmaceutical standards committees, chairing the IPEC for many years. Janeen's current role is with Biogen in the US as Senior Manager Quality/cGXP Intelligence and Pharmacopoeial Affairs, where she uses her vast knowledge of the regulatory world and its processes to guide and advise on quality aspects of new and proposed pharmaceutical legislation.

Faculty

Susan Schniepp, *Regulatory Compliance Associates*

Susan has over 38 years' experience in Quality Assurance. She has served on the PDA Board of Directors, as the PDA / FDA Joint Regulatory Affairs Conference Chair, conference presenter, and Chair of the PDA's Regulatory Affairs / Quality Advisory Board. Sue co-edited and contributed to the book Pharmaceutical Outsourcing: Quality Management and Project Delivery. Since 2007, Sue has served as a columnist and member of the editorial advisory board for Pharmaceutical Technology Magazine. She was also Chair of a USP Monograph Development Expert Committee from 2005-2010.

Wednesday, 15 May 2019	9:00 – 17:00
09:00	**Welcome and Introduction** • Gathering expectations of participants

09:30	**Introduction into Ph. Eur., USP, JP and ChP**
	• Purpose
	• Legal recognition and applicability
	• Relationship to
	  • Marketed medicines
	  • Drug development
	  • Drug submission
	  • National and international inspections
	  • Expected impact of EU-US Mutual Recognition Agreement
	• Highlight key differences of Ph. Eur., USP and JP to other important global pharmacopeias (CP, India, Brazil)
	  • Public notice
	  • Commenting processes
	• Situation of BP after Brexit

10:30	**Coffee Break**

11:00	**How to Use Pharmacopoeias**
	• Structure and text hierarchy
	  • General Notices
	  • General Chapters
	  • General monographs
	  • Drug product and substance monographs
	• How to use and apply pharmacopoeias
	• Required versus informational text
	• Highlight key differences in product scope
	  • CP: containing TCM
	  • USP: containing dietary supplements

11:45	**Interactive Exercise 1**
12:15	**Lunch Break**

13:15	**Substances and Raw Materials**
	• Discuss for Ph. Eur., USP and JP about
	  • Organic impurities
	  • Excipients
	• Brief introduction into CEPs of Ph. Eur.

14:00	**Reference Standards** • Overview into the available compendial reference standards • Proper use of compendial reference standards • Brief introduction into manufacturing and characterization of secondary reference standards • Lifecycle aspect of reference standard
14:45	**Interactive Exercise 2**
15:30	**Coffee Break**
15:45	**Multiple Choice Test for Attendees**
16:15	**Discussion of Questionnaire and Presentation of Correct Answers**
16:45	**Wrap-up**
17:00	**End of Training Course**