

Project “USP General Chapters – Packaging & Distribution Expert Committee in the University”

Braga, G.K.¹; Hunt, D.G.²

¹ Glauca Karime Braga, PhD – USP General Chapters Packaging & Distribution Expert Committee

² Desmond G. Hunt, PhD – USP Sr Scientific Liaison

Introduction and Goals

As drug products are manufactured, stored and administered, these drug products come into direct contact with packaging systems and their plastic materials of construction. Because such contact may result in an interaction between the product and its packaging system, it is important that both the drug product and the packaging materials are not adversely affected by such interactions. The use of well-characterized plastic materials of construction in components, containers and packaging systems and the appropriate testing of packaging systems help to determine if such adverse interactions are taking place and whether the packaging material of choice is suitable for its intended use.

Another point is that proper storage and transportation of final drug products are critical activities in an integrated supply chain. With the globalization of the pharmaceutical industry, various individuals and organizations from locations around the world can come into contact with the finished drug product. The storage and transportation processes for a drug product may involve a complex movement with differences in documentation, handling requirements and communication between the various entities within the supply chain. To maintain the original quality of a drug product, every party involved in the storage and transportation of a finished product should have an in-depth understanding of the storage and transportation risks and to have in place the appropriate mitigation strategies to control these risks.

These are the working areas of USP General Chapters Packaging & Distribution Expert Committee that USP would like to present to you in a seminar. Our goals are providing you an overview on USP, how to use the compendium and how that chapters within our scope can help you while in University and after, at work and, ultimately, invite you to participate contributing to Pharmacopeial Forum.

During this seminar you will hear:

- An overview of US Pharmacopeia/National Formulary covering origin, purpose and structure of compendium: General Chapters, General Notices, Monographs, etc...;
- How General Chapters and monographs are created, reviewed and approved. The role of Expert Committees;
- USP General Chapters Packaging & Distribution Expert Committee: structure and activities; General Chapters sponsored by this EC, the rationale for coverage (Packaging and Distribution) and the stakeholders.
- How the General Chapters sponsored by the Packaging & Distribution EC can help your research at University and at work
- Pharmacopeial Forum: how you can contribute
- Questions & Answers about USP

Duration: 1 to 2 hours