



Suitability and Compatibility for Packaging and Delivery Systems: Extractables and Leachables

December 9–10, 2013 • USP Headquarters, Meetings Center • Rockville, MD

Co-sponsored by the U.S. Pharmacopeial Convention (USP) and the Product Quality Research Institute (PQRI)



Plastic packaging systems for pharmaceutical products should adequately protect the product, be compatible with the product and be composed of materials that are safe for use. From a chemical perspective, ingredients from a pharmaceutical product should not be absorbed onto the surface or into the body of the plastic packaging system. Furthermore, the packaging system should not release substances that can accumulate in the pharmaceutical product in quantities sufficient to affect its stability or to present a risk of toxicity.

To this end, the U.S. Pharmacopeial Convention (USP) is proposing the revision and development of a suite of plastic packaging system standards that will be published in *Pharmacopeial Forum* 39 (5) (September 2013). The PQRI Extractables and Leachables Working Group is also working to develop guidelines, specifically for packaging systems used for parenterals and ophthalmic drug products. The purpose of this workshop is to bring stakeholders together to discuss and collect feedback on the new standards and recommendations by both organizations.

Topics Include

- *USP General Chapter <661> Plastic Packaging Systems and Their Materials of Construction*
 - <661.1> *Plastic Materials of Construction*
 - <661.2> *Plastic Packaging Systems for Pharmaceutical Use*
- <1663> *Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems*
- <1664> *Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems*
 - <1664.1> *Orally Inhaled and Nasal Drug Products*
- PQRI safety thresholds and best practices for extractables and leachables in parenterals and ophthalmic drug products

Who Should Participate

Professionals working in or with pharmaceutical packaging and delivery systems, including:

- Research and development
- Contract research organizations
- Contract manufacturing organizations
- Regulatory affairs
- Quality assurance/quality control

REGISTRATION AND ADDITIONAL INFORMATION

Early registration and group discounts are available. Visit <http://uspgo.to/extractables-leachables>, email conferences@usp.org, or call +1-301-816-8136.