Pharmaceutical Packaging: Moisture Permeation and Integrity Testing

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Co-sponsored by the Product Quality Research Institute (PQRI) and USP

Package integrity is necessary to maintain a drug product's quality throughout its shelf life. Thus, packaging systems must demonstrate satisfactory container-closure integrity. Package moisture permeation is a critical quality attribute for solid oral dosage forms, with moisture uptake being a common cause for product package failures. Current permeation methods in *USP–NF* General Chapter ‹671› Containers—Performance Testing establish equivalence for packaging (cap/bottle and blister packs) based on the *USP–NF* standards of well-closed or tight containers. Chapter ‹671› is being revised to include a new permeation method for pharmaceutical manufacturers.

This workshop will provide a platform for stakeholders to discuss proposed revisions to *USP–NF* permeation and leak standards and to future chapters.

Topics Include

- USP activities regarding the revision to current Chapter ‹671›
- New permeation tests for pharmaceutical manufacturers
- Current permeation test classification (well-closed or tight container) and future classification expansion
- Moisture permeation testing for high barrier vs. low barrier materials
- Desiccant choice and amount

Who Should Participate

Stakeholders (industry, regulators, and associations) interested in furthering the science of maintaining packaging integrity for solid oral dosage forms, including professionals working in or with:

- Research and development
- Contract research organizations
- Contract manufacturing organizations
- Contract packagers and repackagers
- Packaging component manufacturing
- Packaging component suppliers
- Regulatory affairs
- Quality assurance/quality control

REGISTRATION AND ADDITIONAL INFORMATION

Early bird and group discounts are available. Visit http://uspgo.to/pharma-packaging-workshop, email conferences@usp.org, or call +1-301-816-8136.