

<1382> Assessment of Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems

Type of Posting: General Chapter Prospectus

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Expert Committee: General Chapters—Packaging and Storage

Input Deadline: January 30, 2017

Suggested audience: Drug product manufacturers using elastomeric component with a packaging system

Estimated proposal Pharmacopeial Forum: *PF* 43(3) [May–Jun. 2017]

Description of scope and application: This chapter contains information and guidance to assist in the functionality assessment of elastomeric closures as part of packaging/delivery systems intended for injectable dosage forms outlined in *Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems <382>*. Such closures include primary packaging components partially or completely made of elastomeric material. Proper selection and design of functionality assessment studies is based on sound and justifiable scientific principles that are consistent with 1) the nature of the packaging system and packaged drug product; 2) the clinical use of the packaged drug product; and 3) the perceived safety risk associated with the packaging system and drug product. Alternative testing strategies for functionality assessment may be appropriate in justified circumstances.

Anticipated proposed design phase activities (stimuli article, workshop, etc.): To initiate an open dialog with stakeholders regarding this revision, the Expert Committee will host a Workshop at USP Headquarters in Rockville, MD on June 19-20, 2017. The input received during this Workshop will provide input to the revision of the General Chapter.

Anticipated implementation timing (routine, extended, etc.): To be determined.

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