<87> Biological Reactivity, In Vitro, <88> Biological Reactivity, In Vivo, and <1031> The Biocompatibility of Materials used in Drug Containers, Medical Devices and Implants

Type of Posting: General Chapter Prospectus

Posting Date: 30–Dec–2016

Expert Committee: General Chapters—Biological Analysis

Input Deadline: January 30, 2017

Suggested Audience: Suppliers and users of elastomeric and plastic materials and components used in medical devices and packaging systems (primary packaging components) for drug product.

Estimated proposal Pharmacopeial Forum: *PF* 43(5) [Sep.–Oct. 2017]

Background and Objectives: The purpose of the revision will be to modernize the family of USP General Chapters dealing with biocompatibility of materials used in packaging systems, medical devices and implants (<87> Biological Reactivity, In Vitro, <88> Biological Reactivity, In Vivo and <1031> The Biocompatibility of Materials used in Drug Containers, Medical Devices and Implants). The General Chapters will provide baseline biocompatibility requirements for selection of elastomeric and plastic materials and components used for medical devices and packaging components, along with information on best practices for biocompatibility testing.

Description of scope and application: Biocompatibility testing of elastomeric and plastic materials and components used for medical devices and packaging components.

Anticipated proposed design phase activities: To initiate an open dialog with stakeholders regarding this revision, the Expert Committee held a Workshop at USP Headquarters in Rockville, MD on June 20-21, 2016. The input received during this Workshop will be used to develop the initial

revision draft of these General Chapters.

Anticipated implementation timing: To be determined

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