IPAC-RS Comments on Pharmacopoeial Forum 49(2) ***Chapter <87> Biological Reactivity Tests, In Vitro*** **and** ***Chapter <88> Biological Reactivity Tests, In Vivo***

General Comments

1. In relationship with USP 1031, please clarify if there is no need to perform chemical characterization and toxicological assessment for elastomeric materials when USP 87 fails? Directly perform USP 88 ?
2. We welcome the update captured in Section 1 Scope of <87> and <88> to make them out of scope for combination products where the packaging or delivery system is considered a device-constituent part and to instead refer to device-specific FDA Guidance for Industry: International Organization for Standardization. ISO 10993-1, Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process. Guidance for Industry and Food and Drug Administration Staff. September 2020

Specific Comments:

Page, Line or Section of the Document	Original Language	Proposed Changed Language or Comment	Justification of Proposed Change or Comment
None at this time			