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Formalized Risk Assessment for Excipients

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Foreword

Joint Initiative between IPEC Federation and PDA

In March 2018, the IPEC Federation and PDA announced their first joint initiative. Both associations signed a memorandum of understanding to collaborate on the development of a joint technical report on excipient good manufacturing practices risk assessment in response to input from their respective memberships. Prior to the collaboration announcement, however, both parties were active on the topic of quality risk management. PDA published the *PDA Technical Report No. 54* series. In March 2016, IPEC Europe published the *How-To Document – A Guide to Support Manufacturing Authorization Holders (MAH) in their Compliance with the European Commission Guidelines on Risk Assessment for Excipients (2015/C 95/02)*. Subsequently, in May 2017, IPEC-Americas and IPEC Europe jointly published the *Risk Assessment Guide for Excipient Makers, Users, and Distributors*.

Both PDA and IPEC Federation believe that presenting a common approach to the legal, regulatory, and related issues concerning excipients is best done as "one voice." Both collaborators see significant potential benefit in leveraging the two organizations' expertise on excipients and drug product manufacture. This technical report will serve as a practical guidance intended for use with existing regulatory and industry standards. The authors expect that the document will enable Manufacturing Authorization Holders of drug product to either set up or benchmark their quality systems, and further establish or continue to collaborate with parties in their excipient supply chain.

This joint PDA-IPEC technical report extends the *PDA Technical Report No. 54* series and provides guidance on risk assessments for excipients by presenting a model risk assessment, guidance on key elements, and a collection of actual examples from excipient users in the pharmaceutical industry.

About Parenteral Drug Association (PDA)

The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance manufacturing science and regulation. Through the expertise of more than 10,000 members worldwide, PDA promotes the exchange of rapidly evolving information on science, technology, and regulations concerning high-quality pharmaceutical production to better serve patients.

About IPEC Federation

The IPEC Federation (IPEC) is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents five regional International Pharmaceutical Excipient Councils (IPECs) — IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China, and IPEC India — and provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. IPEC's objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace, and the development of good manufacturing and good distribution practices for excipients.

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