



PRESS RELEASE

PDA and IPEC Federation Publish Technical Report No. 54-6 Formalized Risk Assessment for Excipients

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The Parenteral Drug Association (PDA) and the International Pharmaceutical Excipients Council Federation (IPEC) as an outcome of its collaboration established in March 2018, today announce the joint publication of a **Technical Report for Formalized Risk Assessment for Excipients**.

To comply with the European Commission Guidelines and PIC/S publication, excipients used in a drug product must be assessed for the risks that they pose to the drug product's quality, safety, and purity. This requires drug manufacturers to ensure appropriate levels of GMP for excipients by using formalized risk assessments.

This joint PDA-IPEC Technical Report extends the PDA Technical Report No. 54 series on Quality Risk Management.

Highlights include:

- a model for quality risk assessment for excipients
- guidance on key GMP elements required for an excipient considering its source, supply chain and subsequent use
- a collection of actual examples from excipient users in the pharmaceutical industry

The Risk Assessment Technical Report is available:

1. To **members** of IPEC sister associations ([IPEC-Americas](#), [IPEC Europe](#), [IPEC Japan](#), [IPEC China](#) and [IPEC India](#)) via their respective members' areas and to members of PDA via its website www.pda.org/.
2. To purchase at www.pda.org/bookstore.

About IPEC Federation

Created in 2010, the IPEC Federation is a global organisation that promotes quality in pharmaceutical excipients. The IPEC Federation represents the five existing regional International Pharmaceutical Excipient Councils (IPECs) – IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India. It provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. Its global membership extends to more than 200 companies.

IPEC Federation asbl

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