



Press Release

Brussels (Belgium), 28 February 2023

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the updated IPEC Significant Change Guide for Pharmaceutical Excipients (Version 5, 2023). The guide was originally published in 2000 as an IPEC-Americas guide with revisions in 2005 and 2009. It was then published as an IPEC Federation Guide in 2014. This guide is widely used globally.

The primary objective of the guide is to provide a consistent approach to evaluate the significance of changes involving the manufacture and distribution of excipients. The purpose of the evaluation is to consider the potential impact of the change on the excipient in order to determine whether pharmaceutical manufacturers (excipient users) and/or regulatory authorities should be notified. It is recommended that excipient suppliers and users refer to this guide as the basis for notification requirements in quality agreements, supply agreements, technical agreements, and regulatory filings.

The content in the 2023 revision, while largely unchanged, is now better aligned with IPEC's general guideline policies and format requirements:

- Harmonised terminology/general statements
- Relocated content to more relevant section(s)
- Reconstructed decision trees and incorporated them into the body of the guide.

Throughout the guide efforts were made to remove redundancies and to update references to include more current regulations and guides/guidelines.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](#) and national/regional members' websites. Thereafter, the guide will be made available to the general public.

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