The International Pharmaceutical Excipients Council

Risk Assessment Guide

for Pharmaceutical Excipients

Risk Assessment for Excipient Manufacturers

Version 1
2025

This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this guide may be used to achieve an equivalent level of assurance for excipient quality.

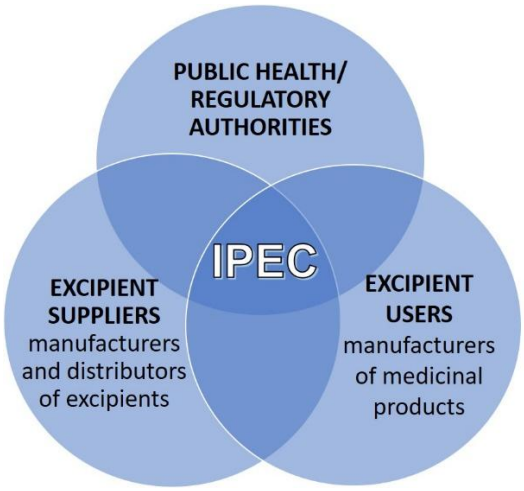
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient **manufacture**rs, distributors, and end-users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major stakeholder groups:

1. Excipient manufacturers and distributors, defined as suppliers in this document,
2. Medicinal (drug) product manufacturers, defined as *excipient users* in this document, and
3. Public health and regulatory authorities.



This guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the laws and regulations applying to excipients will vary

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

from region to region and country to country. In addition, the rules and regulations are continually evolving. It is the responsibility of the reader to review the most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

In this guide, pharmaceutical excipient(s) will be referred to as excipient(s). This guide may be applied to veterinary medicines, as appropriate and include reference to specific veterinary guidance and regulations.

Throughout the guide, **justification** implies that a decision is made based on scientific, quality and/or regulatory considerations.

This document offers best practice and guidance in **risk assessment** related to excipients covering the principles of quality **risk management**, including risk assessment methodologies and providing an overview of methods in the ICH Q9 **guideline**. It includes areas where risk assessment may be used by the excipient manufacturer in the lifecycle of excipient.

This document is a revised version of The IPEC Risk Assessment Guide for Pharmaceutical Excipients, first published in 2017 by IPEC-Americas and IPEC Europe.

NOTE: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms" for definitions [1]. The first use of a term found in the glossary will be in ***BOLD.***

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

Table of Contents (TOC)

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

ACKNOWLEDGEMENTS

This guide was developed by representatives of the associations which constitute the IPEC Federation (IPEC). The IPEC Federation greatly appreciates the many hours devoted by the core team of individuals and other contributors listed below, to make this guide available to IPEC members and the broader excipient community. Equally, IPEC extends its thanks to the employers of those same contributors who provided the necessary time and resources, without which this guide would not be possible.

List of Contributors from IPEC-Americas

Dale Carter, Evonik
George Collins, Vanderbilt Minerals, LLC
Christian Moreton, FinnBrit Consulting
Meera Raghuram, Lubrizol Advanced Materials, Inc.
Lucien Sergile, Eli Lilly
Paul Smutz, Henkel Corporation
Erika Vergara, Dow
Priscilla Zawislak, IFF

List of Contributors from IPEC China

Shine Gao, Ingredion
Elly Song, Dow
Cissy Wang, Ashland

List of Contributors from IPEC Europe

Luc Brans, Ashland
Karl Kuma, AstraZeneca
Philippe Lienart, Roquette Frères
Roberto Mastrantonio, Eli Lilly
Sandra Millet, Roquette Frères
Iain Moore, GMP Risk Assessment Consulting
Bev Stout, GSK
Cécile Subra, Gattefossé

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region