



The International Pharmaceutical Excipients Council

Risk Assessment Guide

for Pharmaceutical Excipients

*Risk Assessment for Excipient
Manufacturers*

Version 1
2025

Copyright © 2025 The International Pharmaceutical Excipients Council

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.

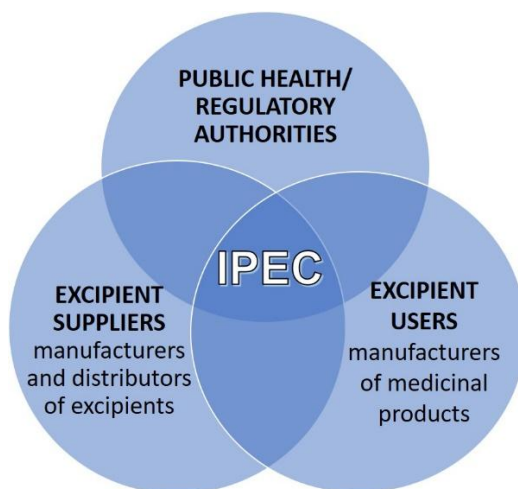
The content of this guide cannot be reproduced without the written authorisation of the IPEC Federation Management Body.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient **manufacturers**, 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

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**.*

Table of Contents (TOC)

ACKNOWLEDGEMENTS	7
1 INTRODUCTION	8
1.1 Purpose.....	8
1.2 Scope	8
1.3 Background	9
1.4 Layout	10
2 PRINCIPLES OF RISK ASSESSMENT AND MANAGEMENT	11
2.1 Phase I: Risk Assessment	11
2.2 Phase 2: Risk Control	13
2.3 Phase 3: Risk Communication	13
2.4 Phase 4: Risk Review	14
2.5 Documentation	14
3 RISK ASSESSMENT METHODS	15
4 RISK ASSESSMENT BY EXCIPIENT MANUFACTURER	15
4.1 Risk Assessment Documentation	15
4.2 Areas Requiring Risk-Based Decision Making.....	16
4.2.1 <i>Hygienic Practices</i>	17
4.2.1.1 <i>Understanding the Requirement for Risk Assessment for Hygienic Practices</i>	17
4.2.1.2 <i>Implementation of the Risk Assessment for Hygienic Practices</i>	17
4.2.1.3 <i>Documentation and Records Supporting Hygienic Practices</i>	19
4.2.2 <i>Building and Facilities</i>	19
4.2.2.1 <i>Implementation of the Risk Assessment for Building and Facilities</i>	20
4.2.2.2 <i>Documentation and Records Supporting Building and Facilities</i>	22
4.2.3 <i>Equipment Construction</i>	22
4.2.3.1 <i>Understanding the Requirement for Risk Assessment for Equipment Construction</i>	22
4.2.3.2 <i>Implementation of the Risk Assessment for Equipment Construction</i>	22
4.2.3.3 <i>Documentation and Records Supporting Equipment Construction</i>	23
4.2.4 <i>Equipment Maintenance</i>	23

4.2.4.1	<i>Understanding the Requirement for Risk Assessment for Equipment Maintenance</i>	23
4.2.4.2	<i>Implementation of the Risk Assessment for Equipment Maintenance</i>	23
4.2.4.3	<i>Documentation and Records Supporting Equipment Maintenance</i>	25
4.2.5	Utilities	25
4.2.5.1	<i>Understanding the Requirement for Risk Assessment for Utilities</i>	25
4.2.5.2	<i>Implementation of the Risk Assessment for Utilities</i>	25
4.2.5.3	<i>Documentation and Records Supporting Utilities</i>	26
4.2.6	Water	26
4.2.6.1	<i>Understanding the Requirement for Risk Assessment for Water</i>	26
4.2.6.2	<i>Implementation of the Risk Assessment for Water</i>	27
4.2.6.3	<i>Documentation and Records Supporting Water</i>	28
4.2.7	Recycled or recovered materials	28
4.2.7.1	<i>Understanding the Requirement for Risk Assessment for Recycled or recovered materials</i>	28
4.2.7.2	<i>Implementation of the Risk Assessment for Recycled or recovered materials</i>	29
4.2.8	Air Handling Systems	29
4.2.8.1	<i>Understanding the Requirement for Risk Assessment for Air Handling Systems</i>	29
4.2.8.2	<i>Implementation of the Risk Assessment for Air Handling Systems</i>	30
4.2.8.3	<i>Documentation and Records Supporting Air Handling Systems</i>	31
4.2.9	Controlled Environments	31
4.2.9.1	<i>Understanding the Requirement for Risk Assessment for Special Environments</i>	31
4.2.9.2	<i>Implementation of the Risk Assessment for Special Environments</i>	31
4.2.9.3	<i>Documentation and Records Supporting Special Environments</i>	32
4.2.10	Cleanliness and Sanitary Conditions	32
4.2.10.1	<i>Understanding the Requirement for Risk Assessment for Cleanliness and Sanitary Conditions</i>	32
4.2.10.2	<i>Implementation of the Risk Assessment for Cleanliness and Sanitary Conditions</i>	32
4.2.10.3	<i>Documentation and Records Supporting Cleanliness and Sanitary Conditions</i>	34
4.2.11	Pest Control	34
4.2.11.1	<i>Understanding the Requirement for Risk Assessment for Pest Control</i>	34
4.2.11.2	<i>Implementation of the Risk Assessment for Pest Control</i>	34
4.2.11.3	<i>Documentation and Records Supporting Pest Control</i>	36
4.2.12	Planning for excipient realization	36

4.2.12.1 Understanding the Requirement for Planning for Excipient Realization	36
4.2.13 Customer Communication.....	36
4.2.13.1 Understanding the Requirement for Risk Assessment for Customer Communication	37
4.2.13.2 Implementation of the Risk Assessment for Customer Communication	37
4.2.13.3 Documentation and Records Supporting Customer Communication.....	37
4.2.14 Control of externally provided quality critical processes, services and materials	37
4.2.14.1 Understanding the Requirement for Risk Assessment for Purchasing Process	37
4.2.14.2 Implementation of the Risk Assessment for Externally provided Processes, Services and Materials.....	38
4.2.14.3 Documentation and Records Supporting Purchasing Process	40
4.2.15 Verification of Purchased Product.....	41
4.2.15.1 Understanding the Requirement for Risk Assessment for Verification of Purchased Product	42
4.2.15.2 Implementation of the Risk Assessment for Verification of Purchased Product	42
4.2.15.3 Documentation and Records Supporting Verification of Purchased Product.....	43
4.2.16 Preservation of Product.....	43
4.2.16.1 Understanding the Requirement for Risk Assessment for Preservation of Product	44
4.2.16.2 Implementation of the Risk Assessment for Preservation of Product	44
4.2.16.3 Documentation and Records Supporting Preservation of Product.....	44
4.2.17 Excipient Packaging Systems	44
4.2.17.1 Understanding the Requirement for Risk Assessment for Excipient Packaging Systems	44
4.2.17.2 Implementation of the Risk Assessment for Excipient Packaging Systems	45
4.2.17.3 Documentation and Records Supporting Excipient Packaging Systems	45
4.2.18 Control of Monitoring and Measuring Equipment.....	45
4.2.18.1 Understanding the Requirement for Risk Assessment for Control of Monitoring and Measuring Equipment	45
4.2.18.2 Implementation of the Risk Assessment for Control of Monitoring and Measuring Equipment ..	45
4.2.18.3 Documentation and Records Supporting Control of Monitoring and Measuring Equipment ..	46
4.2.19 Reworking.....	46
4.2.19.1 Understanding the Requirement for Risk Assessment for Reworking	46
4.2.19.2 Implementation of the Risk Assessment for Reworking	46
4.2.19.3 Documentation and Records Supporting Reworking	47

5	REFERENCES	48
---	------------------	----

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