IPEC FEDERATION

The International Pharmaceutical Excipients Council

Incorporation of Pharmaceutical Excipients into Product Development using Quality-by-Design (QbD)

First Version
2020

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

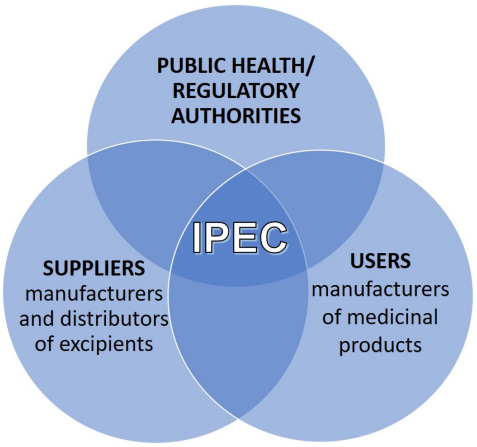
This guide was created to help companies understand current expectations on this topic and is not intended for use by third parties to conduct audits. The content of this guide cannot be reproduced without the written authorisation of the IPEC Federation Management Body.

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 international excipient standards development and harmonization, new excipient development and introduction, and best practice and guide development concerning excipients.

IPEC has three major stakeholder groups;

1. Excipient manufacturers and distributors, defined as suppliers in this document
2. Pharmaceutical manufacturers, defined as users in this document
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 rules 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 users of the Guide to determine whether there are any additional legal or regulatory requirements, in addition to the recommendation given in this Guide, applicable to a particular region or country in which they are doing business.

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 210 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

This Guide offers current best practice and voluntary guidance on the incorporation of excipients and excipient variability into Quality-by-Design (QbD) pharmaceutical finished product development programs. It is important that the reader confirms this is the latest version of the guide as found on www.ipec-federation.org or regional IPEC websites.

NOTE: Refer to the "International Pharmaceutical Excipient 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**.

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This guide was developed by the International Pharmaceutical Excipients Council members representatives. IPEC Federation, or in short the Federation, is a global organisation that promotes quality and safety in pharmaceutical excipients. The Federation consists of the five existing regional IPECs: IPEC-Americas, IPEC China, IPEC Europe, IPEC India, IPEC Japan. The representatives who worked on this Guide are listed below:

List of Contributors from IPEC-Americas

Brian Carlin, Ph.D. (Chair), DFE Pharma
David Schoneker (Vice-Chair), Black Diamond Regulatory Consulting, LLC
George Collins, Vanderbilt Chemicals LLC
Ann Gray, Evonik
David Klug, Sanofi US
Bretta Lichtenhan, MilliporeSigma
Lisa Milano, Genentech
R. Christian Moreton, FinnBrit Consulting
Meera Raghuram, Lubrizol Advanced Materials, Inc.
Jerry Schalau, DuPont
Chandra Sekhar, Chandra V. Sekhar Consulting
Heather Sturtevant, Johnson & Johnson
Katherine Ulman, KLU Consulting, LLC
Priscilla Zawislak, DuPont
Joseph Zeleznik, IMCD US

List of Contributors from IPEC Europe

Aurelia Defachelles, Roquette
Bastiaan Dickhoff, DFE Pharma
Tobias Hess, Budenheim
Carsten Huettermann, DuPont
Yasemin Koybasi, Kerry
Clara Sachwitz, BIOGRUND
Manuel Streib, Merck Group
Mike Tobyn, Bristol-Myers Squibb
Bhushan Thekedar, Clariant
Kim Verwaest, Johnson & Johnson

List of Contributors from IPEC India

Shraddha Joshi, Evonik

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