IPEC FEDERATION

The International Pharmaceutical Excipients Council

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

Version 2
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.

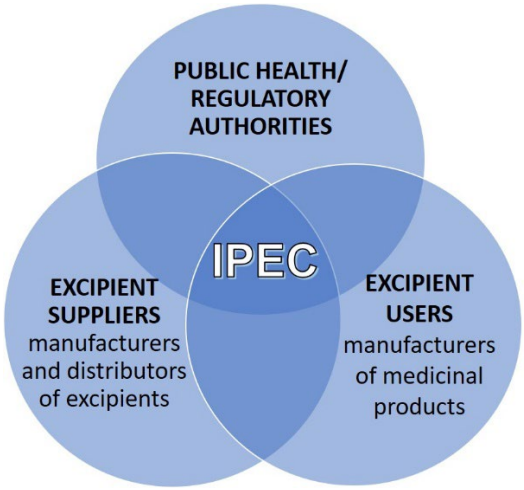
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with this guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and end-users. At the time of 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, provide useful information 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

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regulatory requirements. Versions referenced in this 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 guidances and regulations.

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

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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