



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.

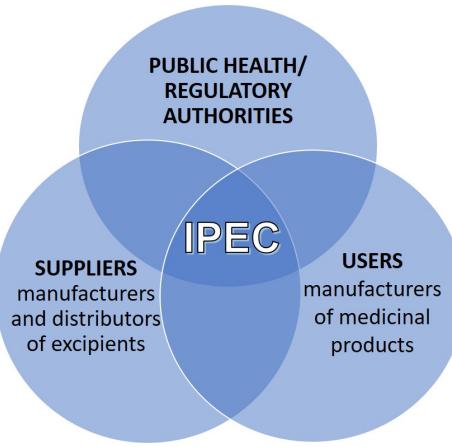
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FOREWORD

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.

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:

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