IPEC FEDERATION

The International Pharmaceutical Excipients Council

Validation Guide

For Pharmaceutical Excipients

First Version
2021

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.

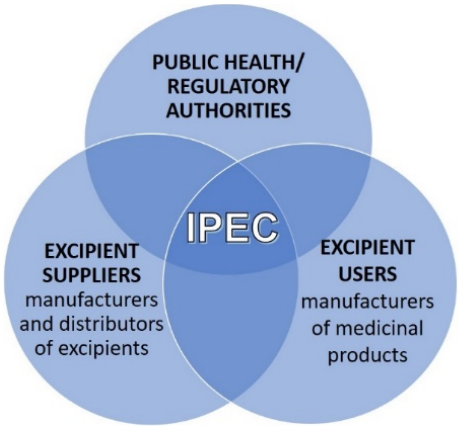
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and 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 manufacture.

IPEC has three major stakeholder groups:

1. excipient manufacturers and distributors, defined as suppliers in IPEC documents,
2. pharmaceutical manufacturers, defined as 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 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

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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 document offers best practice and guidance on the validation of excipient processes and product. It is the responsibility of, and expectation for, each company to determine/extrapolate the applicable level of validation activities necessary for their processes and/or products and to document their strategy, as appropriate, in their quality policies and procedures manual.

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**.

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