



The International Pharmaceutical Excipients Council

GMP Certification Scheme and Certification Body Qualification Guide

For Pharmaceutical Excipients

Version 2
2026

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.

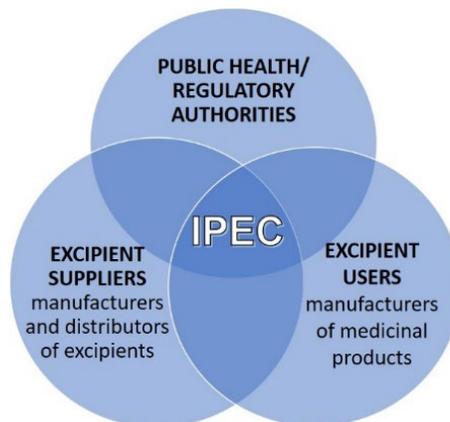
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FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and 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 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. 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 recognised 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 best practice and guidance for excipient users qualifying Certification Schemes and Certification Bodies (CBs) involved in third-party excipient GMP certification. Excipient suppliers may find the information in this guide useful in their selection of a certification body.

Throughout the Guide, GMP will be used to represent both GMP and GDP. An excipient supplier will be used to indicate an excipient manufacturer or a distributor (or both).

NOTE: Refer to the “International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms” [1] for definitions. The first use of a term found in the glossary will be in **BOLD**.

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ACKNOWLEDGEMENTS

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