



The International Pharmaceutical Excipients Council

# Qualification of Excipients for Use in Pharmaceuticals Guide & Checklist

Second Version  
2020

**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.**

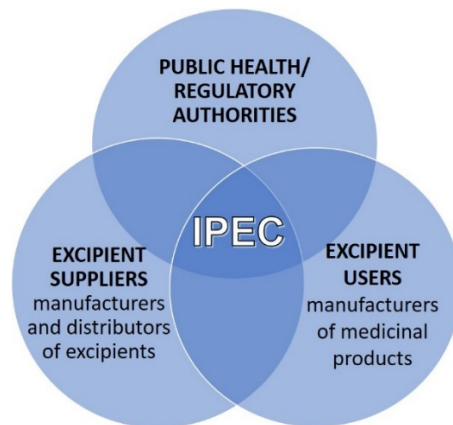
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## FOREWORD

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

IPEC has three major stakeholder groups;

1. Excipient manufacturers and distributors, defined as *excipient suppliers* in this document
2. Pharmaceutical manufacturers, defined as *excipient 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 best practice and guidance in the establishment of an effective relationship between an excipient supplier and excipient users. The excipient supplier may be an excipient manufacturer or a distributor (or both). This guide concentrates on the issues that the two parties are likely to encounter and offers advice as to how to address them, thereby ensuring a smoother relationship and easier use of the excipient by the excipient user and in their dealings with the regulatory authorities.

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

## **ACKNOWLEDGEMENTS**

This guide was developed by representatives of many International Pharmaceutical Excipients Council members. IPEC is a global industry association whose members consist of excipient manufacturers, distributors, and users, as well as experts from academia. The association representatives who worked on this guide are listed below:

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