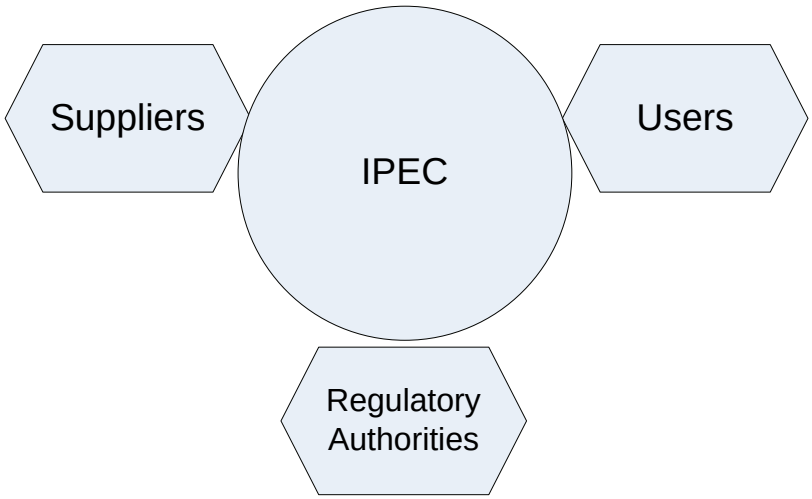
QUALIFICATION OF EXCIPIENTS FOR USE IN PHARMACEUTICALS

FOREWORD

IPEC is an international industry association formed in 1991 by manufacturers and users of excipients. It is an association comprising three regional pharmaceutical excipient industry associations covering the United States, Europe, and Japan (which are known respectively as IPEC-Americas, IPEC Europe, and JPEC). IPEC's objective is to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of best practice and guidance concerning excipients.

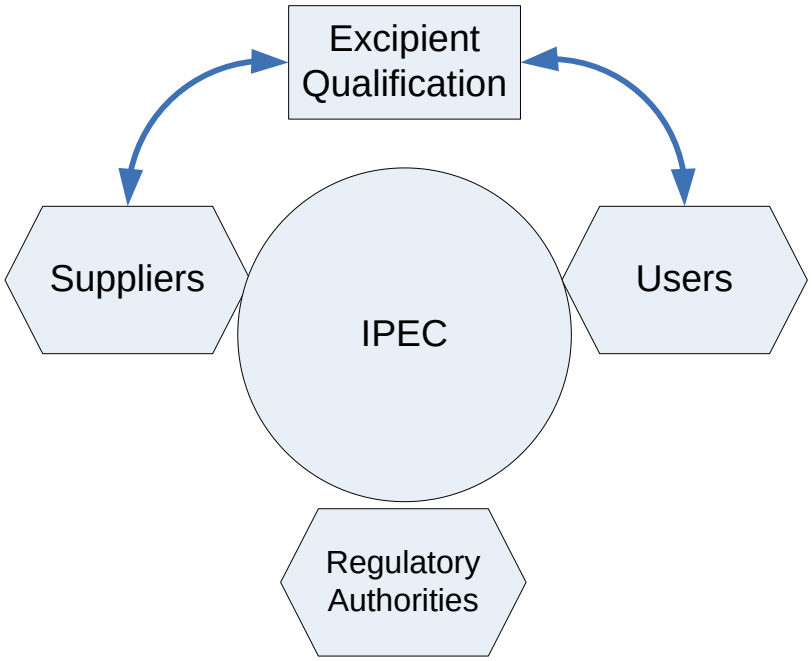
IPEC has three major stakeholder groups;

1. Excipient manufacturers and distributors, who are considered suppliers in this document,
2. Pharmaceutical manufacturers, who are called users, and
3. Regulatory authorities who regulate medicines.



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

Because excipients are diverse and often have uses other than in pharmaceutical applications, a supplier may discover that their product is being used by the pharmaceutical industry as an excipient. This document will be especially valuable in such situations because many of the issues described will be new to the supplier.



Thus any material used in the pharmaceutical drug product will be required to be manufactured under appropriate Good Manufacturing Practices (GMP) and supplied under Good Distribution Practices (GDP). The exact definition of GMP or GDP will depend on the material in question (e.g. excipient, active pharmaceutical ingredient, packaging etc) and legislation where the excipient is supplied or sold. Within this guide the terms GMP and GDP are used to encompass all of these various definitions.

Like all guides this document is not meant to be proscriptive, and suppliers and users may follow the guideline as written or find their own manner to address the subjects highlighted. The guide is intended to be comprehensive and covers the essential aspects of the supplier-user relationship. In this regard not every topic may be appropriate for all relationships.

To facilitate reading, the excipient qualification process has been presented in flow charts as a means of linking the activities and steps in a logical manner. This aids comprehension and places these steps into context.

There is no specific requirement to follow the exact sequences of actions as detailed in the flowcharts although users will find these helpful to ensure all aspects are considered.

Although excipient qualification does not directly involve the regulatory authorities, they set many of the conditions that have to be satisfied if a user is to employ an excipient in their medicine.

This document describes the three phases of the excipient qualification process. The layout and content are as follows:

Section 1	Introduction: describes the scope, purpose, and layout of this guide.
Phase 1	**The Excipient Supplier's Process**
Section 2	General Guidance: provides background concerning excipient manufacture, regulation, and controls.
Section 3	Excipient Development and Specification Process: provides guidance to excipient suppliers on the development of an excipient and its specifications.
Phase 2	**The User's Process**

Section 4	Excipient User Assessment, Selection, and Specification Process: provides guidance on how users should assess the excipients for inclusion in their formulations.
Phase 3	**The Negotiation Process**
Section 5	Excipient Supplier-User Negotiation Process: provides guidance on the development of an agreement between the excipient supplier and pharmaceutical user to define excipient quality requirements.
Glossary	Terms defined in the glossary appear in **bold** the first time they are used in this document.
Appendices	Flow diagrams that illustrate the development of a material for sale as an excipient, the approval of the use of an excipient in a dosage form, the negotiation process used to determine the appropriateness of the requirements, and the specific requirements for the excipient.

Each Phase of the process is also described by a flowchart illustrating the process:

Phase One- The Excipient supplier's Process shows the steps a chemical manufacturer may take to evaluate the market and regulatory requirements for the proposed excipient and the steps leading up to the market launch,

Phase Two- The User's Process illustrates the path a pharmaceutical company ordinarily follows in evaluating the excipient and its manufacturer for use in a formulation, and

Phase Three- The Negotiation Process shows the process by which the supplier and user interact to reach a mutual agreement on quality requirements.

As an international guidance document, the guide cannot specify all national legal requirements or cover in detail the particular characteristics of excipient qualification in all territories. Although the details in this document highlight European and United States issues, the principles can be applied to any excipient supplier – excipient user relationship worldwide.

By setting out all the stages in excipient qualification both suppliers and users will be better placed to use the tools in ICH Q9 Quality Risk Management[i] to better assess which steps in this guide are most appropriate and necessary for their particular situation.

[i] ICH Q9, *Quality Risk Management*, http://www.ich.org/LOB/media/MEDIA1957.pdf

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