

Regulatory requirements for Excipients

IPEC Europe recently publicized:

Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients.

The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients says:

Excipients are essential components of the drug product formulation and have a wide range of applications. The quality of excipients is critical to assure the safety, quality and efficacy of medicines. Characteristics that excipients impart to formulated drug products include cosmetic appearance, stability and delivery of the active ingredient. Pharmaceutical excipients are substances other than the API, which have been appropriately evaluated for safety and are intentionally included in a drug delivery system.

For example excipients can:

- aid in the processing of the drug delivery system during its manufacture,
- protect, support or enhance stability, bioavailability or patient acceptability,
- assist in product identification,
- enhance any other attribute of the overall safety, effectiveness or delivery of the drug during storage or use.

The **application of GMP is relevant** once it has been determined that a chemical is intended **for use as a component of a drug** product. Excipient manufacture should be carried out in accordance with the GMP concepts consistent with this IPEC-PQG Guide.[1]

IPEC Good Distribution Practices Guide for Pharmaceutical Excipients says:

Parties involved in the supply chain should be aware that an excipient can only be **pharmaceutical grade** when it is in compliance with **pharmacopoeial specification** and/or **appropriate regulatory requirements** (if existing for the specific excipient) and is **manufactured, repackaged, and handled in accordance with excipient GMPs** (e.g. IPEC PQG GMP, WHO Excipient GMP). Upgrading technical or industrial grade material to pharmaceutical grade quality only on the basis of analytical results found in conformance with the requirements of a pharmacopoeial monograph is an unacceptable practice [2].

Customers can be assured that excipients manufactured according to the Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical excipients 2006 will meet internationally accepted good manufacturing practice (GMP) principles.[1]

Mallinckrodt Baker is a basic manufacturer and supplier of High Purity and Performance Excipients for the manufacture of traditional synthetic and biopharmaceutical therapeutics in accordance with the above mentioned publications.

We supply acids, solvents, salts and solutions in grades suitable for the pharmaceutical, nutritional, ophthalmics (contact lens manufacturers), cosmetics, food and beverage, dental health, special batteries and other industrial markets.

For BPEs (Bulk Pharmaceutical Excipients), the company adheres to Q7A and IPEC (International Pharmaceutical Excipient Council) guidelines.



What cGMP Means on a J.T.Baker and a Mallinckrodt Label

A J.T.Baker or Mallinckrodt manufactured product that is labelled as USP, NF, FCC, or cGMP-produced is:

- Produced in an FDA-registered facility*
- Manufactured in a GMP compliant facility
- Made according to validated processes when required
- Documented via controlled procedures and records
- Change Control, 4-tiered Management of Change process for our chemical products
- Traceable from raw materials to the customer

We maintain extensive documentation, including batch production record (BPR), label accountability, stability data and QC test results.

*Registration does not denote FDA approval of a firm or product.

IPEC



IPEC is an international industry association formed in 1991 by manufacturers and end-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 harmonisation of international excipient standards, the introduction of useful new excipients to the marketplace and the development of good manufacturing practice for excipients.[1]

For further information see www.ipec.org.

PQG



The PQG was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practice. The group has since expanded, and in 1990 the PQG published three codes of practice to cover pharmaceutical raw materials, printed and contact packaging materials.[1]

For further information see www.pqg.org.

Please contact your Mallinckrodt Baker sales representative or one of our local offices to discuss your requirements.



[1] source: **The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients**, 2006
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[2] source: **IPEC Good Distribution Practices Guide for Pharmaceutical Excipients**, 2006 Copyright © The International Pharmaceutical Excipients Council.

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