

## What is International Pharmaceutical Excipients Council?



IPEC presently is a federation of four independent regional industry associations headquartered in the United States (IPEC-Americas), Belgium (IPEC Europe), Japan (IPEC Japan), and China (IPEC Association [China] Ltd.). Creation of affiliated IPEC organizations in Brazil and India is being considered.

Each association focuses its attention on the applicable law, regulations, science, and business practices within its region to accomplish its members' goals. They also cooperate on common excipient-related safety and public health issues, in connection with international trade matters, and pharmacopeial specifications. Currently about 250 national and multi-national excipient producer, distributor and user companies are members of at least one IPEC regional unit and many are members of at least two.



## Why IPEC-Americas Is Needed

Under U.S. law, a new pharmaceutical excipient, unlike an active ingredient (API), has no regulatory status unless it can be qualified through one or more of the three approval mechanisms presently available for components used in finished product dosage forms.

These are:

- GRAS determination;
- Approval of a food additive petition; and
- Through an NDA or ANDA approval.

Differences in excipient monograph specifications among the three major pharmacopeias, the EP, JP, and USP also serve to make it difficult for companies to develop and manufacture global pharmaceutical products without repetitive testing of excipients for compliance with all three pharmacopeias and national regulations.

As a result, IPEC-Americas and its affiliate associations work with global health authorities and the pharmacopeias to:

- Seek acceptance of IPEC-developed guidance as recognized industry standards in the absence of applicable national regulation;
- Promote expansion of national pharmaceutical approval systems to permit appropriate procedures for acceptance of new excipients and new uses for excipients in drug formulations;
- Harmonize compendial standards for widely used pharmaceutical excipients; and
- Establish adequate recognized mechanisms for qualifying excipients and their producers as part of the International Conference on Harmonization (ICH) process.



## Progress to Date

Since its founding in 1991, IPEC-Americas focus has been on how excipients and their uses are identified and proven;

- how they are qualified for pharmaceutical use;
- how excipients are produced and protected throughout their distribution chain; and
- the functions they can provide in a finished pharmaceutical formulation to improve its quality and performance.

This has led to IPEC development, publication, and in several instances implementation of guidance on:

- Excipient safety evaluation;
- Excipient good manufacturing practices (GMP) and GMP auditing;
- Excipient good distribution practices (GDP) and GDP auditing to determine an excipient's "pedigree" at every stage;
- The excipient qualification process for makers, suppliers and users of excipients, which includes:
  - an excipient information package, template and user guide;
  - a quality agreement guide and template;
  - guidance for reporting changes that occur during an excipient's manufacturing process;
  - an excipient's certificate of analysis (COA);
  - an excipient master file;
  - excipient composition guidance; and
  - necessary elements of an excipient stability program.

Also under development are guidance relating to equipment qualification and validation of excipient manufacturing processes, analytical methods and cleaning practices.



## How Companies Benefit Through IPEC-Americas Membership

IPEC-Americas is directed by its elected officers and operates through volunteer committees composed of member company employees from excipient producers, suppliers, and pharmaceutical product manufacturers. Where appropriate, U.S. Food and Drug Administration (FDA) and United States Pharmacopeia (USP) representatives also attend IPEC-Americas committee meetings as observers or participants. This is leading IPEC-Americas and IPEC to be more able to develop guidance that is gaining acceptance, not only within the global industry, but also among international regulators and compendial authorities. If this continues, as is planned, finished drug manufacturers will benefit from access to and use of better quality components in their pharmaceutical products worldwide, products which will have fewer manufacturing issues and fewer recalls.

This remains a key IPEC goal, which is why IPEC members are doing all they can to develop global guidance and programs that are designed to ensure continued availability of excipients and related components for finished drugs that meet only the highest appropriate standards for:

- quality;
- safety; and
- functionality

*during their manufacturing process and through the distribution supply chain until final acceptance and use.*



## International Pharmaceutical Excipients Council OF THE AMERICAS

The industry association that develops, implements, and promotes global use of appropriate quality, safety, and functionality standards for pharmaceutical excipients and excipient delivery systems



IPEC-Americas members are finished pharmaceutical manufacturers, excipient producers, distributors, and other suppliers of specialized services related to pharmaceutical use of excipients.

For more information about IPEC-Americas and to learn how your company can advance its future through membership and committee involvement, you are invited to contact:

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