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. It is through our key industry & regulatory partnerships that finished drug manufacturers can benefit from access to and use of better quality components in their pharmaceutical products worldwide with the ultimate goal of patient safety.

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.

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:

IPEC-Americas
3138 N 10th St
Suite 500
Arlington, VA 22201
Tel: 571-814-3449

Email: ipecamer@ipecamericas.org

ipecamericas.org

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

What is International Pharmaceutical Excipients Council?

IPEC presently is a federation of five independent regional industry associations headquartered in the United States (IPEC-Americas), Belgium (IPEC Europe), Japan (IPEC Japan), and China (IPEC Association [China] Ltd.) and India (IPEC India).

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 major pharmacopeias, also serve to make it difficult for companies to develop and manufacture global pharmaceutical products without repetitive testing of excipients for compliance with the pharmacopeias and national regulations.

IPEC-Americas Vision Statement:

IPEC-Americas will be the preeminent authority and resource on pharmaceutical excipients.

IPEC-Americas Mission Statement:

To promote patient safety, IPEC-Americas will support its stakeholders by using collaboration, science and risk based methodologies to:

- Provide interpretation, education, training and guidance for current and future pharmaceutical excipient regulations and science.
- Develop and implement appropriate quality practices throughout the supply chain for continued availability of pharmaceutical excipients for use in the development and manufacture of medicines.
- Encourage the development and use of new and novel excipients.

Progress to Date

Total Excipient Control

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.