

Driving safety  
and innovation for  
pharmaceutical  
excipients



# What is the International Pharmaceutical Excipients Council of the Americas?

## Our "Why"

What substances are essential for pharmaceutical drug products?

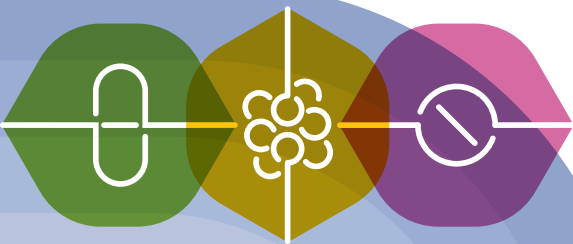
**Active Pharmaceutical Ingredients (APIs) and EXCIPIENTS.**

Nearly all finished pharmaceutical products use excipients, which may comprise up to 95% of a drug product. Their role is vital in all medicines and routes of administration — to bind, coat, preserve, lubricate, modify viscosity, solubilize, modify release, flavor, and provide a delivery vehicle for active pharmaceutical ingredients.

Excipients also aid in the drug product manufacturing process by overcoming active ingredient and equipment limitations. This allows for greater efficiency and contributes to new developments in pharmaceutical manufacturing.

**Throughout history, instances of contaminated or adulterated excipients or the inappropriate use of unsafe ingredients, resulted in medicines that inflicted harm, and in some cases, leading to death.**

*The need for improved safety and industry standards was clear. In 1991 a group of 16 manufacturers of excipients and finished drug products joined forces to form IPEC, the International Pharmaceutical Excipients Council, (which later became the International Pharmaceutical Excipients Council of the Americas).*



IPEC-Americas now celebrates 35 years with a mission to advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety. IPEC-Americas is part of the IPEC Federation which is headquartered in Belgium and consists of five independent regional industry associations: IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China and IPEC India.

Each association focuses on applicable laws, regulations, science, and business practices specific to their region and designs their strategies to support their members' goals.

The regional associations also collaborate on common excipient related safety and public health issues, in connection with international trade matters, and pharmacopeial specifications. About 250 national and multinational excipient producers, distributors and user companies are members of at least one IPEC regional unit and many are members of two or more.



## Progress to Date

Since its founding in 1991, IPEC-Americas focus has been on:

- how excipients and their uses are identified and demonstrated;
- how they are qualified for pharmaceutical use;
- how excipients are produced and protected throughout the supply chain; and
- how excipient functionality can be used in finished pharmaceutical formulations to improve drug product quality and performance.

This has led to development, publication and implementation of guidance on:

- Excipient safety evaluation;
- Excipient good manufacturing practices (GMP) and GMP auditing;
- Excipient good distribution practices (GDP) and GDP auditing to establish an excipient's "pedigree" at every stage;
- An 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;
- > a significant change guide for defining best practices in reporting changes that occur during an excipient's manufacturing process;
- > an excipient certificate of analysis (COA) guide;
- > an excipient master file guide;
- > an excipient composition guide; and
- > an excipient stability program guide.



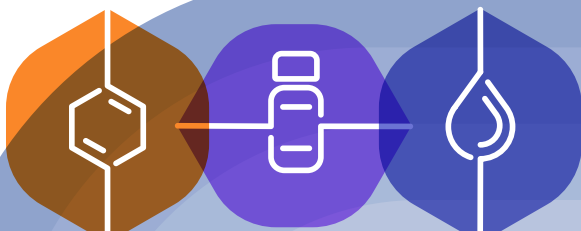
## Why IPEC-Americas Is Needed

Under U.S. law, a new pharmaceutical excipient, unlike an active pharmaceutical ingredient (API), has no regulatory status unless it is qualified through one or more of the approval mechanisms presently available for components used in finished product dosage forms, e.g. via an NDA, ANDA, or 505(b)(2) filing.

Differences in excipient monograph acceptance criteria among the major pharmacopeia also make it difficult for pharmaceutical companies to develop and manufacture drug products for the global market without repetitive testing of excipients to ensure compliance with regional pharmacopeias and national regulations.

IPEC-Americas offers educational opportunities through events such as:

- the annual Excipient World Conference & Expo
- public and private workshops
- peer reviewed publications including the International Journal of Pharmaceutical Excipients
- and digital resources — providing year-round access to industry-leading education.



# Membership

IPEC-Americas member companies are excipient manufacturers, distributors, and pharmaceutical companies as well as other suppliers of specialized services related to the pharmaceutical use of excipients. IPEC-Americas is directed by its elected officers and operates through volunteer committees composed of member company employees. Where appropriate, U.S. Food and Drug Administration (FDA) and United States Pharmacopeia (USP) representatives may be invited to 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 a focus on patient safety. This remains a key

IPEC goal, which is why IPEC members are relentless in their efforts 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 standards for:

- **quality;**
  - **safety;** and
  - **performance**
- during their manufacturing process and through the distribution supply chain.

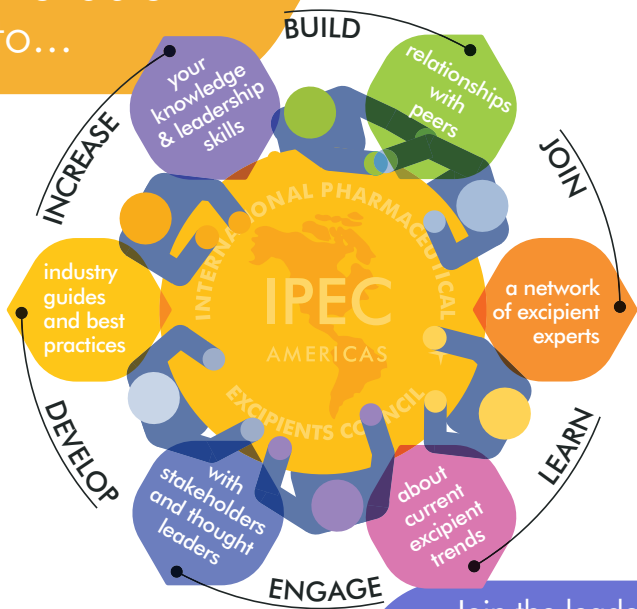
## VISION STATEMENT

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

## MISSION STATEMENT

To advocate, educate, innovate and develop best practices for excipients, with a focus on patient safety.

Have a seat at the table to...



Join the leaders in advancing excipient relevance. Contact us today!

## Multiple stakeholders, one objective

IPEC brings together diverse stakeholders that share a common objective: Safe and effective production and use of excipients

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