

# How we are contributing to global pharmaceutical standards

The evolving global pharmaceutical regulatory environment and the increasing interest of new countries in joining the ICH highlights the importance of maintaining consistent interpretation and implementation of ICH guidelines among industry and regulatory authorities worldwide.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), along with other [ICH Members and Observers](#), has an important role in promoting global convergence toward ICH regulatory standards and their harmonized interpretation.

As a Standing Observer of ICH, IFPMA can:



Attend meetings of the Assembly and the Management Committee (MC) without voting rights



Nominate up to 2 delegates to attend the meetings of the Assembly and the MC



Appoint experts to Working Groups (1 expert and 1 alternate per WG)



Appoint an ICH Coordinator

## About ICH

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a unique platform bringing together regulatory authorities (RAs) and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals, as well as establishing common standards and guidelines.

Implementation of the ICH guidelines supports the alignment of regulatory requirements across regions, reducing duplication of efforts and promoting consistent regulatory standards worldwide. This makes the role of ICH crucial in facilitating the development, registration, and access to safe, effective, and high-quality medicines and vaccines worldwide, contributing to better health outcomes.



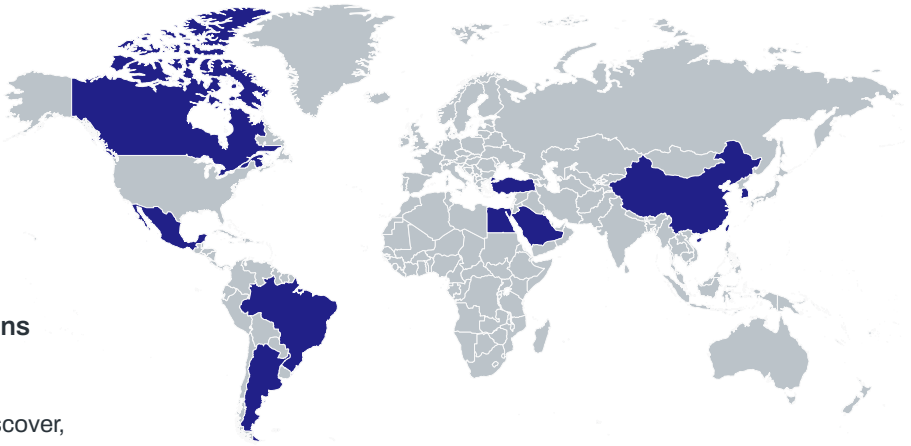
## Representing the pharmaceutical industry in ICH

IFPMA represents over 90 innovative pharmaceutical companies and associations around the world.

Our industry's almost three million employees discover, develop, and deliver medicines and vaccines that advance global health.

Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community improve the lives of people everywhere.

At ICH level, IFPMA represents research-based national or regional pharmaceutical trade associations that operate within the regulatory jurisdiction of one or more ICH Regulatory Members outside the European Union, Japan, and the United States.

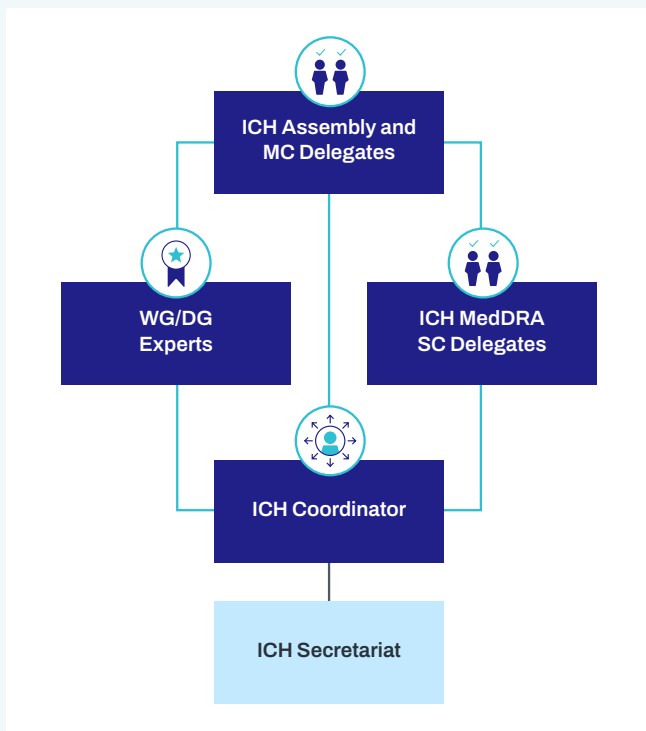


### IFPMA represents 14 National Trade Associations (NTAs) in ICH from 11 countries:

- Argentina
- Brazil
- Canada
- China
- Chinese Taipei
- Egypt
- Mexico
- Republic of Korea
- Saudi Arabia
- Singapore
- Türkiye

## How we engage

IFPMA convenes a diverse and consensus-driven industry voice in shaping global regulatory standards and guidelines.



Over 40 IFPMA experts and alternates actively represent IFPMA's view in more than 20 ICH Expert/Implementation Working Groups (EWG/IWGs) and Discussion Groups (DGs). They collaborate with experts from IFPMA's different NTAs to provide consolidated input. With their specialized knowledge, experience, and scientific expertise, they contribute to the development of harmonized guidelines focused on quality, safety, efficacy, and multidisciplinary topical areas. Additionally, they play a vital role in developing training materials to facilitate the effective implementation of these guidelines at national and regional levels.

IFPMA ICH Assembly and MC Delegates participate in biannual meetings, MC interim meetings, and regular MC teleconferences, supporting the successful operation of the ICH Assembly and ICH MC.

IFPMA MedDRA Steering Committee (SC) Delegates attend biannual meetings and regular teleconferences of the MedDRA SC, which is responsible for managing, supporting, and facilitating the maintenance, development, and dissemination of the Medical Dictionary for Regulatory Activities (MedDRA).

IFPMA's ICH Coordinator facilitates communication, coordination, and collaboration between all IFPMA ICH delegates, experts, and NTAs and serves as the main point of contact with the ICH Secretariat.

