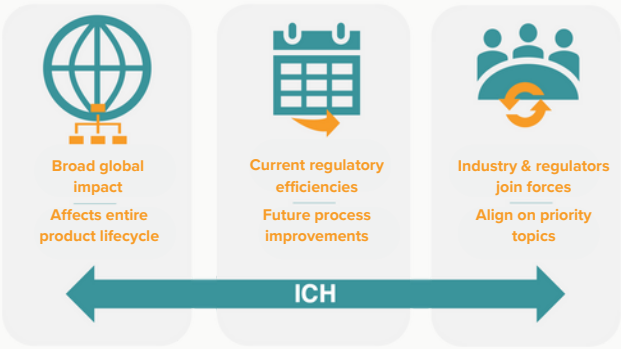
EFPIA contributes to global regulatory convergence via ICH

EFPIA's overarching ICH strategy leverages the scientific excellence of the European industry to lead achievement of global consensus on a harmonised, science-based regulatory framework enabling patient access to new medicines. EFPIA's members bring a particular expertise based on a history of international cooperation and global provision of medicines.



ABOUT ICH

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has driven consistency in global regulatory standards for the last 30+ years. More than 700 regulators and industry experts are involved in developing and updating 160+ ICH guidelines, which support the alignment of regulatory requirements across regions, reduce duplication of efforts, and promote consistent regulatory standards worldwide in QSEM* aspects.

ICH improves the entire Product Lifecycle which impacts most R&D Functions:

*Quality, Safety, Efficacy and Multidisciplinary

The European Federation of Pharmaceutical Industries and Association in collaboration with other ICH Members and Observers, plays a vital role in promoting global alignment with ICH regulatory standards and their harmonised implementation.

Through ICH, EFPIA has an exceptional opportunity to ensure that the global regulatory environment keeps pace with forthcoming innovations.

As 1 of the 6 Founding Members of ICH, EFPIA can:

- **Attend meetings of the Assembly and the Management Committee (MC) with voting rights and form a quorum**
- **Have two Permanent Management Committee Representatives + one coordinator making up the EFPIA ICH team**
- **Appoint up to two MedDRA** Management Committee Representatives**
- **Appoint experts in all Working Groups (WG)**

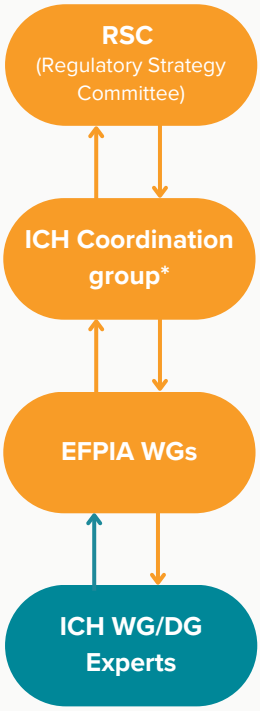
**Medical Dictionary for Regulatory Activities

REPRESENTING THE EUROPEAN PHARMACEUTICAL INDUSTRY IN ICH

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs). EFPIA creates a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe.

EFPIA's integral contribution to these successes can be easily traced through ICH's history. Since hosting the inaugural ICH meeting at its offices in Brussels in 1990, EFPIA has continued to deliver strategic leadership and deep subject matter expertise across many critical topics such as good clinical practices (GCP), global pharmacovigilance, global submission standards, and global good manufacturing practices (GMP).

INTERNAL EFPIA ICH STRATEGY DEVELOPMENT



*experts from RSC and WGs + EFPIA ICH team

60+ experts on working groups

Contributing to each ICH meeting

2 rapporteurs at the moment**

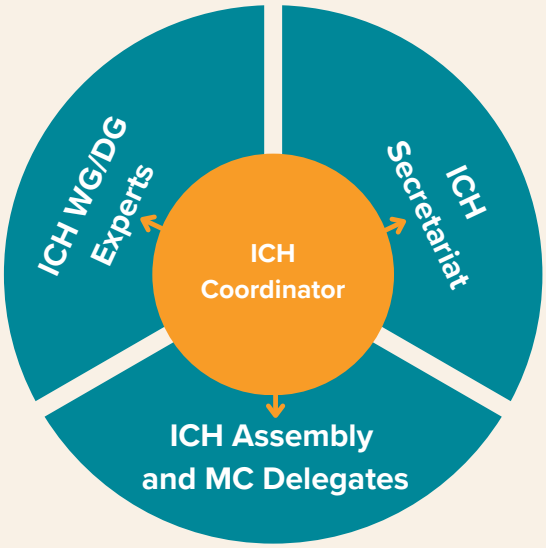
**September 2024

6 months rotating chair role for ICH IEC***

***ICH Industry Executive Council

EFPIA'S ROLE IN ICH

EXTERNAL COORDINATION AND COLLABORATION WITH ICH



EFPIA experts actively contribute to over 30 ICH Expert/Implementation Working Groups (EWGs/IWGs) and Discussion Groups (DGs), providing consolidated input from EFPIA's diverse membership. Their specialized knowledge, experience, and scientific expertise contribute to the development of harmonized guidelines focusing on quality, safety, efficacy, and multidisciplinary topics. They also play a crucial role in developing training materials to facilitate effective guideline implementation at national and regional levels.

EFPIA's ICH delegates participate in bi-annual Assembly and Management Committee meetings, interim meetings, and regular teleconferences, ensuring the smooth operation of ICH activities.

EFPIA's ICH Coordinator ensures effective communication, coordination, and collaboration among all EFPIA ICH delegates and serves as the main contact with the ICH Secretariat.

FOR MORE THAN 30 YEARS, ICH HAS BROUGHT TOGETHER EXPERTISE FROM REGULATORS AND INDUSTRY FROM DIFFERENT REGIONS TO DEVELOP VALUABLE TECHNICAL GUIDELINES THAT HAVE ENABLED PHARMACEUTICAL INNOVATION AND COOPERATION BETWEEN REGULATORY AUTHORITIES AND INDUSTRY.

EFPIA WILL CONTINUE CONTRIBUTING TO THE MISSION OF ICH TO ENABLE GLOBAL REGULATORY CONVERGENCE, WHICH CAN LEAD TO ACCELERATION OF REGULATORY PATHWAYS GIVING PATIENTS ACESS TO HIGH QUALITY MEDICINES GLOBALLY.
LEARN MORE ABOUT ICH ON THEIR WEBSITE.