Advancing global health through harmonisation:

Enabling safe, effective and innovative medicines for patients

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© 2026 International Council for Harmonisation of Technical Requirements for Pharmaceutical Products for Human Use (ICH)

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ICH: a unique harmonisation initiative for public health



- The **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)** was first launched in 1990. In 2015, the ICH Association was officially established as a non-profit legal entity under Swiss law.



- **Vision:** A world where all patients benefit from **safe, effective and high-quality medicines and timely treatment innovations** that meet harmonised, science-based requirements to protect and advance public health.



- **Mission:** ICH works to **protect and advance public health** by bringing together regulatory authorities and the pharmaceutical industry to **harmonise scientific and technical requirements** across all stages of the pharmaceutical lifecycle, enabling safe, effective and high-quality medicines for the benefit of all patients.

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ICH objectives



- To reduce the use of animal testing without compromising the safety and effectiveness of pharmaceutical products.



- To prevent unnecessary duplication of clinical trials and evaluations.



- To improve efficiency of new drug development and manufacturing.



- To promote public health and improve the registration process and oversight of new medicines.

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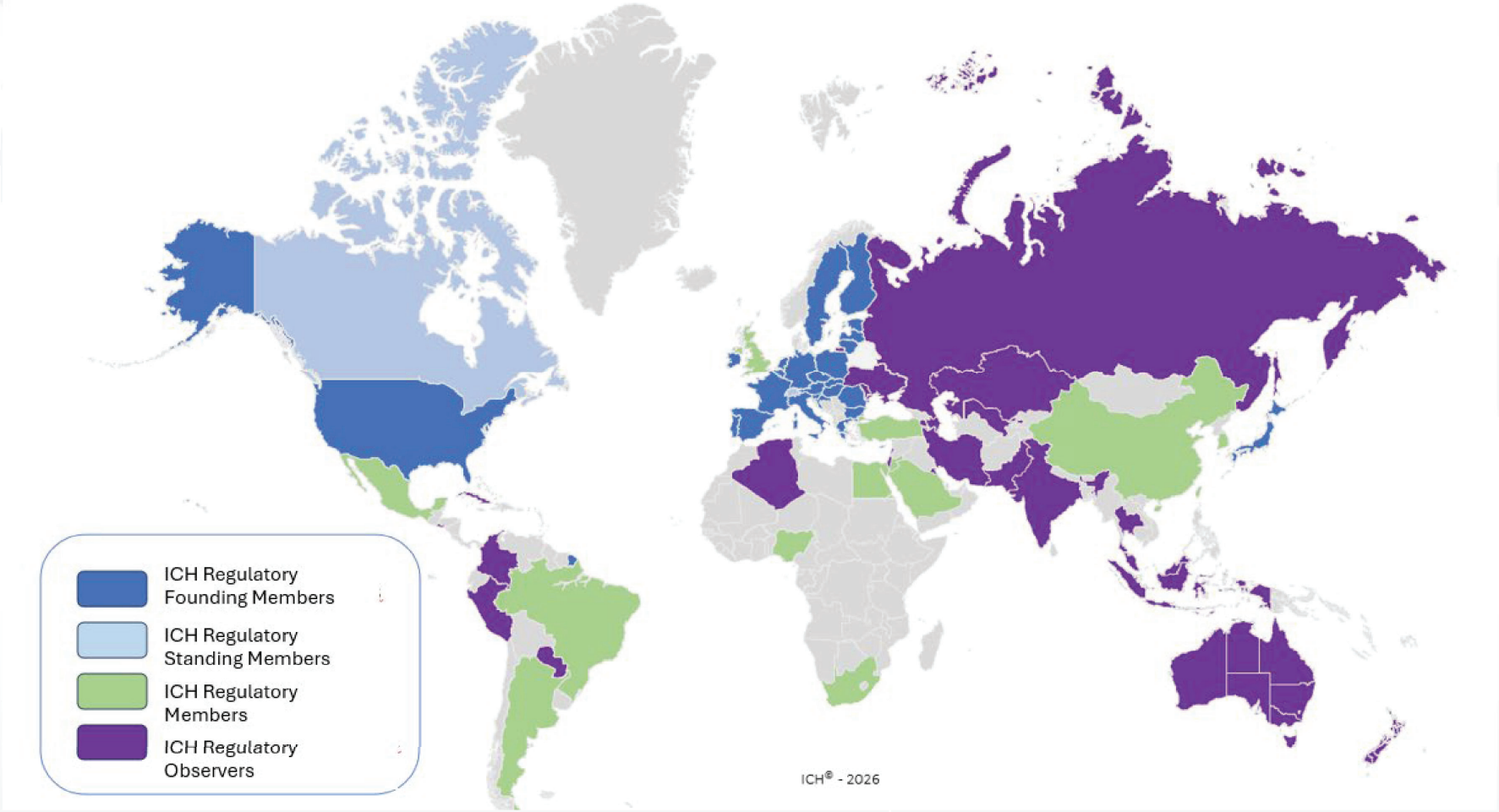
25 Members and 43 Observers



ICH has a network of around 700 scientific experts in 27 Working Groups

- ICH Working Groups are **specialised groups of scientific experts** who develop ICH harmonised technical guidelines.
- **85% of experts** are provided by **ICH Members**, who actively contribute to ICH Working Groups.
- **Process** of ICH harmonised guideline development:
  - **Science-based, consensus-driven**
  - Includes **public and regulatory consultation**
  - **Clear and effectively managed process**

https://www.ich.org/page/process-harmonisation

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ICH products as of June 2026

- Nearly 70 Guidelines on technical requirements covering **Quality, Safety, Efficacy** and **Multidisciplinary** domains.
- ICH Guidelines that are **approved and implemented by the regulatory authorities.**

- Find all ICH Guidelines here: https://www.ich.org/page/ich-guidelines

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ICH harmonisation at all stages of drug development process

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Discovery

- Testing molecular compounds against a disease target
- Documenting absorption, distribution, dosing, route of admin., etc.

Preclinical research

ICH Safety Guidelines uncover potential risks like carcinogenicity, genotoxicity and repro-toxicity

Clinical research

ICH Efficacy Guidelines focus on the design, conduct, safety and reporting of clinical trials.

Chemistry & manufacturing controls

ICH Quality Guidelines include the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on GMP risk management.

Preparation marketing application

Regulatory review

Post-approval activities

ICH Multidisciplinary Guidelines are the cross-cutting topics which do not fit uniquely into one of the Q, S or E categories.

They include the **ICH medical terminology (MedDRA)**, the **Common Technical Document (CTD)** and the development of **Electronic Standards for the Transfer of Regulatory Information (ESTRI)**.

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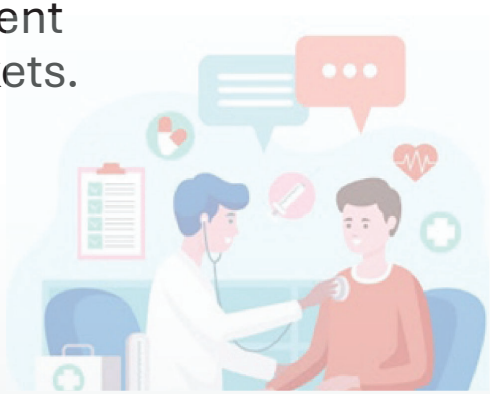
Harmonisation in action: Efficacy Guidelines

E6(R3): Good Clinical Practice (GCP)

- Modernises GCP standards to reflect the evolution of clinical research and provides a more flexible and risk-proportionate approach to clinical trials design and conduct.
- Enables the production of meaningful evidence more efficiently.

E22: General Considerations for Patient Preference Studies *(draft)*

- Provides an agreed harmonised framework to guide use of patient preference studies to inform drug development for global markets.
- Reduces uncertainty about global regulatory acceptance.



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Harmonisation in action: Quality Guidelines

Q3E: Guideline for Extractables and Leachables *(draft)*

- Harmonises the assessment and control of extractables and leachables in drug products and combination devices, to identify, quantify and toxicologically qualify any chemical compounds migrating from packaging or manufacturing equipment into the final drug.
- Provides a clear and harmonised framework to assist companies and regulators in taking consistent and timely decisions, and to reduce delays in bringing medicines to market.



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Harmonisation in action: Multidisciplinary Guidelines

M7 Sub-Group: Risk Assessment and Control of Nitrosamine Impurities

- The M7 sub-group is defining the Acceptable Intake (AI) for Novel-Nitrosamines without robust carcinogenicity data.
- A harmonised risk assessment framework minimises divergent requirements, effectively addresses potential carcinogenic risks, and enables innovation and the global availability of safe medicines.



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Collaboration and harmonised implementation for better health

The impact of ICH in fostering innovation and improving public health mainly relies on collaboration consistent implementation of ICH Guidelines across regions, supported by ICH through:

- the development of **training resources**: https://www.ich.org/page/training-library
- the publication of a periodic **implementation survey**: https://www.ich.org/page/ich-guideline-implementation
- the **exploration of a Digital Technology Platform** for document sharing and regulatory collaboration: https://www.ich.org/page/ich-technology-task-force

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ICH's impact on innovation and public health

- Trusted, **globally harmonised, science-based requirements** to support the **safety, efficacy and quality of medicines**, for the benefit of patients everywhere.
- **Faster access to medicines** through streamlined development, reduced duplication, fewer animal tests, more consistent and more efficient regulatory processes – without compromising quality or safety.
- **Increased regulatory certainty**, which supports innovation and the development of advanced technologies.
- Important **contributions to international regulatory convergence**, supporting global equity of product quality and clinical evidence, and more aligned assessment of medicines worldwide.
- Shared, **standardised medical language** for global medicine safety monitoring and reporting through MedDRA (Medical Dictionary for Regulatory Activities).

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ICH's opportunities for further harmonisation for better health

- **Expanding global participation** across regulatory authorities and industry stakeholders.
- **Identifying emerging areas requiring harmonisation**, including novel products and innovative technologies.
- Helping **reduce uncertainty** across regions by:
  - Promoting harmonised implementation of ICH Guidelines,
  - Enhancing transparent communication between regulators and industry,
  - Supporting with knowledge sharing and training.
- Facilitating more efficient global drug development and consistent related regulatory processes.

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Thank you

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