

International conference on harmonization of technical requirements for registration of pharmaceuticals for human use

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The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Download the [ICH 20th Anniversary Publication](#)

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www.ich.org

The pharmaceutical industry is one of the largest global businesses. It is also associated with steady innovation in terms of development of new drugs and has to keep abreast of the constantly changing regulatory and technical aspects associated with the process. In addition, there are a number of ethical and economic issues ranging from safety, quality, profits, patent rights, and protection that need to be considered.

Following famous cases such as the Nazi's experiments on concentration camp prisoners in WWII and the Tuskegee syphilis study (1932–1972), agreements for the conduct of clinical research were created. These included the 1947 Nuremberg code, the 1964 Declaration of Helsinki, and the 1979 Belmont Report. These led to the realization that it was important to have an independent evaluation of medicinal products before they are allowed on the market. This was followed by introduction of new regulations and guidelines for reporting and evaluating the data on safety, quality, and efficacy of new medicinal products in almost every country. The variance in technical requirements from country to country made it necessary to duplicate many time-consuming and expensive test procedures in order to release new medicines in the international market. This resultant increase in cost of research and health care made it necessary to rationalize and harmonize regulation so as to make safe and efficacious new treatments available to patients in the minimum amount of time.

The idea of harmonization of regulatory requirements was decided by Europe, Japan, and the United States. This idea gave rise to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in 1990 at a WHO conference on Drug Regulatory Authorities in Paris.

The formalization of the concept of harmonization led to immediate benefits to the regulatory authorities and the pharmaceutical industry. The ICH recommendations helped in preventing duplication of clinical trials and minimizing the use of animal testing at the same time taking care of safety and effectiveness. The recommendations also streamlined the regulatory process for new drug applications, thereby reducing the development times and optimizing resources for drug development. The ICH has since then entered the electronic era with a stress on paperless application process and sharing of real-time information among the stakeholders.

The website of the ICH (<http://www.ich.org>) is the portal for the organizations' activities and links information for various meetings, policies, trainings, and news.

The history of the organization and the algorithm of the harmonization process are explained in the introductory link. The Steering Committee that governs the activities of ICH

consists of representatives from the founders (European Union, European Federation of Pharmaceutical Industries and Associations, Ministry of Health Labour and Welfare, Japan, Japan Pharmaceuticals Manufacturer's Association, Food and Drug Administration, USA, Pharmaceutical Research and Manufacturers of America, Swissmedic and Health Canada). The WHO participates as an observer and International Federation of Pharmaceutical Manufacturers and Associations as a non-voting member.

Work Products link to downloadable Quality, Safety, Efficacy, and Multidisciplinary guidelines. The Quality guidelines include topics relevant to good manufacturing practices (GMP) and cover diverse topics related to stability studies, analytical validation, pharmacopoeias, and quality risk management amongst others. The Safety guidelines relate to genotoxicity, reproductive toxicity, and other safety evaluations. Efficacy guidelines are comprehensive and relate to the design, conduct, safety and reporting of clinical trials. The section also includes novel medicines derived from biotechnological processes and the use of pharmacogenetics/pharmacogenomics techniques to produce better targeted medicines. The Multidisciplinary guidelines consist of ICH medical terminology (MedDRA), the Common Technical Document (CTD), and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

In order to share regulatory information, ICH has formulated a standardized Medical Dictionary for Regulatory Activities (MedDRA). This is a general medical terminology that supports data analysis, communication, and data management. It is regularly updated and can be easily translated to other languages. Details are available on the sister website, www.meddra.org.

The Common Technical Document (CTD) contains the elements of quality, safety, and efficacy information in a common format. This makes the regulatory review processes simpler and allows for electronic submission. There are five modules in the CTD designed to harmonise submission of new drug applications (NDAs) in the electronic format. These have now evolved into the non-proprietary Electronic Standards for the Transfer of Regulatory Information (ESTRI).

The reach of the ICH is not limited to the partner countries and training programs on regulatory and pharmacovigilance issues are conducted in many regions that have active pharmaceutical manufacturing facilities. Another initiative aimed at involving non-ICH regions is the regulators forum that aims at involving various countries: Brazil, China, India and Russia, which have no formal agreement with the organization but are major clinical research hubs.

The publications link includes general documents and those related to MedDra and position papers. Surprisingly, it does

not archive older publications which could be of help in understanding implementation of the guidelines.

Current advances in global pharmaceutical manufacturing involve harmonizing drug regulation. ICH guidelines reduce the expense of preparing registration dossiers and ensure improved quality, safety, and efficacy of marketed products. These initiatives are excellent value additions for the drug developers and regulatory authorities. Increased sharing of information and pharmacovigilance activities leads the consumer to repose more trust in the process. Public health

in the developing countries also benefits by improved access especially to essential medicines.

The website of ICH and its content is essential reading for anyone who aims to gain an insight into regulations in drug development.

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Conflicts of interest

There are no conflicts of interest.