

# Guidelines: International Conference on Harmonisation

The need to rationalize and harmonize regulations around the development of pharmaceutical products arose due to the concerns over the rising costs of health care, escalating costs of research and development, and the call to meet public expectation that there be minimal delay in making safe and effective medications available to patients.<sup>1</sup>

The International Conference on Harmonisation (ICH [[www.ich.org](http://www.ich.org)]) was initiated in Brussels in 1990 and the various topics selected for harmonization were divided into four major key areas; safety, efficacy, quality and multidisciplinary topics. Representatives from regulatory agencies and industry associations from Europe, the US and Japan attended.

The members of the ICH are:

- Japan's Ministry of Health, Labour and Welfare
- Japan Pharmaceutical Manufacturers' Association
- European Union
- European Federation of Pharmaceutical Industries and Associations
- US Food and Drug Administration
- Pharmaceutical Research and Manufacturers of America

Additional members include observers from the World Health Organization, the European Free Trade Association, and Canada.

ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of testing procedures required to ensure the efficacy, safety and quality of medicines. Its objective is to increase the international harmonization of technical requirements to ensure that safe, effective and high-quality medicines are developed and registered in the most efficient and cost-effective manner possible. By doing so, ICH aims to promote public health, prevent unnecessary duplication of clinical trials in humans, and minimize the use of animal testing without compromising safety and effectiveness.

To ensure compliance, drug developers are encouraged to closely examine the pertinent guidelines during the drug development process. As regulators use the guidelines to determine whether a drug has been appropriately developed, it is important to become familiar with the relevant guidelines early in the process. The goal of the harmonized guidelines is to reduce the duplication of work in meeting the technical requirements of various regulators in different regions in the world, thereby saving financial and material resources.

The exhibit below summarizes the key topics covered under each of the main areas of harmonization.

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<sup>1</sup>International Conference on Harmonisation. (2000). *History and Future of ICH*. Retrieved February 19, 2010, from [www.ich.org/cache/compo/276-254-1.html](http://www.ich.org/cache/compo/276-254-1.html)

## Exhibit 1: Summary of ICH guidelines

<b>Efficacy</b>	<b>Safety</b>	<b>Quality</b>	<b>Multidisciplinary Topics</b>
Clinical safety	Carcinogenicity studies	Stability	Medical terminology
Clinical study reports	Genotoxicity studies	Analytical validation	Electronic standards for the transfer of regulatory information
Dose response studies	Toxicokinetics and pharmacokinetics	Impurities	Non-clinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals
Ethnic factors	Toxicity testing	Pharmacopoeias	The common technical document
Good clinical practice	Reproductive toxicology	Quality of biotechnological products	Data elements and standards for drug dictionaries
Clinical trials	Biotechnological products	Specifications	
Guidelines for clinical evaluation by therapeutic category	Pharmacology studies	Good manufacturing practice	
Clinical evaluation	Immunotoxicology studies	Pharmaceutical development	
Pharmacogenomics	Joint safety/efficacy topic	Quality risk management	
		Pharmaceutical quality system	

Source: [www.ich.org](http://www.ich.org)

For specific details on ICH guidelines, visit:

- Efficacy guidelines: <http://www.ich.org/cache/compo/475-272-1.html>
- Safety guidelines: <http://www.ich.org/cache/compo/502-272-1.html>
- Quality guidelines: <http://www.ich.org/cache/compo/363-272-1.html>
- Multidisciplinary-topic guidelines: <http://www.ich.org/cache/compo/2196-272-1.html>