

ICH (INTERNATIONAL CONFERENCE ON HARMONISATION)

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The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

PURPOSE OF ICH

The objective of ICH is to promote 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. These activities have been undertaken to promote public health, prevent unnecessary duplication of clinical trials in humans and minimize the use of animal testing without compromising safety and effectiveness.

GOAL OF ICH

The goal of ICH is to promote international harmonization by bringing together representatives from the three ICH regions (EU, JAPAN, USA) to discuss and establish common guidelines. Another goal of ICH is to make information available on ICH activities and ICH guidelines to any country or company that requests the information and to promote a mutual understanding of regional activities in order to facilitate harmonization processes related to ICH guidelines regionally and globally and to strengthen the capacity of drug regulatory authorities and industry to utilize them.

MEMBERS

ICH is comprised of representatives from six parties that represent the regulatory bodies and research-based industry in the European Union, Japan and USA. In Japan, the members are the ministry of health, labor and welfare (MHLW), and the Japan pharmaceutical manufacturers association (JPMA). In Europe, the members are the European Union (EU), and the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the USA, the members are the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). Additional members

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Terry C. Jones



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

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