International Council for Harmonisation [ICH]

Formerly the International Conference on Harmonisation. The International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) produces harmonised guidelines for global pharmaceutical development, and their regulation. It brings together the regulatory authorities and the pharmaceutical industry from five regions (Europe, Japan, USA, Canada and Switzerland).

ICH has been established in order to reduce the duplication of clinical trials and create a more streamlined regulatory assessment process for new applications. As such, ICH has developed four sets of guidelines provided for specific topics including quality, safety, efficacy and multidisciplinary (e.g. ICH medical terminology (MedDRA), or the Common Technical Document (CTD)) which are implemented by the regulatory authorities of its membership.