U.S. FOOD & DRUG ADMINISTRATION

ICH Overview

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ICH Overview

- The International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) is a unique harmonization organisation involving regulators and the pharmaceutical industry.
- Launched in 1990 by the US, EU, and Japan. Canada, Swissmedic and WHO as observers.
- Well-defined objectives:
  - **To improve efficiency of new drug development and registration processes**
  - **To promote public health, prevent duplication of clinical trials in humans and minimize the use of animal testing without compromising safety and effectiveness**
- Accomplished through development of harmonized, technical guidelines and standards that are implemented by regulatory authorities.

ICH Association

Reformed as a non-profit legal entity under Swiss Law in 2015 to promote public health through international harmonization that contributes to:

- Focus global pharmaceutical regulatory harmonization work in a single forum for constructive dialogue on scientific issues
- Promote more involvement from regulators around the world and wider inclusion of global industry sectors
- Continue to harmonize and streamline the global drug development process for the benefit of patients around the world
- Facilitate greater adoption of new and improved research and development approaches, common standards, and therapeutic advances
- Maintain efficient and well-managed operations

ICH Members and Observers

Members

Founding Regulatory Members
- EC, Europe
- FDA, US
- MHLW/PMDA, Japan

Founding Industry Members
- EFPIA
- PhRMA
- JPMA

Standing Regulatory Members
- Health Canada, Canada
- Swissmedic, Switzerland

Regulatory Members
- ANVISA, Brazil
- COFEPRIS, Mexico
- EDA, Egypt

Regulatory Members, continued
- HSA, Singapore
- MFDS, Republic of Korea
- MHRA, UK
- NMPA, China
- SFDA, Saudi Arabia
- TFDA, Chinese Taipei
- TITCK, Turkey

Industry Members
- BIO
- Global Self-Care Federation
- IGBA

Observers

Standing Observers
- IFPMA
- WHO

Legislative or Administrative Authorities
- AEC, Azerbaijan
- ANMAT, Argentina
- ANPP, Algeria
- CDSCO, India
- CECMED, Cuba
- CPED, Israel
- DPM, Tunisia
- EDA, Egypt
- Indonesian FDA, Indonesia
- INVIMA, Colombia
- JFDA, Jordan
- MMDA, Moldova
- MOPH, Lebanon
- NAFDAC, Nigeria
- National Center, Kazakhstan
- NPRA, Malaysia
- NRA, Iran
- PPBHK, Hong Kong, China
- Roszdravnadzor, Russia
- SAHPRA, South Africa
- SCDMTE, Armenia
- SECMOH, Ukraine
- TGA, Australia

Regional Harmonization Initiatives
- APEC
- ASEAN
- EAC
- GHC
- PANDRH
- SADC

Int'l Pharmaceutical Industry Organizations
- APIC

Int'l Orgs regulated by or affected by ICH guidelines
- Bill & Melinda Gates Foundation
- CIOMS
- EDQM
- IPEC
- PIC/S
- USP

ICH Governance

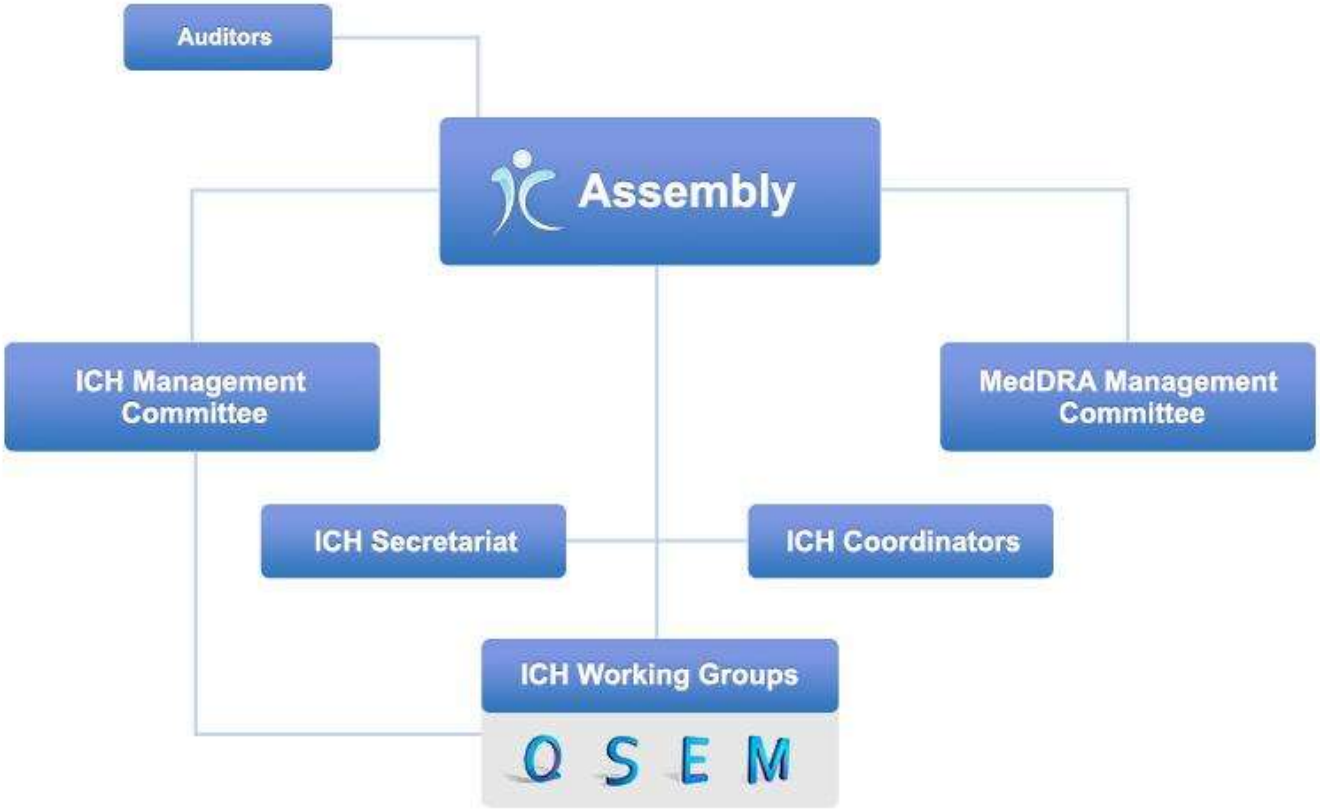
Assembly

- The overarching body, comprised of all ICH Members and Observers, that makes decisions regarding the Articles of Association and its rules and procedures, admission of new members, election of Management Committee representatives, adoption of ICH guidelines, etc.

Management Committee

- Oversees operational aspects on behalf of all members of the Association, including administrative and financial matters and oversight of WG operations.
- Financial responsibilities include preparation of the ICH budget and, during a transition period, ensure funding of ICH operations.
- Includes Permanent and Standing Members, and Elected Members

ICH Governance



ICH Products

- ~70 guidelines on technical requirements related to human drugs
- Electronic Standards for the Transfer of Regulatory Information (CTD/eCTD, ICSRs)
- Medical Dictionary for Regulatory Activities (MedDRA) -- standardized medical terminology to facilitate regulatory information sharing
- Q&A documents and training materials to support implementation of guidelines
- Reflection papers to provide a more strategic approach to development of new topics

Major ICH Topic Areas

Safety

- Carcinogenicity studies
- Genotoxicity studies
- Toxicokinetics and Pharmacokinetics
- Duration of chronic toxicity testing
- Reproductive toxicology
- Safety pharmacology studies
- Immunotoxicology studies
- Nonclinical evaluation for anticancer pharmaceuticals
- Photosafety evaluation
- Nonclinical pediatric safety

Efficacy

- Clinical safety
- Clinical study reports
- Dose-response studies
- Good clinical practice
- Clinical trials
- Clinical evaluation by therapeutic category
- Clinical evaluation
- Pharmacogenomics

Quality

- Stability
- Analytical validation
- Impurities
- Pharmacopoeias
- Specifications
- Good manufacturing practice
- Pharmaceutical development
- Quality risk management
- Pharmaceutical quality system
- Development and manufacture of drug substances

Multidisciplinary

- MedDRA terminology
- Electronic standards
- Nonclinical safety studies
- CTD and eCTD
- Bioanalytical Method Validation
- Biopharmaceutics Classification System-based Biowaivers
- Data elements and standards for drug dictionaries
- Gene therapy
- Mutagenic impurities
- Drug Interaction Studies
- Bioequivalence for IR solid

Annual New Topic Selection Process

- Any ICH Member or Observer may submit proposals for new topics.
- The Management Committee annually collects and prioritizes new topic proposals – and provides recommendations for harmonization to the Assembly.
- The Assembly formally approves new topics during its spring biannual meeting.

ICH Pre-Step Process

The ICH Assembly endorses a New Topic.

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The ICH Assembly endorses the Concept Paper Outline.

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An informal WG is established to develop a final Concept Paper.

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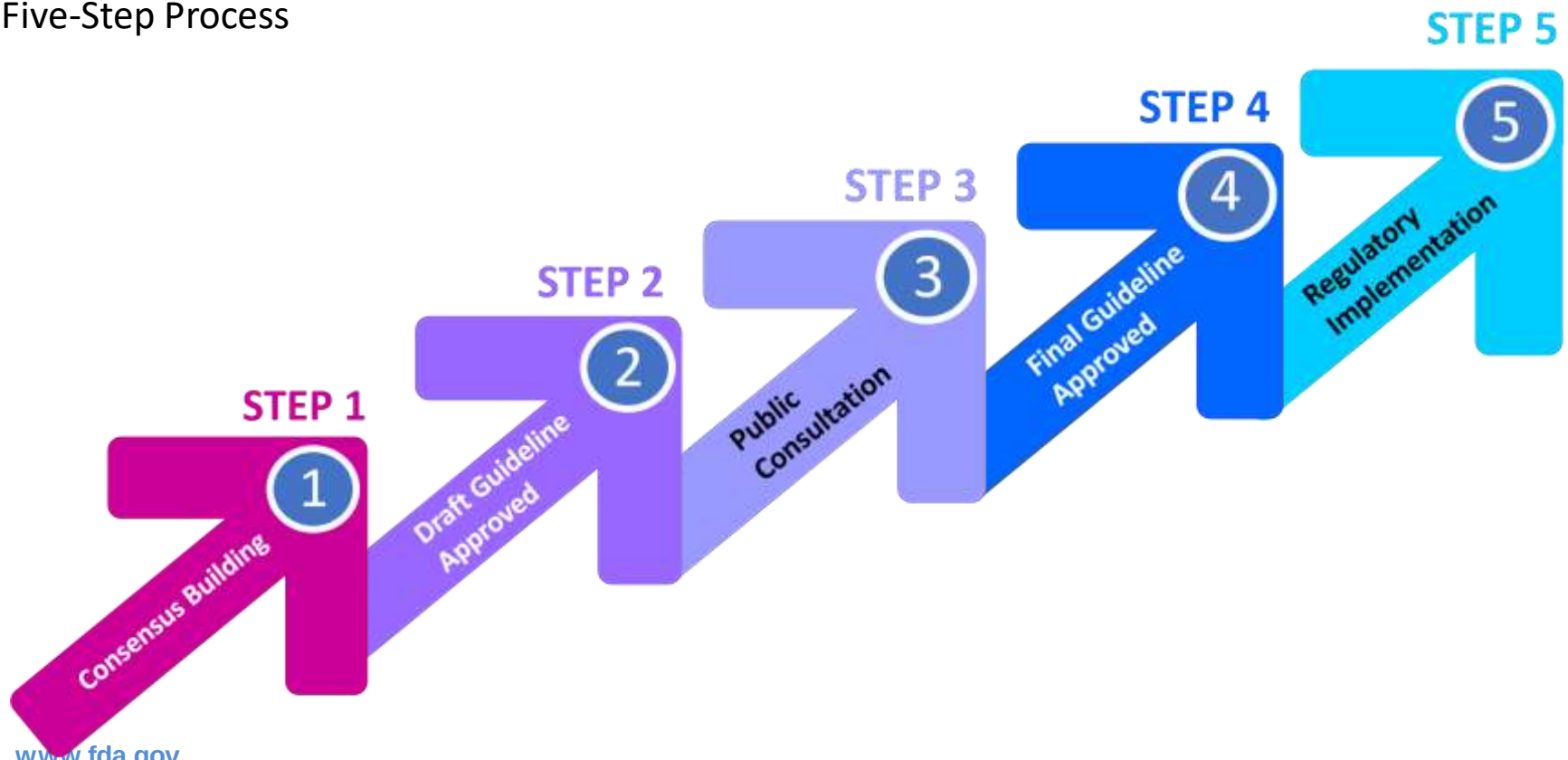
The MC approves the final Concept Paper
and a formal EWG/IWG is established.

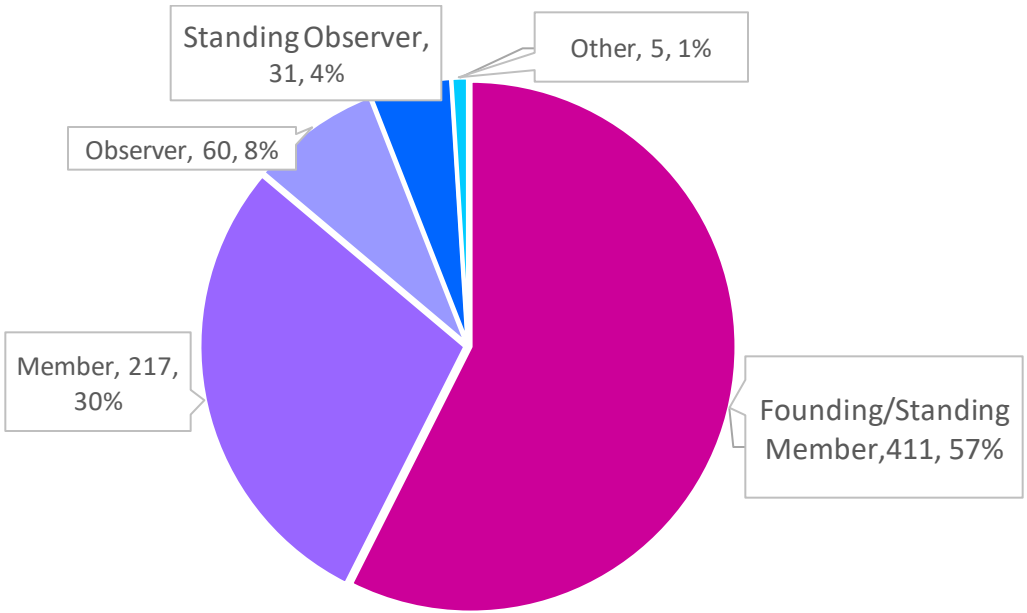
ICH Guideline Development

Five-Step Process



Composition of ICH Working Groups

Over 700 experts



ICH Training

Guideline Training:

- ICH is working to ensure that high quality training is available based upon scientific and regulatory principles outlined in its guidelines.

Efforts include:

- Development of a Training Library on the ICH website with access to all training materials including Step 4 working group presentations.
- Funding support for training programs organized by ICH regulatory members and observers.
- ICH Recognized Training Programs hosted by a variety of organizations, associations, regulatory authorities and academia. Offered in-person, virtually, and online. Information available on the ICH website.
- Online training materials development including some translations.

ICH Topics: Launching Soon

Guidelines:

- Revision to Q6A and Q6B on Specifications
- General Considerations for Patient Preference Studies
- Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics
- Structured Product Quality Submissions

Summary

ICH:

- Draws on expertise of regulators and industry to achieve international harmonization of technical guidelines to enhance public health
- Uses a transparent, science- and consensus-based process for guideline development including opportunities for public comment
- Includes commitment of regulators to implement guidelines
- Has expanded global participation and engagement through recent reforms