Overview of ICH

June 2017

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICH

INTERNATIONAL COUNCIL FOR HARMONISATION of Technical Requirements for Pharmaceuticals for Human Use

• Unique harmonisation initiative for regulators and pharmaceutical industry
• Originally founded in 1990
• Reformed as a non-profit legal entity under Swiss Law on October 23, 2015
**Purpose of ICH**

Promotion of public health through *international harmonisation* that contributes to:

- Prevention of unnecessary duplication of clinical trials and post market clinical evaluations
- Development and manufacturing of new medicines
- Registration and supervision of new medicines
- Reduction of unnecessary animal testing without compromising safety and effectiveness

Accomplished through **Technical Guidelines** that are implemented by the regulatory authorities.

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**ICH Members**

*(after Montreal meeting, June 2017)*

**Members:**

- Founding Regulatory:
  - EC, Europe; MHLW/PMDA, Japan; FDA, US
- Founding Industry:
  - EFPIA; JPMA; PhRMA
- Standing Regulatory:
  - Swissmedic, Switzerland; Health Canada, Canada
- Regulatory:
  - ANVISA, Brazil; CFDA, China; MFDS, Republic of Korea
- Industry:
  - IGBA; WSMI; BIO

See http://www.ich.org/about/membership.html for details
ICH Observers (after Montreal meeting, June 2017)

Standing Observers:
- WHO; IFPMA

Observers:
- Regulatory authorities; Regional Harmonisation Initiatives; international industry pharmaceutical organisations; international organisations with an interest in pharmaceuticals

See http://www.ich.org/about/membership.html for details

ICH Successes (1)

GCP (Good Clinical Practice)

Clinical trials conducted in one ICH region can be used in other ICH regions by setting the common standards on science and ethics.
ICH Successes (2)

CTD/eCTD (Common Technical Document)

ICH Guidelines → CTD eCTD ↔ Review

CTD brings together all Quality, Safety and Efficacy information in a common, harmonised format, accepted by regulators in all ICH regions. It has revolutionised regulatory review processes for regulators and industry.

ICH Successes (3)

MedDRA (Medical Dictionary for Regulatory Activities)

• Highly specific, standardised medical terminology developed by ICH to facilitate sharing of regulatory information

• It is used for registration, documentation and safety monitoring of medical products both before and after marketing authorisation
ICH Products (as of June 2017)

- Over 60 Guidelines on technical requirements
- Electronic Standards for the Transfer of Regulatory Information (ESTRI, E2B)
- Consideration documents (e.g. participation of women in clinical trials)

See http://www.ich.org/products/guidelines.html for details

Structure of the ICH Association

* Transfer from IFPMA to ICH currently being concluded
Remit of the Assembly and the Management Committee

Assembly is:
- The overarching body of the Association, composed of all Members that take decisions, regarding Articles of Association, Rules of Procedures, admission of new Members, Adoption of ICH Guidelines, etc.

Management Committee is:
- The body that oversees operational aspects of the Association on behalf of all Members, including administrative and financial matters and oversight of the WGs.

Decision-making for ICH Guidelines

- The Management Committee provides:
  - recommendations on the selection of new topics for harmonisation as well as on the adoption, withdrawal or amendments of ICH Guidelines

- The Assembly takes decisions:
  - By consensus
  - In the absence of consensus: vote in accordance with the Articles of Association, where only regulatory members have the right to vote
Membership in the Assembly—Eligibility Criteria for Regulators

Engagement in the ICH Process
- Past regular attendance in ICH meetings
- Past appointment of experts in WGs

Application of ICH Guidelines
- Have implemented at least the following ICH Guidelines (“Tier 1”):
  - Q1: Stability Testing Guidelines
  - Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
  - E6: Good Clinical Practice Guideline

See http://www.ich.org/products/guidelines.html for details

Membership in the Assembly—Eligibility Criteria for Industry

Type of Organisation
- International pharmaceutical industry organisation

Engagement in the ICH Process
- Past regular attendance in ICH meetings
- Past appointment of experts in WGs

Impact of ICH Guidelines
- The organisation and/or its members must be regulated or affected by ICH guidelines

See http://www.ich.org/about/membership.html for details
ICH Observers

- Limited eligibility criteria for new Observers
- Rights of Observers:
  - To attend ICH Assembly meetings, but no right to vote or automatically appoint experts in WGs
  - Standing Observers (WHO and IFPMA) maintaining their right to appoint experts in WGs
- No duties are imposed on Observers

See http://www.ich.org/about/membership.html for details

Steps in the ICH Process for Guideline Development

1. Consensus building - Technical Document
2. a. ICH Parties consensus on Technical Document / b. Draft Guideline adoption by Regulators
3. Regulatory consultation and Discussion
4. Adoption of an ICH Harmonised Guideline
5. Implementation
The ICH Step Process (1)

• **Step 1:**  
  - WG works to prepare a consensus draft of the technical document.

• **Step 2:**  
  - **Step 2a:**  
    - The Assembly is invited to endorse the technical document.
  - **Step 2b:**  
    - The ICH Regulatory Members of the Assembly are invited to endorse the draft Guideline.

Cont.

The ICH Step Process (2)

• **Step 3:**  
  - Public consultation by the ICH Regulatory Members and ICH Secretariat. All comments are considered by the WG.
  - Step 3 is finalised once consensus is reached in the WG.

• **Step 4:**  
  - The Regulatory Members of the Assembly adopt the final document.

• **Step 5:**  
  - Implementation by the ICH Regulatory Members.
Keys to ICH Success

- Involves expertise from both regulatory authorities and regulated industry
- Science-based, consensus driven
- Clear and effectively managed process
- Close collaboration of parties with comparable regulatory and technical capability
- Commitment of regulators to implement products of harmonisation
- Common global platform and tools
- Revised processes and governance

Summary

- ICH has achieved international harmonisation of technical guidelines, with engagement of regulators and industry
- ICH has clear governance and increasingly global membership following ICH reform
- Five transparent steps in the ICH process for Guideline development
Thank you for your attention

Visit our websites for more information on the work of ICH:
www.ich.org
www.meddra.org

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