Overview of ICH

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
Presentation Objectives

• To provide a brief overview of ICH
• Explain the role of the Experts / Rapporteurs
  o Responsibilities
  o Membership
  o Function

Overview of ICH
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ICH

INTERNATIONAL CONFERENCE ON HARMONIZATION of Technical Requirements for the Registration of Pharmaceuticals for Human Use

http://www.ich.org

Hosted by ICH Secretariat
Geneva, Switzerland
ICH Background

• Unique harmonisation project involving the regulators and research-based industries of US, EU and Japan → started in 1990
  o WHO, Canada, and EFTA are observers

• Well-defined objectives:
  o to improve efficiency of new drug development and registration process
  o To promote public health, prevent duplication of clinical trials in humans and minimise the use of animal testing without compromising safety and effectiveness

• Accomplished through the development and implementation of harmonised Guidelines and standards
The ICH Steering Committee

- Governs the ICH
- Determines ICH policies and procedures
- Decides on the adoption of ICH projects
  - Selects topics for harmonisation
  - Endorses the creation of ICH Working Groups
- Monitors and facilitates the progress of ICH Working Groups
- Signs off ICH documents
Overview of ICH

Technical Working Groups Structure

Interested Parties
- IGPA
- WSMI
- Biotechnology Industry
- IPEC
- API Industry

Pharmacopoeias
- Europe
- Japan
- United States

Observers: WHO, Canada, EFTA

DRAs/DoH
- DRA of Australia
- DRA of Brazil
- DRA of China
- DoH of Chinese Taipei
- DRA of India
- DRA of Korea
- DRA of Russia
- DRA of Singapore

RHIs
- APEC
- ASEAN
- EAC
- GCC
- PANDRH
- SADC

*Experts are nominated by their regional Coordinators*
ICH Products

• 60 Guidelines on technical requirements on:
  o Quality - 21 Guidelines
  o Safety - 14 Guidelines
  o Efficacy - 20 Guidelines
  o Multidisciplinary - 5 Guidelines

• Electronic Standards for the Transfer of Regulatory Information (ESTRI, E2B)

• Common Technical Document (CTD & eCTD)

• Medical dictionary for adverse event reporting and coding of clinical trial data (MedDRA)

• Consideration documents
Overview of ICH

Process of Harmonisation

- **New topic for harmonisation of ICH?**
  - *New Information to be added to an existing ICH Guideline?*
    - *Content of an existing ICH Guideline out of date or no longer valid?*
      - *Change to be made to either Q3C Guideline or M2 Recommendations?*

- **Formal ICH Procedure**
  - Concept Paper & Business Plan required

- **Q&A Procedure**
  - Concept Paper required (Business Plan may be required in certain cases)

- **Revision Procedure**
  - Concept Paper required

- **Maintenance Procedure**
  - Proposal/Concept Paper required for Q3C maintenance. No Concept Paper required for M2 Recommendations maintenance
Overview of ICH

Steps in the ICH Process

Step 1: Consensus Building – Technical Document

Step 2a: Confirmation of six-party consensus on Technical Document

Step 2b: Adoption of draft guideline by Regulator Parties

Step 3: Regulatory consultation and Discussion

Step 4: Adoption of an ICH Harmonised Tripartite Guideline

Step 5: Implementation
Steps in the ICH Process

- **At Step 1**, Experts from all six ICH Parties are requested to sign-off the consensus text. Observers / Interested Parties / RHIs/DRAs/DoH may also sign in recognition of their contribution.

- **At Step 2a**, Steering Committee members from all six ICH Parties are requested to sign-off the consensus text.

- **At Step 2b**, the consensus text approved by the three regulatory ICH Parties is signed-off by the three regulatory ICH Parties as Step 2b draft Guideline with a view to releasing it for public consultation. The technical document is made public on the ICH website alongside the draft Guideline.

- **At Step 3**, the comments received by each of the three Regulatory Parties shall be consolidated. The Step 3 experts document is signed-off by the regulatory Topic Leaders in the group.

- **At Step 4**, the Steering Committee Regulatory Parties are signing-off the final document.

- **At Step 5**, the Regulatory Parties implement the Guideline in their country/region according to their national/regional procedures.
**Overview of ICH**

### Biannual Face to Face meeting

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<td>ICH MedDRA</td>
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<td>Regulators Forum</td>
<td>ICH Global Cooperation Group</td>
<td>ICH Steering Committee*</td>
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**ICH Technical Working Groups**

*Evening Caucuses

- *ICH EWGs/IWGs are invited to submit a work plan ahead of the meeting based on which the SC will decide on the groups that will meet at the next face-to-face meeting*
- *ICH EWGs/IWGs are invited to present their work to the SC at the end of the meeting*
- *All ICH Parties must be represented for a face to face meeting to be considered official*
In between Meetings

- ICH EWGs/IWGs are encouraged to make use of modern communication technologies (e-mail, web-conferences, teleconferences, etc.) to progress draft Guidelines.
- Interim face-to-face meetings (should be exceptional) can be approved by the SC in cases where the group is facing very tight timelines.
- The ICH Secretariat is primarily concerned with preparations for, and documentation of, meetings of the Steering Committee as well as coordination of preparations for Working Group (EWG, IWG, Informal WG) meetings.

All ICH Parties must be represented for a teleconference / web-conference / Interim meeting to be considered official.
ICH: Keys to success

- Effective management and administration
  - Through ICH Steering Committee and Secretariat
- Joint participation of regulators and industry
- Science based and consensus driven
- Frequent, concurrent meetings of SC and Working Groups that are outcomes based
- Commitment of all parties to implement harmonised Guidelines
- Well-defined process and procedures
Thank you for your attention

Visit our websites:

www.ich.org
www.meddra.org

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