



# Overview of ICH

# Presentation Objectives

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

# ICH

**INTERNATIONAL CONFERENCE ON  
HARMONIS/ZATION  
of  
Technical Requirements  
for the Registration of  
Pharmaceuticals for Human Use**

<http://www.ich.org>

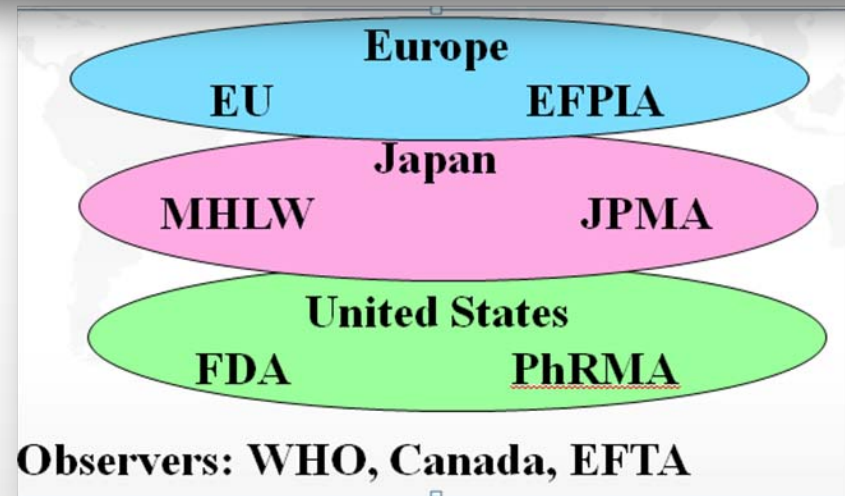
Hosted by ICH Secretariat  
Operates from the IFPMA offices  
Geneva, Switzerland

## ICH Background

- **Unique harmonisation project involving the regulators and research-based industries of US, EU and Japan**  
→ **started in 1990**
  - WHO, Canada, and EFTA are observers
- **Well-defined objectives:**
  - to improve efficiency of new drug development and registration process
  - 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

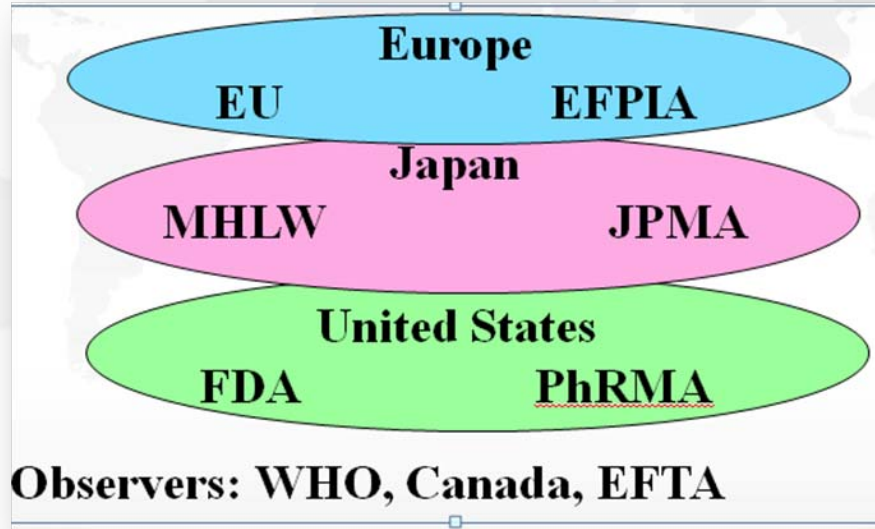
- **Governs the ICH**
- **Determines ICH policies and procedures**
- **Decides on the adoption of ICH projects**
  - Selects topics for harmonisation
  - Endorses the creation of ICH Working Groups
- **Monitors and facilitates the progress of ICH Working Groups**
- **Signs off ICH documents**



# Technical Working Groups Structure

## Interested Parties

- IGPA
- WSMI
- Biotechnology Industry
- IPEC



## 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

## Pharmacopoeias

- Europe
- Japan
- United States

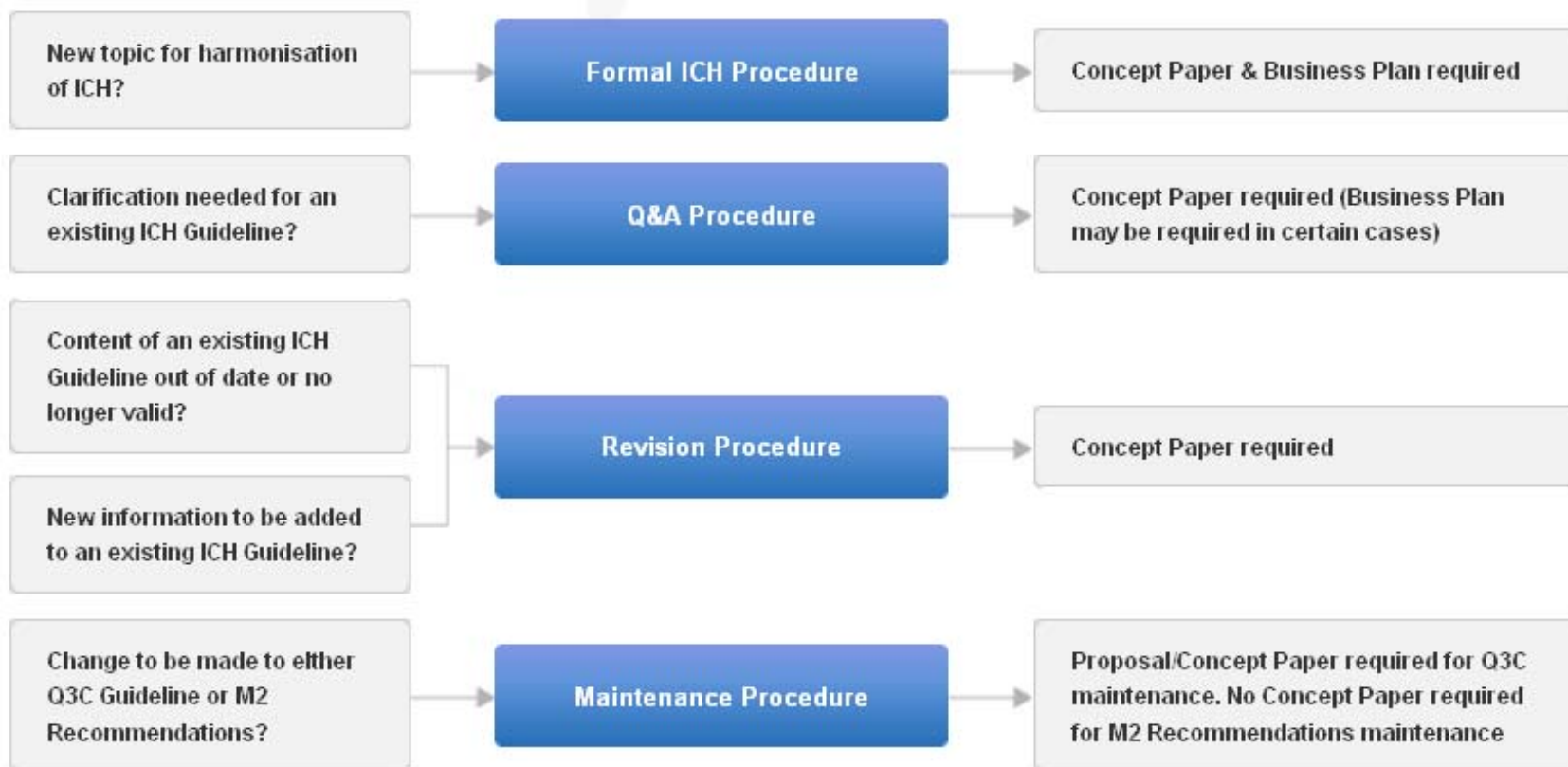
## RHIs

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

# ICH Products

- **Over 50 Guidelines on technical requirements on:**
  - Quality - 20 Guidelines
  - Safety - 14 Guidelines
  - Efficacy - 21 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**

# Process of Harmonisation



# Steps in the ICH Process

Step 1

Consensus building

Step 2

Confirmation of six-party consensus

Step 3

Regulatory consultation and Discussion

Step 4

Adoption of an ICH Harmonised Tripartite Guideline

Step 5

Implementation

# Steps in the ICH Process



- ***A formal sign-off can be achieved only when consensus is reached within the 6 ICH Parties.***
- *The Secretariat should be contacted to initiate the sign-off process.*
- *At **Step 2**, all six Parties are requested to sign-off the consensus text. Observers / Interested Parties / RHIs/DRAs/DoH may also sign in recognition of their contribution, if they wish.*
- *At **Step 3**, the comments received by each of the three Regulatory Parties shall be consolidated.*
- *At **Step 4**, Regulatory Parties are requested to sign the Step 4 final document.*

# Biannual Face to Face meeting

Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
ICH MedDRA Management Board		Regulators Forum	ICH Global Cooperation Group	ICH Steering Committee *	
ICH Technical Working Groups *					

*\*Evening Caucuses*

***All ICH Parties must be represented for a face to face meeting to be considered official.***

- *ICH EWGs/IWGs are invited to submit a work plan ahead of the meeting*
- *Alternate expert(s) may be nominated if needed*
- *ICH EWGs/IWGs are invited to present its work at the SC*

# In between Meetings

***All ICH Parties must be represented for a teleconference/web-conference to be considered official.***

- *Between face-to-face 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)*
- *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.*

## 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 website:  
[www.ich.org](http://www.ich.org)**