Report on Virtual ICH Inchon Meeting- Japanese ICH Coordinator

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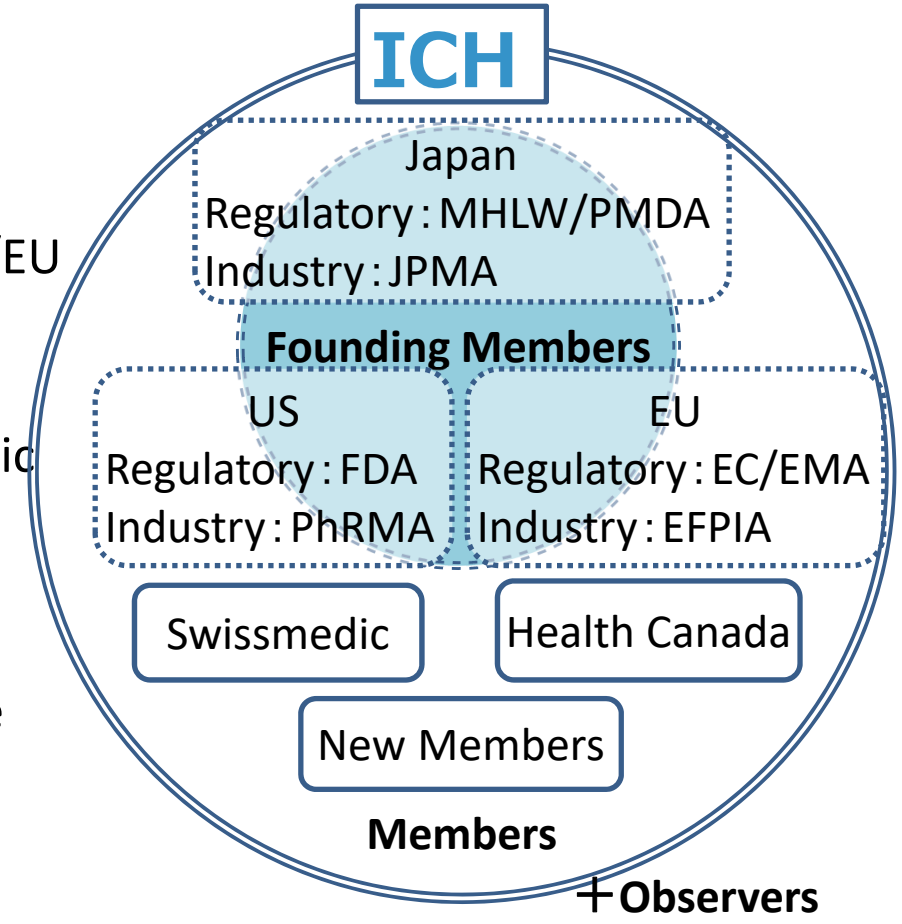
ICH (INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE)

History：

- ◆ Originally founded in 1990
- ◆ Regulatory and Industry of Japan/US/EU are Founding Members
- ◆ In 2014 Health Canada and Swissmedic joined
- ◆ Reformed as a non profit legal entity under Swiss Law in 2015 (Opened the door to regulatory authorities and international pharmaceutical organisations)



Purpose：

- ◆ promote public health through international harmonisation of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients via ICH Guide Lines

Virtual ICH Inchon

Continued ICH Growth and Advancement

Major discussion:

- Further expansion of ICH Membership
- ICH Management Committee elections
- Results of new implementation survey
- Progress on ICH Guidelines
- New areas of ICH harmonisation
- Training
- MedDRA
- Communication

Continued

3 New Topic Proposals endorsed by Assembly

- Revision of ICH Q1 Guidelines on Stability Testing and related ICH Q5C Guideline on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products.
- Revision of ICH Q6A and Q6B on Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances and Biotechnogical/Biological Products.
- New ICH Guideline on General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of a Medicine.(Proposed by MHLW/PMDA)

Step 4 Regulatory Member endorsement GLs

- The Q3C(R8) Guideline on Impurities: Guideline for Residual Solvents, revised to include the Permitted Daily Exposure (PDE) levels for 2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether and Tertiary Butyl Alcohol.
- The M8 eCTD v4.0 Question and Answer (Q&A) Document v.1.5, Specification for Submission Format for eCTD v.1.3, and eCTD v4.0 Implementation Package v.1.4.

Step 2b Regulatory Member endorsement GLs

- The draft ICH S1B(R1) Addendum to the Guideline on Testing for Carcinogenicity of Pharmaceuticals.
- The new, draft ICH S12 Guideline on Nonclinical Biodistribution Considerations for Gene Therapy Products.

How MHLW/PMDA cope with these discussion??

Creation of experts network in Japan

- To make support system by topics basis
  - ICH participants TL and DTL (**2 persons**) from MHLW/PMDA
  - Backup from domestic experts (more 2-3 persons)

- In case of more technical expertise needed,
  - MHLW/PMDA ask NIHS/other specialists (Academia) for support utilizing Health and Labor Sciences Research Grants.

Output our experience to outside

Share ICH's result with various people

[In Japan]

- **ICH Result Seminar** (after every ICH session; 2 times per year)
- **Specific Workshop/Seminar** (as needed)

  e.g. Q12 Seminar, E9 Seminar, Quality Seminar

  Utilize ICH Grants (in some cases)

[Expansion]

- **China and Japan Regional Joint Public Meeting on ICH** (today)

  Expect its evolution to the Asian region

ICH
harmonisation for better health

Take home message

- Thank You!!