

### Report on Virtual ICH Inchon Meeting-Japanese ICH Coordinator

June 18,2021

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China and Japan Regional Joint Public Meeting on ICH

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)

#### Japan Regulatory: MHLW/PMDA Industry: JPMA **Founding Members** US EU Regulatory: FDA Regulatory: EC/EMA Industry: PhRMA Industry: EFPIA Health Canada Swissmedic **New Members Members** Observers

#### 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

#### 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



## Take home message

► Thank You!!