ICHの歩み

20 years of ICH (and beyond)

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厚生労働省　医薬食品局審査管理課
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Today's Contents

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

- Mission of ICH
- History of ICH
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- Challenges and Future

Mission of ICH

- To achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

History of ICH

- In1990, ICH was established as a joint regulatory/industry project in Europe, Japan and the United States. -WHO, Canada, and EFTA are observers.
- ICH has been successful in achieving harmonisation of more than 50 technical guidelines and the format and content of registration applications (the CTD).
- More than 10 new guidelines and revision of existing guidelines are now under discussion.

Beyond the ICH regions

- Recently, the ICH emphasize the global co-operation, extending ICH's harmonized approach beyond the traditional ICH regions.
  - ICH created the Global Cooperation Group (**GCG**) in 1999 to promote a better understanding of ICH guidelines and ICH itself.
  - Since 2008, regulators have been invited to the **Regulators Forum** (RF) to discuss of important issues regarding ICH guidelines etc.

Further Involvement of non-ICH Regions and Countries

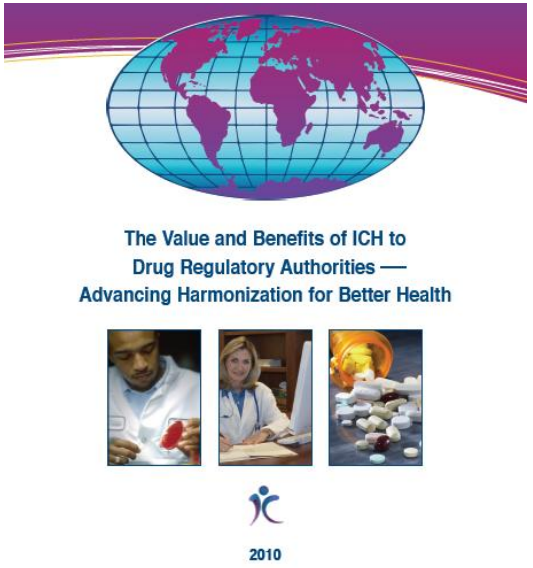
- Today, representatives from the following have been invited to attend the GCG and RF.
  - Drug Regulatory Authorities (DRAs)
    - Australia, Brazil, China, Chinese Taipei, India, Russia, Singapore and South Korea.
  - Regional Harmonization Initiatives (RHIs)
    - APEC (Asia-Pacific Economic Cooperation)
    - ASEAN (Association of the Southeast Asian Nations)
    - GCG (Gulf Cooperation Council)
    - PANDRH (Pan American Network for Drug Regulatory Harmonization)
    - SADC (Southern African Development Community)
- In Fukuoka meeting, the ICH Steering Committee endorsed the opening of ICH technical working groups to the active participation of experts from qualifying members of the GCG.

Challenges and the Future

- New technology
- Globalization and emerging economies
- Transparency, openness and inclusivity
- Operational Efficiency

Thank you for your attention.

- For further information, visit http://www.ich.org/
  and/or refer the booklet “The Value & Benefits of ICH to Drug Regulatory Authorities. –Advancing Harmonization for Better Health”



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