Connecting People, Science and Regulation

ICH Q7:
Background & History

PDA - PIC/S
ICH Q7 Training 01/2014

Disclaimer

- **The slides set is based on the training sessions developed and performed by the members of the ICH Q7 Expert Working Group (EWG) on ICH Q7 2001/2002**
- **The slides have been updated 2012 and represents the views of the PDA / PIC/S committee for the purposes of a general training for regulators and industry.**

◆ ***We focused on elements in ICH Q7 where further explanation and/or clarification is useful.***

What is ICH?

I nternational

C onference on

H armonisation

of Technical Requirements for the Registration of Pharmaceuticals *for Human Use*

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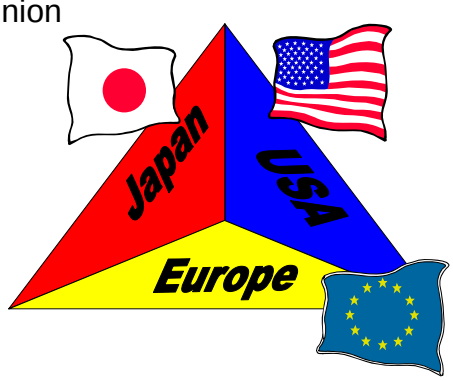
What is ICH?

- **Established in 1990 by the European Union, Japan, and the United States**
- **Committed to reducing duplication during research and development of new medicinal / drug products whilst safeguarding quality, safety and efficacy**
- **Has developed over 40 harmonised guidance documents mostly addressing technical and regulatory requirements for registering new human medicinal / drug products**

ICH Parties

- **Regulatory agencies**
  - EC/EMA - European Union
  - MHLW/PMDA - Japan
  - FDA - US
- **Trade associations**
  - EFPIA - Europe
  - JPMA - Japan
  - PhRMA - US



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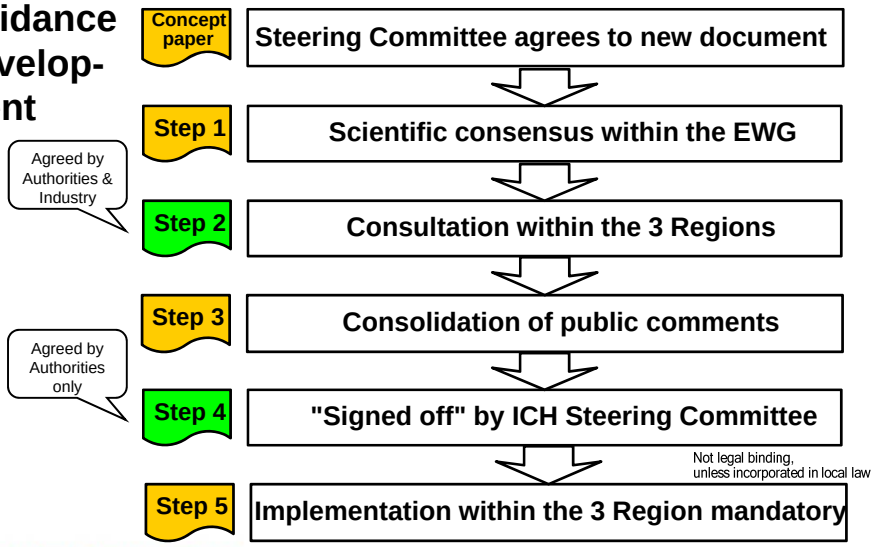
Guidance Develop-ment



ICH Technical Topics

- **Quality**
  (chemical and pharmaceutical Quality Assurance)

- **Safety**
  (in vitro and in-vivo pre-clinical studies)

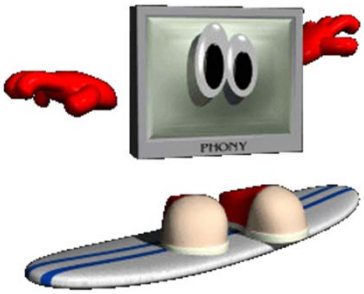
- **Efficacy**
  (clinical studies in human subject)

- **Multidisciplinary**
  (general topics)

ICH Quality Topics

- Q 1 Stability
- Q 2 Analytical Validation
- Q 3 Impurities
- Q 4 Pharmacopoeias
- Q 5 Quality of Biotechnological Products
- Q 6 Specifications
- Q 7 Good Manufacturing Practice
- Q 8 Pharmaceutical Development
- Q 9 Quality Risk Management
- Q10 Pharmaceutical Quality System
- Q11 Development and Manufacturing of APIs

For additional information on ICH



www.ich.org

What is an Active Pharmaceutical Ingredient (API)?

- **The *intended use* clause:**

  "Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug (medicinal) product."

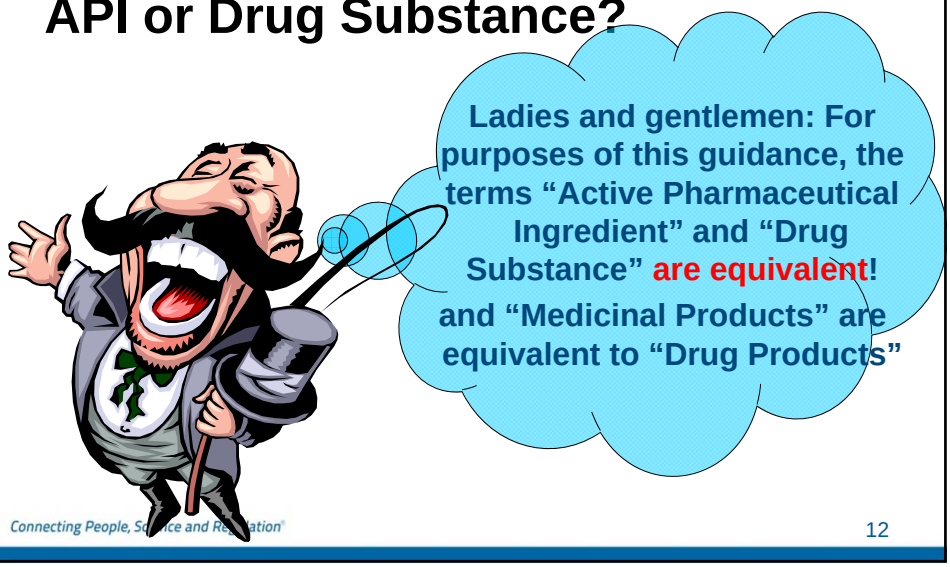
- **The *pharmacological activity* clause**

  "Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body."

What is an Intermediate?

- **"A material produced during API processing that undergoes further molecular change or purification before it becomes the API"**
- **"May or may not be isolated"**

API or Drug Substance?

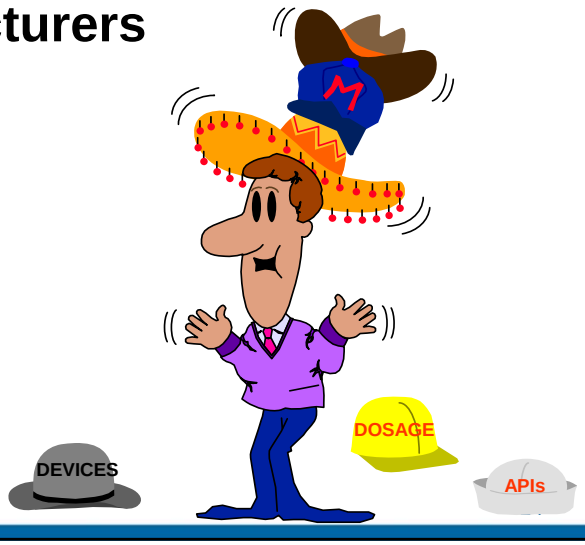


ICH Q7 is implemented world wide

- **EU, US, Japan, PIC/S**
  - Implemented as Note for guidance / Guidance for industry
- **WHO has implemented ICH Q7**
  - Technical Report *Series 957, Annex 2*, 2010, 130-189.
- **PIC/S has implemented ICH Q7**
  - GMP-Guide PE 009-9 (Part II) 1 Sept. 2009.
- **International implementation of ICH Q7**
  - Many countries implemented ICH Q7 as is (e.g. Australia, Canada, Switzerland)
  - Some countries reference to WHO or PIC/S requirements, if needed (e.g. ASEAN and SFN, Brazil)
  - Some countries use the content (e.g. China: Annex 2 of GMP 2010.)

When inspecting or auditing API Manufacturers

Please wear your API hat!



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