

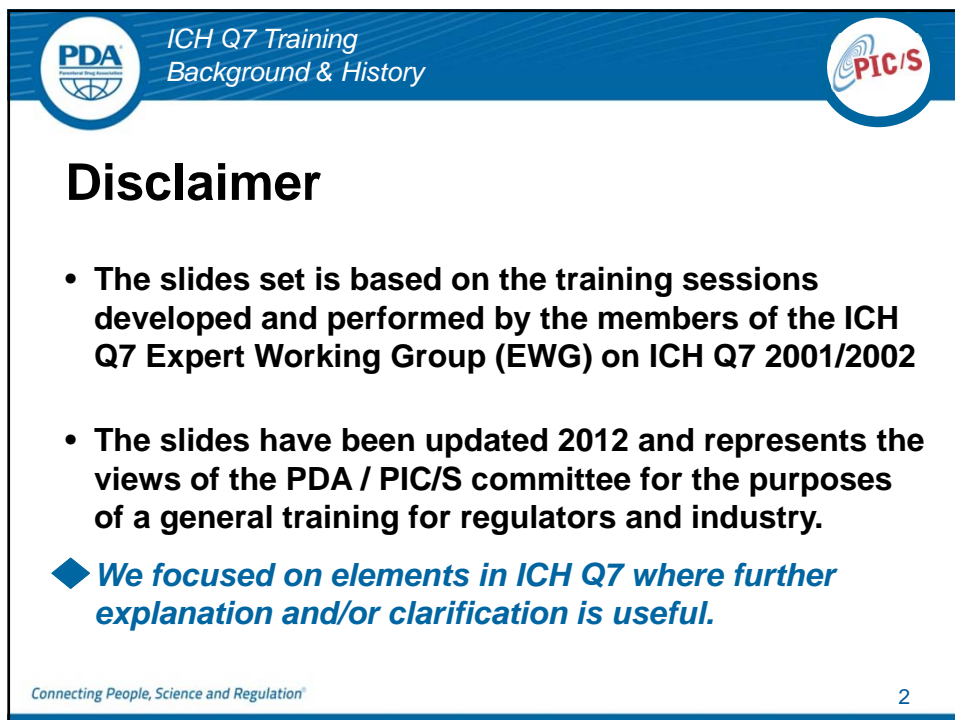
The slide features a blue background with white diagonal lines. In the top left corner is the PDA logo with the tagline "Connecting People, Science and Regulation". In the top right corner is the PIC/S logo. The main title "ICH Q7: Background & History" is centered in white. Below the title are three circular inset images: a laboratory machine, a person in a lab coat and mask, and a close-up of a syringe. At the bottom left, the text "PDA - PIC/S ICH Q7 Training 01/2014" is displayed.

PDA
Connecting People, Science and Regulation

PIC/S

ICH Q7: Background & History

PDA - PIC/S
ICH Q7 Training 01/2014



The slide has a white background with a blue header bar. The header bar contains the PDA logo and the text "ICH Q7 Training Background & History" on the left, and the PIC/S logo on the right. The main content is a "Disclaimer" section with three bullet points. The first two are black text, and the third is blue text with a diamond icon. At the bottom left is the PDA tagline, and at the bottom right is the number "2".

PDA
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ICH Q7 Training
Background & History

PIC/S

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.*

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 ICH Q7 Training
Background & History 



What is ICH?

 ICH
harmonisation for better health

International
Conference on
Harmonisation

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



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 ICH Q7 Training
Background & History 

What is ICH?

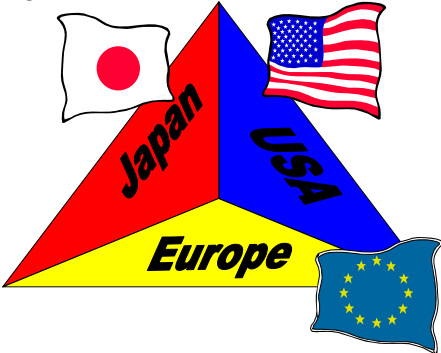
- Established in 1990 by the European Union, Japan, and the United States
- Committed to reducing duplication during research and development of new medicinal / drug products whilst safeguarding quality, safety and efficacy
- Has developed over 40 harmonised guidance documents mostly addressing technical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

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ICH Q7 Training
Background & History


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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ICH Q7 Training
Background & History


Guidance Development



Agreed by Authorities & Industry

Agreed by Authorities only

Concept paper	Steering Committee agrees to new document
↓	
Step 1	Scientific consensus within the EWG
↓	
Step 2	Consultation within the 3 Regions
↓	
Step 3	Consolidation of public comments
↓	
Step 4	"Signed off" by ICH Steering Committee
↓	
Step 5	Implementation within the 3 Region mandatory

Not legal binding, unless incorporated in local law


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 ICH Q7 Training
Background & History 

ICH Technical Topics

- Q** • **Quality**
(chemical and pharmaceutical Quality Assurance)
- S** • **Safety**
(in vitro and in-vivo pre-clinical studies)
- E** • **Efficacy**
(clinical studies in human subject)
- M** • **Multidisciplinary**
(general topics)

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 ICH Q7 Training
Background & History 

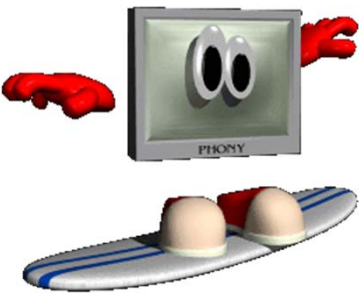
ICH Quality Topics

- 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**

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For additional information on ICH



www.ich.org

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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.”



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 ICH Q7 Training
Background & History 


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”

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 ICH Q7 Training
Background & History 

API or Drug Substance?



Ladies and gentlemen: For purposes of this guidance, the terms “Active Pharmaceutical Ingredient” and “Drug Substance” **are equivalent!** and “Medicinal Products” are equivalent to “Drug Products”

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PDA ICH Q7 Training
Background & History **PIC/S**

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.)

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PDA ICH Q7 Training
Background & History **PIC/S**

When inspecting or auditing API Manufacturers

Please wear your API hat!



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Acknowledgement

- **This version represents an update of the 2001/2002 version by ICH Q7 EWG members organised in a joint initiative between PDA and PIC/S developed in 2012**
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