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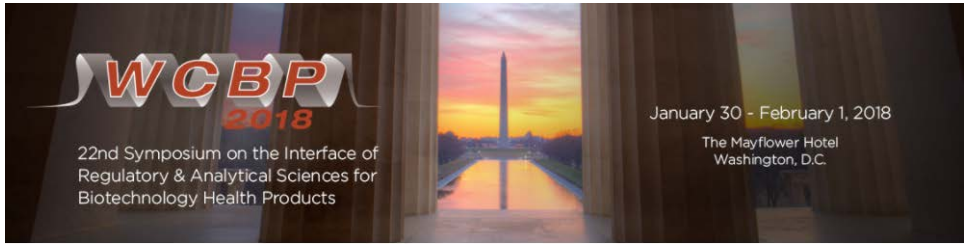

Regulatory ICH Countries: Current Harmonization Challenges and Future Opportunities

WCBP, PlenShop workshop, 31 Jan 2018
Presented by: Peter Richardson
Head of Quality, European Medicines Agency

ICH and other groups / stakeholders

- Government / Agencies
- WHO
- Pharmacopoeia
- Trade Associations
- Harmonisation Centres
- Consortia
- Standards Bodies

Members & Observers / About ICH /

Current Members and Observers

As of June 2017, the ICH Association comprises the following Members and Observers:

MEMBERS
Click here for the list

Founding Regulatory Members
- EC, Europe
- FDA, US
- MHLW/PMDA, Japan

Founding Industry Members
- EFPIA
- JPMA
- PhRMA

Standing Regulatory Members
- Health Canada, Canada
- Swissmedic, Switzerland

Regulatory Members
- ANVISA, Brazil
- CFDA, China
- HSA, Singapore
- MFDS, Republic of Korea

Industry Members
- BIO
- IGBA
- WSMI

OBSERVERS
Click here for the list

Standing Observers
- IFPMA
- WHO

Legislative or Administrative Authorities
- CDSCO, India
- CECMED, Cuba
- COFEPRIS, Mexico
- INVIMA, Colombia
- MCC, South Africa
- National Center, Kazakhstan
- Roszdravnadzor, Russia
- TFDA, Chinese Taipei
- TGA, Australia

Regional Harmonisation Initiatives (RHIs)
- APEC
- ASEAN
- EAC
- GHC
- PANDRH
- SADC

International Pharmaceutical Industry Organisation
- APIC

International Organisation regulated or affected by ICH Guideline(s)
- Bill & Melinda Gates Foundation
- CIOMS
- EDQM
- IPEC
- PIC/S
- USP

European Commission

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Quality Topics 2018, Possible Approaches

ICH Q12 (ongoing)

continuous manufacturing (* new),

extractables and leachables (new),

analytical methods /ICH Q2 (* new),

oligonucleotides (new),

excipient standards (new),

QOS (* 2017),

{ * from Quality Vision - Reflection Paper }

Can be many existing sources, e.g. E&L:

Other possible means to deliver guidance

↓

Regulators: Uni-Multilateral

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Cluster activities / Ad hoc: Technology Group

The European Medicines Agency (EMA) holds regular meetings by phone or videoconference with other non-EU regulators in so-called 'clusters'. The clusters are areas of cooperation focusing on special topics and therapeutic areas identified as requiring an intensified exchange of information and collaboration.

i-p-r-f.org
International Pharmaceutical Regulators Forum
(now: IPRP)

World Health Organization

icdra | Ireland 2018

non-exhaustive examples

Thank you

Peter Richardson,

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Specialised Scientific Disciplines Department, EMA

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