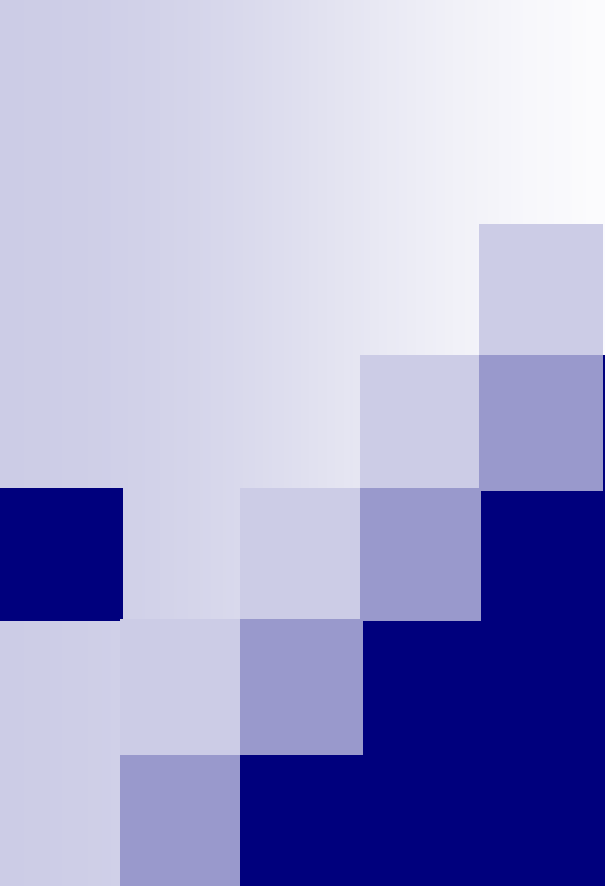




ICH Regulators Forum

Dr Peter Arlett EU

International Conference on Harmonisation of Technical
Requirements for Registration of Pharmaceuticals for Human Use





ICH Regulators Forum

- In this presentation
 - ICH Regulators Forum: Background
 - ICH Regulators Forum: Objectives
 - ICH Regulators Forum: Membership
 - ICH Regulators Forum: Outlook



ICH Regulators Forum

■ Background

- Harmonisation of technical requirements in regulation:
 - Shares expertise
 - Builds mutual understanding
 - Builds relationships and trust
 - Increases regulatory capacity
 - Reduce duplication of animal, pharmaceutical and human testing
 - Reduces the costs of drug development
 - Promotes public health by facilitating access of patients to new treatments
 - Promotes public health by ensuring robust criteria for quality, safety and efficacy.



ICH Regulators Forum

■ Background

□ Harmonisation success factors:

- Participant commitment in guideline development and implementation (political and technical)
- Technical expertise
- Secretariat and organisational support
- Organisational stability
- A minimum amount of funding
- A minimal amount of technology

□ ICH has all these factors



ICH Regulators Forum

■ Background

- ICH evolution from guideline development to maintenance, implementation and outreach:
 - First years mainly guideline development (now > 50)
 - New guidelines continue but less frequent
 - Now the guideline collection is being maintained (new science / evolution based on experience)
 - Major focus on implementation in the ICH regions
 - Major focus on leveraging with other organisations (e.g. ISO)
 - Major focus on sharing the expertise and ICH guidelines beyond the traditional ICH regions

ICH Regulators Forum

■ Background

□ ICH - beyond the traditional ICH regions:

■ GCG:

- Promotes harmonisation process related to ICH guidelines
- Facilitates capacity to utilise them
- *Key focus on training and capacity building*

■ Regulators Forum:

- Implementation of ICH guidelines
- *Share expertise and best practice*
- *Solve common challenges related to implementation*



ICH Regulators Forum

■ Background

□ Regulators Forum

- Proposal from FDA Autumn 2007
- First meeting Portland June 2008
- Second meeting Brussels November 2008
- Next meeting Yokohama June 2009

ICH Regulators Forum

■ Objectives /Vision

- Provide a venue to discuss and examine ICH Guidance and implementation throughout the world.
- Sharing of best practices on implementation of ICH guidelines and impact on regulatory systems.
- Identifying training and capacity needs for action by GCG.
- Support the GCG activities and promote a more comprehensive understanding of ICH guidelines.
- Supplement, not replace the GCG.
- Create a regulators environment for open discussion of challenges on the implementation of ICH guidelines.
- Build confidence and trust in the ICH Guidelines.

ICH Regulators Forum

■ Membership

□ ICH Members:

- EU, FDA, Japan,

□ ICH Observers:

- Canada, EFTA, WHO

□ Regional Harmonisation Initiatives:

- APEC, ASEAN, SADC, GCC, PANDRA

□ Individual Drug Regulatory Authorities:

- Australia, Brazil (invited), China, Chinese Taipei, India, Korea, Russia, Singapore.



ICH Regulators Forum

■ Outlook 1 Priorities

- ☐ CTD and eCTD
- ☐ Clinical trials (GCP – ICH E6)
- ☐ Manufacturing (particularly API – ICH Q7)
- ☐ Product safety



ICH Regulators Forum

- Outlook 2 – collaboration on clinical trials
 - Inform and invite the local authority to inspections where possible
 - Explore more sharing of information on GCP inspections
 - Inform planning based on each others inspections, where possible
 - Encourage clinical registries



ICH Regulators Forum

■ Outlook 3 GMP for APIs

- Build on Q7 as the common industry standard for API GMP
- Opportunity for working together facilitated by sharing common standard
- Encourage coordination of inspections and information sharing



ICH Regulators Forum

■ Outlook 4 – Product safety

□ PSURs:

- PSURs are useful tools for monitoring safety but need to be optimised
- Consensus that there is a need to review the E2C guideline
- Collection of feedback on the guideline and whether it should be revised



ICH Regulators Forum

■ Conclusions

- Drug development and manufacture is more and more global
- Harmonisation is more important than ever
- One standard facilitates: work sharing and efficient use of resources, dialogue and access to medicines of high quality
- Implementation is much more than publishing guidelines: promotion of common understanding and training are key.
- Different authorities and regions have different capacities and needs
- Relationships are key to successful collaboration
- Through the Regulators Forum we can share expertise and information and built mutual trust
- Thereby better protecting public health