ICH Regulators Forum

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

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- 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.

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- 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

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- 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

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- 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*

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- Background
  - Regulators Forum
    - Proposal from FDA Autumn 2007
    - First meeting Portland June 2008
    - Second meeting Brussels November 2008
    - Next meeting Yokahama June 2009

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- 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.

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- 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.

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- Outlook 1 Priorities
  - CTD and eCTD
  - Clinical trials (GCP – ICH E6)
  - Manufacturing (particularly API – ICH Q7)
  - Product safety

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- 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

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- 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

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- 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

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- 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