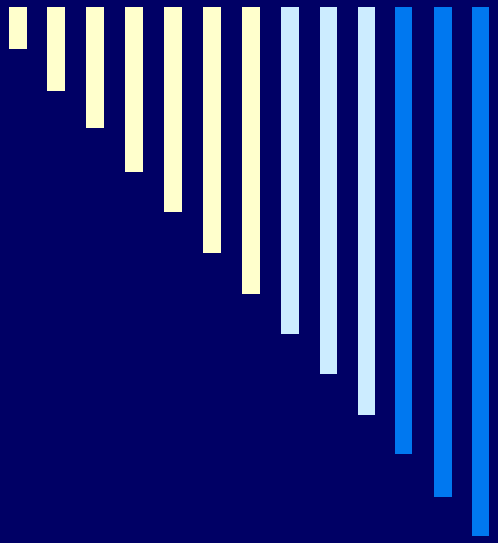


Study Group C

Members

- Capacities
  - 13 Regulators
    & 22 Industry Representatives
- Economies
  - 6 with Developed Regulations
    - Germany, China, Korea, Thailand, UK, USA
  - 3 in the process of developing Regulations
    - Hong Kong, Malaysia, Singapore

How we feel

- Target group
  - Regulators – opportune timing to obtain guidance from GHTF recommendations which could act as building blocks for future legislations
  - Industries – understand the principles and rationale behind recommendations and get better prepared for compliance

How we feel

- Format
  - Case study approach – good way of learning how to apply principles
  - Interactive discussion – stimulate our way of thinking and sharing our experiences

“EFFECTIVE WAY OF LEARNING”

Difficulties in Implementation of Harmonization of Regulation

- Regulators
  - Developed Systems
    - Difficulty to change laws in different jurisdiction
    - Still could add on areas that have not been covered before, e.g. Implementation of AER

      -> Improvement in Post-market Surveillance
  - In the process of developing system
    - Different demands and aspirations from legislators and community

Difficulties in Implementation of Harmonization of Regulation

- Industries
  - Worry about proliferation of different regulatory systems
  - Rigid standards promulgated in the law
  - Different languages required in labelling requirement
  - Requirement of documents not related to demonstration of safety of products
  - Redundancy of documents for diff. dept.

Possible solutions

- Acceptance of “approval from other countries” as a criteria for registration
  - ASEAN
- Common Dossier for submission
- Use of Standards and Common Technical Specification of Products – flexibility in the requirements in the law
- Risk based approach for different devices
- More communication between R & I

Way Forward

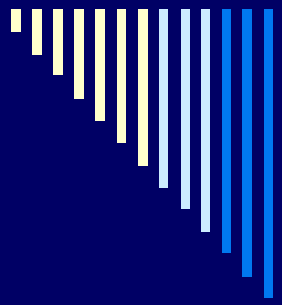
- Future Training
  - In depth training for specific topics (e.g. risk analysis)
  - Target specific (how to monitor CABs, sharing of experience in non-compliance)
  - Run in parallel sessions + Video-recording to save time
  - Invite Regulators to be facilitators for training of potential regulators

Way Forward

- GHTF guidance
  - Develop guidance on IVDD classification and conformity requirements, CAB designation and monitoring
  - Think ahead of time on regulation of new technologies – biologics, gene therapies, combination products

VISION

We would like to avoid undue delay in the access of SAFE and EFFECTIVE medical devices in our markets



THANK YOU