

Advantages and Challenges of Working with Non-ICH Countries

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ASEAN: Harmonization and streamlining regulation

10 ASEAN Member Countries

- Brunei
- Cambodia
- Indonesia
- Lao PDR
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Vietnam

ASEAN Consultative Committee for Standards and Quality (ACCSQ):

- Harmonize “Standard & Requirement” posed by regulation
- Work to facilitate the “ASEAN Free Trade Area-AFTA”
- Establish “Mutual Recognition Arrangement-MRA”
- Comply to “HLTF-Recommendation”
- **PPWG: 1998**
- **TWG on Biologics: 2010**

Agreement and outcome of ACCSQ-PPWG

(1) Harmonize of standards & requirements (Pharmaceuticals & vaccines)

- ACTD & ACTR on quality, non-clinical and clinical : Format, content, glossary of term
- ASEAN Guidelines: Stability study, BA/BE study, Process validation, Analytical validation, Post licensure variation (ASEAN Variation Guideline-AVG)
- ASEAN SOPs for conflict of interest and data confidentiality

(2) ASEAN Sectoral MRA on GMP inspection (for pharmaceutical products, excluding biopharmaceuticals)

- PIC/S membership
- Alternative approaches (determine the equivalency through assessment performed by a Panel of Expert comprising of members ASEAN Listed Inspection Service)

(3) Capacity building: ASEAN GLs implementation workshop, Learning from experts

(4) New challenges: Biosimilars, etc.

ACCSQ to support and implement GRP

- ASEAN approach for GRP implementation being recognized by **policy level**
- Harmonization of standards & requirements
- Provision of **flexibility** and **adaptability** to changes in regulation
- Reduction of work duplication through MRA
- Strengthening GMP implementation and enforcement
- Strengthening Quality Control Laboratories : Upgrade capacity to achieve intra- ASEAN/International recognition
- Developing Harmonized Template for Approved Product Information: Build harmonized health information and consumer protection tools
- Strengthening post marketing quality monitoring system: Build comparable consumer protection and quality assurance