Plen-shop: Regulatory ICH Countries: Current Harmonization Challenges and Future Opportunities

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Regulatory ICH Countries

• ICH was founded in 1990, mission to increase harmonization
• Regulatory divergence is a key challenge to speed up global patient access to new medicines while still maintaining the necessary standards for quality, safety, and efficacy
• Varying regulatory expectations and review times for marketing applications and postapproval changes cause complexity
• ICH participation has expanded - 15 Members and 24 Observers
• Regulators from ICH countries (FDA, EMA, PMDA, Health Canada, ANVISA) will share insights
  • Procedures for adoption of Quality guidelines in ICH member countries
  • Experiences of newly added ICH countries
  • Perspectives from established ICH countries on future ICH efforts
  • Suggestions for new ICH Quality topics
• For newly added ICH countries, what are the timelines and challenges for adoption of new and current quality guidelines?
• What are your thoughts on new ICH guidelines or revisions to existing guidelines?
• What are the audience’s experiences with country-specific vs ICH requirements in recent submissions?
• What are the plans regarding CTD implementation for new ICH countries?
• Can the regulators comment on CMC challenges for accelerated approvals of products with high unmet medical needs, and are there any plans for harmonization of requirements for these types of products (for example, stability, specifications, or validation)?
• Are there comments on other harmonization efforts (such as WHO or regional organizations)?