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ICH Reform – Industry's View

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Engineering the Future
of Generic + Biosimilar Medicines

Why Promote Regulatory Harmonization?

- Faster access to medicines around the world
- Better use of limited resources
- Reduced duplication
- Sharing experience and knowledge
- Fewer clinical trials needed
- Fewer animals needed for basic research
- Training and capacity building with regulators and industry will be key

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Impact of ICH Guidelines

In 2016, PhRMA conducted a survey of key stakeholders within our member companies on the value and benefits of ICH.

- 93% of survey respondents agree that existing ICH guidelines provide value in addressing intended challenges
- 87% of respondents rate the consistency of guideline implementation across regions as satisfactory, good or excellent
- Over 80% believe ICH is well-positioned for future regulatory harmonization efforts

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Looking Forward to New Opportunities Through the Recent ICH Reforms

- Expand and improve implementation of existing ICH guidelines in more regions around the world
  - e.g., new ICH regulatory members now include Brazil, South Korea, China, Singapore, Taiwan, with more poised to join

- Further decrease regulatory divergences in high-impact areas of regulatory science
  - e.g., GCP "Renovation," common protocol template, adaptive trial designs, continuous manufacturing, analytical methods, drug-drug interactions

- Sponsor forward-looking, strategic themes (including innovative areas of regulatory science) and topics for harmonization – address active disharmony and avoid future disharmony (proactive approach)
  - e.g., pharmacovigilance/safety reporting, modern drug development tools, enhancing the patient voice in drug development, new manufacturing technologies, etc.
  - ICH endorsed GCP and Quality Reflection Papers (with more under development)

Areas of Focus and Key Enablers to Advance Convergence of Regulatory Science Across the Globe

- New topics & strategic themes/long-term topics
- Forums outside ICH (e.g., APEC and WHO)
- Partnerships (e.g., joint new topic / strategic proposals)
  - Regulators
  - Sister industry associations
- Training and capacity building in partnership with regulators and academia
- ICH Implementation – 3rd party assessment tool

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Connecting the Dots

Opportunity to strategically connect the ICH infrastructure that develops harmonized guidelines to other regulatory training and capacity initiatives globally

APEC Regulatory Harmonization Steering Committee: Strategic Framework for Regulatory Convergence for Medical Products by 2020 **6 Priority Work Areas and Centers of Excellence (CoE) training model:**	**ICH Training Subcommittee:** **ICH training pilots/programs with trusted training providers on prioritized ICH guidelines (per survey of ICH members & observers)** **Training partners & targeted guidelines:**
• **MRCT/GCP** - Japan PMDA, Peking U., Duke NUS, Harvard MRCT • **Pharmacovigilance** – PMDA, KIDS, Peking U. • **Supply chain integrity** – USP, University of Tennessee • **Biotherapeutics/biosimilars** - Northeastern University • **Good regulatory management** - RAPS w/ Taiwan FDA, Mexico COFEPRIS • **Cell therapies**	• Duke NUS - Series of Q guidelines, E17 • Harvard MRCT- E6, E5, E17 • Northeastern University - Q1, Q5 • RAPS- M4/M8 CTD/eCTD • DIA – multiple areas of regulatory science Future/potential partners: • Peking University – E17, E5, E6; E2 series • Korea KIDS – E2 series

THANK YOU

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