



**Asia-Pacific
Economic Cooperation**

2020/CTI/A2C2-2/005

**Overview of the APEC Life Sciences Innovation
Forum Regulatory Harmonization Steering
Committee**

Submitted by: RHSC



**Eleventh APEC Alliance for Supply Chain
Connectivity Meeting
29 October 2020**

Overview of the APEC LSIF Regulatory Harmonization Steering Committee

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October 2020

**Regulatory Harmonization
Steering Committee**



**Asia-Pacific
Economic Cooperation**



**Life Sciences
Innovation Forum**

Regulatory Harmonization Steering Committee

- Mission: facilitate regulatory cooperation among medical product regulatory authorities, build human capacity in regulatory science among medical product regulatory staff, and promote political will for convergence among regulatory policymakers in APEC
- Est 2009
- Scope: Pharmaceutical Products & Medical Devices
- Members:
 - Regulators from APEC Economies
 - Industry coalitions:
 - Research-based Pharmaceuticals
 - Medical Devices
 - Generic Pharmaceutical
 - Biotechnological Products
 - Advanced Therapies
 - CoE Coalition of Training Partners

RHSC Guiding Principles

- Mandate: To promote a more strategic, effective and sustainable approach to regulatory convergence
- RHSC doesn't produce harmonized guidances - promotes use & implementation of existing international standards, guidelines and best practices
- Voluntary basis for engagement: ensures participation of those economies interested and committed to cooperation
- Leverage work with other international harmonization initiatives to avoid duplication of work & most effective use of resources

Regulatory Convergence

Voluntary process whereby regulatory requirements across economies become more aligned over time as a result of the adoption of internationally recognized technical guidances, standards and best practices

- It does not seek to establish new or change existing legal frameworks, laws, or regulations. It does not require regulators to be subject to any outside authority or prevent regulatory authorities from protecting and promoting public health. It does not have a specific endpoint; regulatory convergence is never “complete” or “achieved” as new products are developed, new standards are established, and new regulatory staff begin careers.
- **Regulatory reliance:** a regulatory authority in one jurisdiction may take into account and give significant weight to – i.e., totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

Focussed Workstreams: Priority Work Areas (PWAs)

(Champion Regulatory Authorities)

- Multi Regional Clinical Trails and Good Clinical Practices Inspections (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutics (US)
- Advanced Therapies (Singapore, US,)
- Good Registration Management (Chinese Taipei, Japan)
- Medical Devices (Japan, Korea, US)
- **Global Supply Chain Integrity (US)**

APEC Training Centers of Excellence for Regulatory Science (CoEs)

- **CoE Operating Model:** define operations
- **PWA Roadmap:** defines key issues, its importance, identifies gaps in capacity, prioritizes needs
- **Core Curriculum:** required elements based on relevant international standards & guidelines that are needed in order to meet the training objectives of the CoEs; promotes consistency in programming CoE-to-CoE
- **Library:** internationally-recognized standards upon which Core Curriculum is based
- **KPIs:** measurable Key Performance Indicators to demonstrate progress over time
- **Accomplishments:** first APEC CoEs endorsed Feb 2017; currently 24 CoEs across 16 host institutions in 9 APEC economies

Global Medical Product Quality & Supply Chain Security PWA



“Final Report: APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security”

Supply Chain Security Toolkit

Contains training materials intended to educate regulators, industry members, and others on specific parts of the supply chain, including items such as best practices, guidance documents



Global Medical Product Quality & Supply Chain Security Centers of Excellence

- **USP** : Rockville, Maryland, USA
- **University of Tennessee Health Sciences Center:**
Memphis, Tennessee, USA
- **Taylor's University:** Malaysia

Thank you