Update from APEC LSIF-RHSC

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TFDA, Chinese Taipei

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Asia-Pacific Economic Cooperation

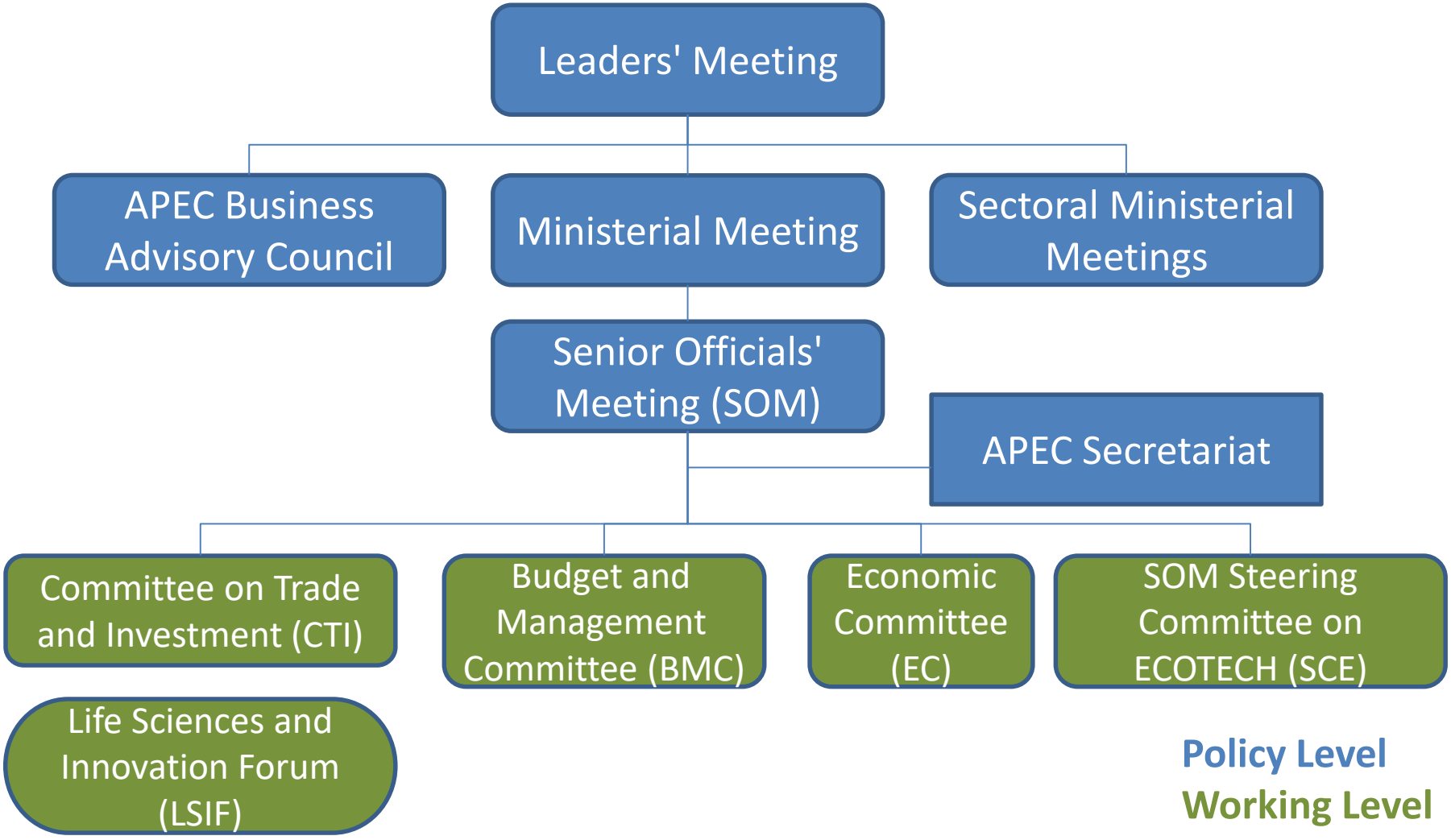
Regulatory Harmonization Steering Committee

Life Sciences Innovation Forum

APEC Member Economies

- Australia
- Brunei Darussalam
- Canada
- Chile
- People's Republic of China
- Hong Kong, China
- Indonesia
- Japan
- Republic of Korea
- Malaysia
- Mexico
- New Zealand
- Papua New Guinea
- Peru
- The Republic of the Philippines
- The Russian Federation
- Singapore
- Chinese Taipei
- Thailand
- United States of America
- Viet Nam

APEC Structure



- Regulatory Harmonization Steering Committee (RHSC)

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 activities
- Leverage work with other international harmonization initiatives to avoid duplication of work & most effective use of resources

Priority Work Areas (PWAs)

- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan and Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US and BIO)
- Advanced Therapy Products (Singapore and US)
- Good Registration Management (Chinese Taipei and Japan)
- Global Supply Chain Integrity (US)
- Medical Devices (Japan, Korea, and US)

Medical Device PWA

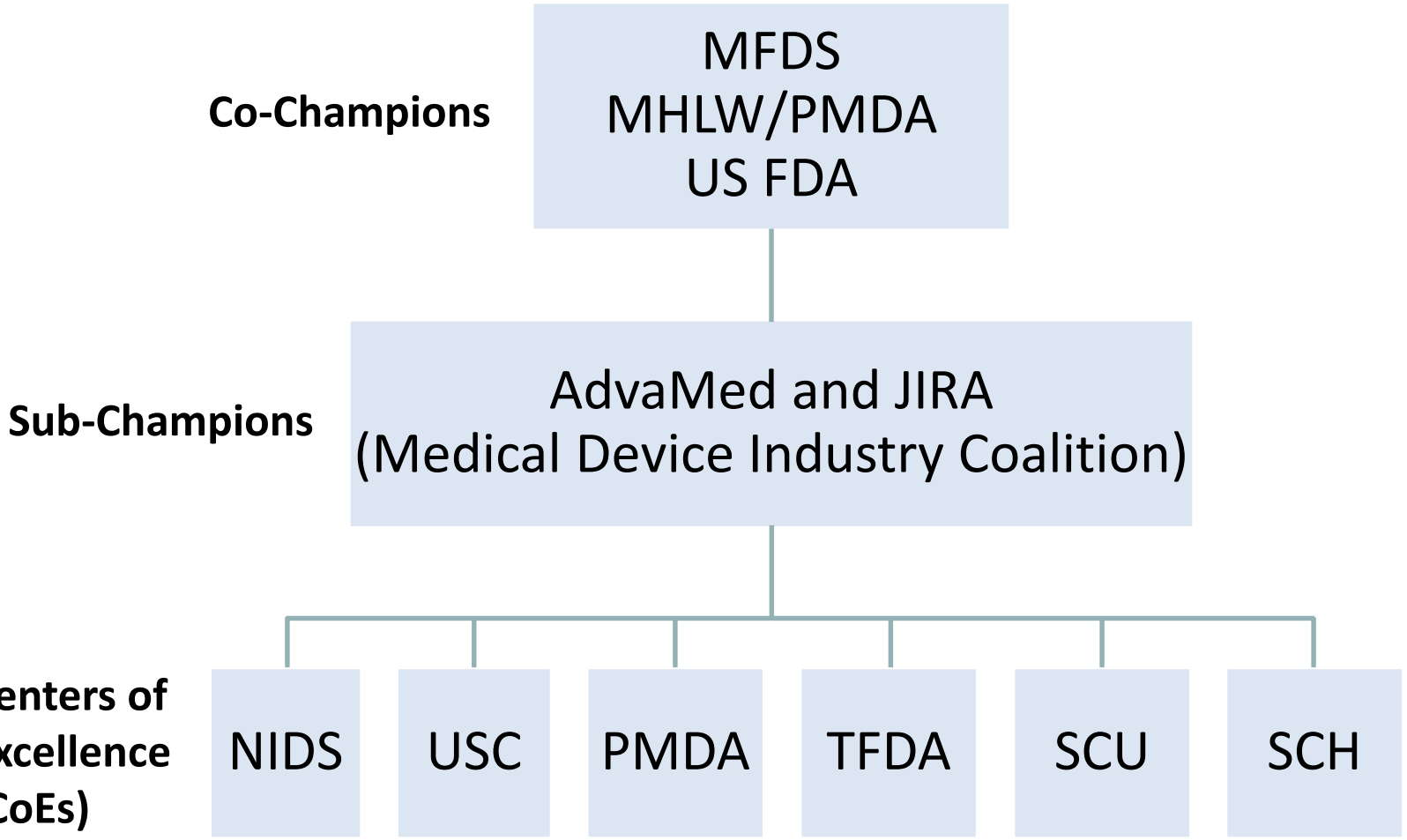
Goals of PWA:

- Promote international harmonization initiatives (i.e., GHTF/IMDRF guidance documents)
- Build regulatory capacity and knowledge
- Support harmonized implementation efforts among APEC economies

Medical Device PWA Roadmap

- Promotes regulatory convergence for medical device regulatory systems
- Focuses on training and education efforts related to topics across the Total Product Life Cycle (TPLC) of medical devices:
  - Premarket
  - Postmarket
  - Quality Management System (QMS)

Medical Device PWA Structure



*Current Pilot CoEs: Duke-NUS Singapore; Northeastern University; and Medical Device Authority, MOH Malaysia (endorsed in principle).

Centers of Excellence (CoEs)

- The Vision
  - A sustainable platform for promoting regulatory convergence, capacity and cooperation in areas of medical products
  - Science and best practice focus

- The Approach
  - Partnership among training institutions/organizations, regulators and industry, to deliver and maintain educational programs
  - CoE Host Institutions collaborate with PWA Champions, PWA Steering Committee and CoE Coalition

- Follow defined principles in CoE Operating Model

- Ensure quality & consistent training programs via PWA Roadmap, Core Curriculum, Training Objectives, Performance Indicators & periodic assessments

Recent Activities & Future Plans

- Virtual Meetings held in May & Oct 2021
- RHSC Website continually updated by RHSC Secretariat
- All PWAs are encouraged to revise their roadmap using the new template, review and update their Core Curriculum and KPIs, and host PWA Steering Committee meetings at least twice a year
- Plan for assessments of current CoEs – 5yr MoUs expiring in 2022
- Continue our work in accordance with LSIF endorsed *2030 Vision and Strategic Framework*

2021 CoE Programs

Priority Work Area	CoE/Pilot	Organization	Location	Dates
Advanced Therapy Products	Pilot CoE	USP	Virtual	2, 4, 9, 10 Mar 2021
Biotherapeutic Products	CoE	Kobe University	Virtual	1-3 Dec 2021
Global Supply Chain Integrity	CoE	Taylor's University & USP	Virtual	27 Jan 2021
Global Supply Chain Integrity	CoE	Taylor's University & USP	Virtual	24 Feb 2021
Global Supply Chain Integrity	CoE	Taylor's University & USP	Virtual	11-12 Mar 2021
Global Supply Chain Integrity	CoE	USP		8 Dec (Americas)/9 Dec (Asia), 2021
Good Registration Management	CoE	Thai FDA	Virtual	9-11 Aug 2021
Good Registration Management	CoE	TFDA with RAPS Taiwan Chapter	Virtual	Online Self-Learning Lectures: 24 Aug-16 Sep Live Videoconferences: 14-16 Sep
Medical Devices	CoE	USC	Virtual	6-9 Apr 2021
Medical Devices	CoE	SCU	Virtual	Labeling: 24-27 May 2021
Medical Devices	CoE	TFDA	Virtual	28 Aug-11 Sep 2021
Medical Devices	CoE	SCH	Virtual	1-21 Sep 2021
Medical Devices	CoE	NIDS	Virtual	27 Sep-8 Oct 2021
Medical Devices	CoE	PMDA	Virtual	15-17 Nov 2021
MRCT/GCP	CoE	PMDA & NCC Japan	Virtual	Online Self-learning: 11-15 Jan 2021 Online Live Sessions: 18-21 Jan 2021
MRCT/GCP	CoE	PKU	Virtual & In-person	Online Self-learning: 14 Jun-13 July 2021 Virtual + Onsite Live Sessions: 13-15 July 2021
MRCT/GCP	CoE	KoNECT	Virtual	Online Self-learning: 3-9 Oct 2021 Online Live Sessions: 13-14 Oct 2021
MRCT/GCP	CoE	MRCT Center	Virtual	10-module Online course – ongoing (from Feb 2020
Pharmacovigilance	CoE	PMDA	Virtual	1-4 Feb 2021
Pharmacovigilance	CoE	KIDS	Virtual	8-10 Sep 2021
Pharmacovigilance	CoE	PKU	Virtual & In-person	31 Oct-4 Nov 2021

2022 CoE Programs

Priority Work Area	CoE/Pilot	Organization	Location	Dates	Target Audience
Advanced Therapy Products	CoE	USP	Virtual	19-20 Jan (Americas)/ 20-21 Jan (Asia), 2022	Regulators only
Advanced Therapy Products	CoE	NEU	TBC	Early 2022	
Biotherapeutic Products	CoE	NEU	TBC	Mid 2022	
Good Registration Management	CoE	TFDA with RAPS Taiwan Chapter	TBC	2nd half of 2022	
Good Registration Management	CoE	Thai FDA	TBC	Late July 2022	
Medical Devices	CoE	USC	TBC	11-17 Mar 2022	
Medical Devices	CoE	NIDS	Virtual	17-21 Oct 2022	
Medical Devices	CoE	SCH	TBC	Sept 2022 (TBA)	
Medical Devices	Pilot CoE	NEU	In-person	TBA	
MRCT/GCP	CoE	PMDA & NCC Japan	Virtual	Online Self-learning + Online Live Sessions: 18-21 Jan 2022	Regulators only
MRCT/GCP	CoE	MRCT Center	Virtual	10-module Online course – ongoing (from Feb 2020	Open to All
MRCT/GCP	CoE	MRCT Center	Virtual	Trainings upon request in Egypt, UAE,AVAREF region: Q1 2022	
MRCT/GCP	CoE	MRCT Center	Virtual	ICH Guideline training: TBA	
MRCT/GCP	CoE	PKU	Virtual & In-person	Q2 2022	
MRCT/GCP	CoE	KoNECT	Virtual & In-person	10-12 Oct 2022	
Pharmacovigilance	CoE	PMDA	Virtual	31 Jan-4 Feb 2022	Regulators only

Thank you!