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International Medical Device Regulators Forum

EU2023
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Update on Medical Device PWA of APEC RHSC

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European Commission

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OVERVIEW

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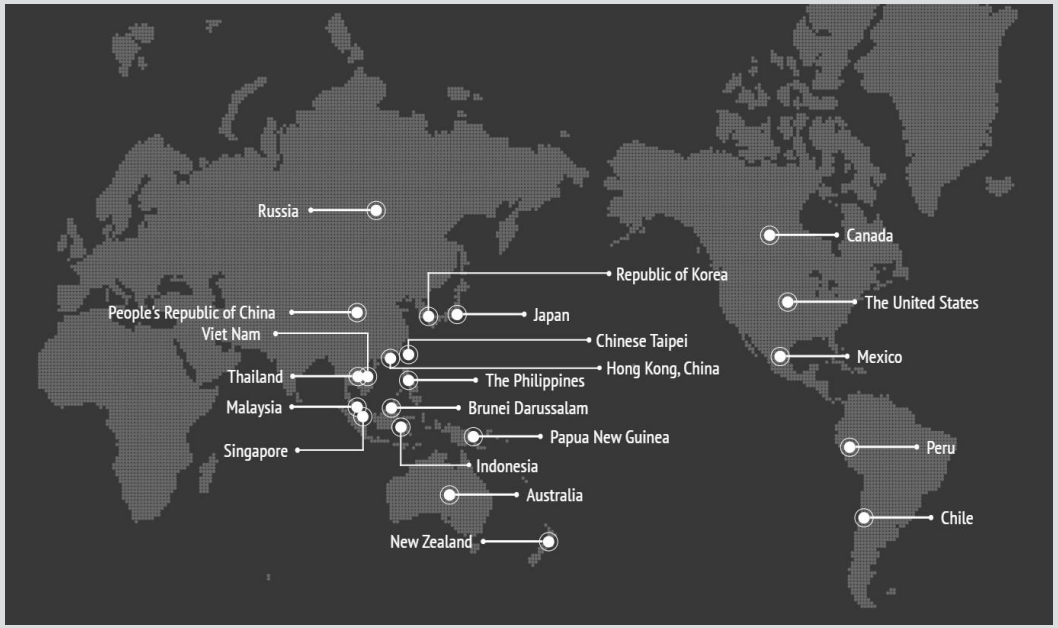
Asia-Pacific Economic Cooperation (APEC)

APEC

21 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; and Viet Nam.



https://www.apec.org/about-us/about-apec/member-economies

Asia-Pacific Economic Cooperation

APEC RHSC

- **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 and reliance among regulatory policymakers in APEC
- **Establishment**: 2009
- **Scope**: Pharmaceutical Products & Medical Devices
- **Members**:
  - Regulators from APEC Economies
  - Industry coalitions:
    - Research-based Pharmaceuticals
    - Medical Devices
    - Generic Pharmaceuticals
    - Biotechnological Products
    - Advanced Therapies
  - CoE Coalition of Training Partners

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RHSC Priority Work Areas

Priority Work Areas (PWAs)

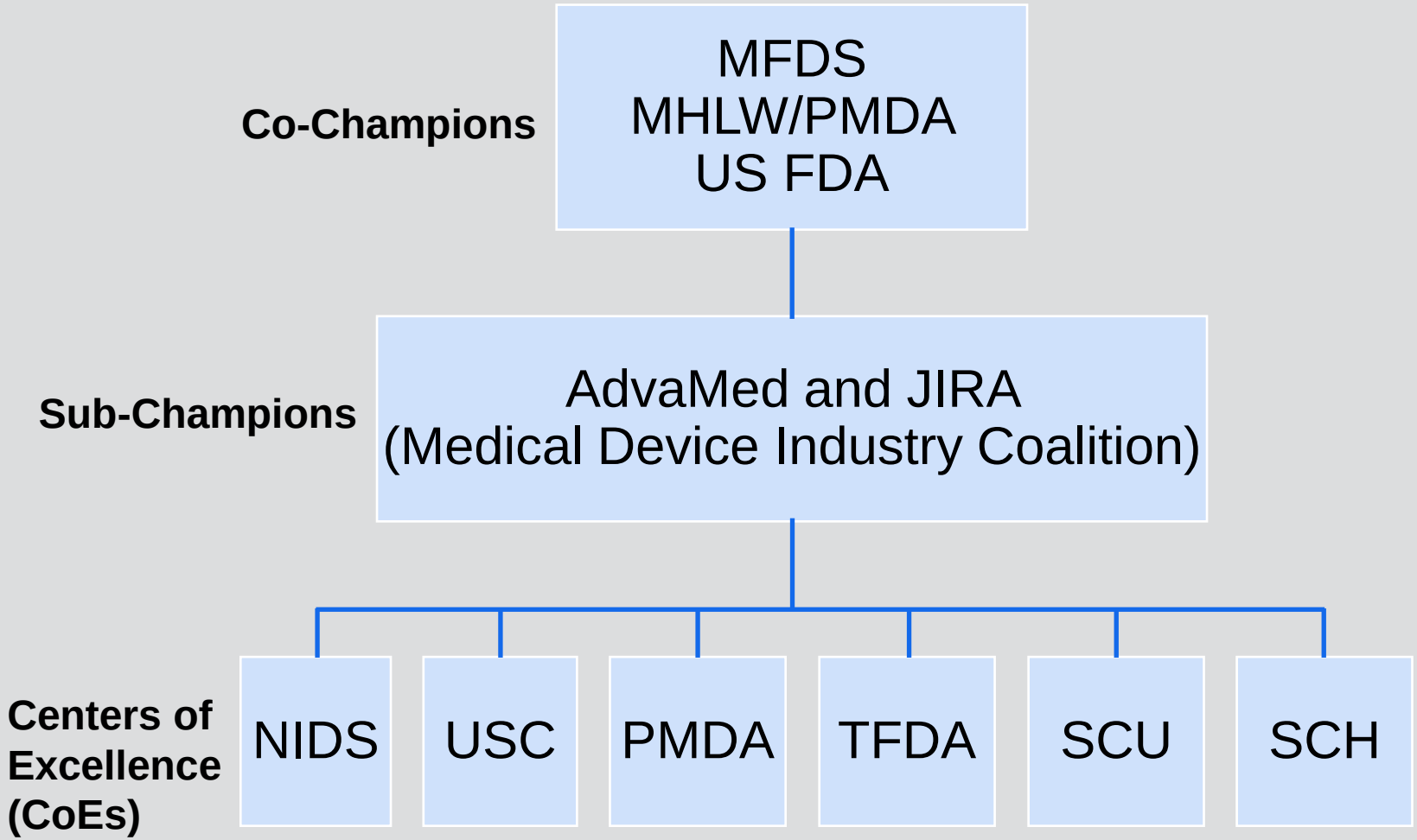
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US, BIO)
- Advanced Therapy Products (Singapore, US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity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



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)

PWA Core Curriculum

- Annex to the PWA roadmap
- “Reference library” of harmonized guidance documents on TPLC topics
- Medical Device PWA includes specified GHTF/IMDRF documents
- Both medical devices and in vitro diagnostic (IVD) medical devices are inclusive
- Co-Champions continuously update Core Curriculum with intersessional approval

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Center of Excellence Programs

CoE Programs Held since IMDRF-23

CoE	Economy	Program	Format	Date
Taiwan Food and Drug Administration (**TFDA**)	Chinese Taipei	2023 APEC Medical Devices Regulatory Science CoE Workshop	In-Person & Virtual	29-31 Aug

CoE Programs Planned for 2023

CoE	Economy	Planned Program	Format	Date
University of Southern California (**USC**)	United States	Medical Devices 2023: Harmonizing Medical Device Regulation	In-Person & Virtual	12-13 Oct
Pharmaceutical and Medical Devices Agency (**PMDA**)	Japan	Medical Devices Review (APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023)	Virtual	14-16 Nov
Soonchunhyang University (**SCH**)	Korea	2023 SCH APEC Medical Device CoE Training	In-Person & Virtual	7-8 Nov (In-Person) & 1-24 Nov (Virtual)
Sichuan University (**SCU**)	China	(CoE workshop)	TBC	TBC
Northeastern University (**NEU**)	United States	(Pilot CoE workshop)	TBC	TBC

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Next Steps

Next Steps

- APEC Senior Officials and Ministers continue to find a new home organization for RHSC under the APEC umbrella.
- To further regulatory convergence and cooperation efforts, RHSC held a face-to-face meeting on 12 April 2023 in Oakland (USA) and is considering the next meeting for December 2023.
- Work is to be continued in accordance with RHSC Vision 2030 and Strategic Framework.

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THANK YOU / QUESTIONS

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