IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

15:55 – 16:10

Asia-Pacific Economic Cooperation (APEC)

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European Commission | European Union

IMDRF International Medical Device Regulators Forum

Update on Medical Device PWA of RHSC

APEC Co-Champion Economies:

Japan – MHLW/PMDA

South Korea – MFDS

USA – FDA

APEC Asia-Pacific Economic Cooperation

IMDRF Stakeholder Open Forum 28 March 2023

Priority Work Areas (PWAs)

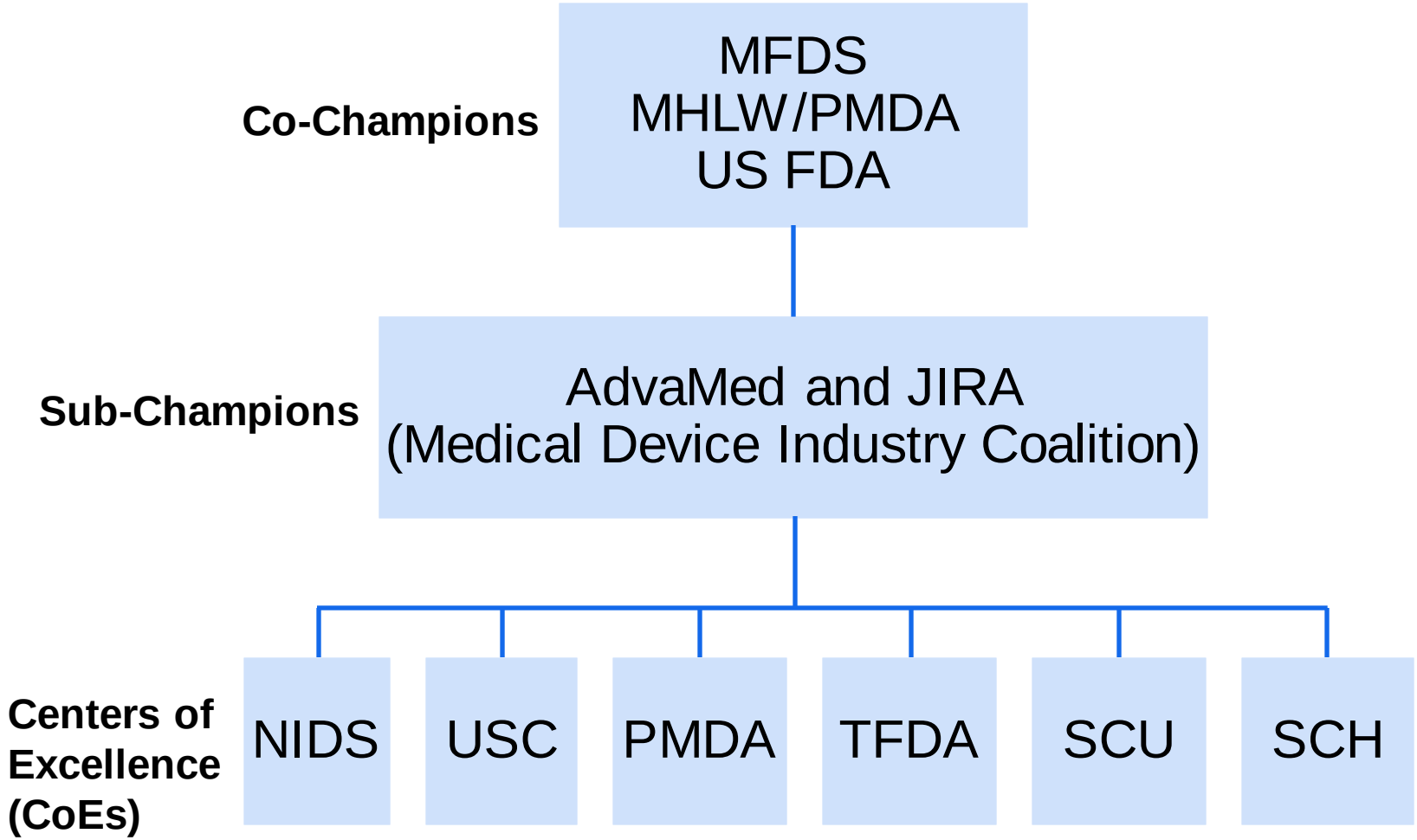
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US, BIO)
- Advanced Therapy Products (Singapore, US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity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

CoE Programs Held in 2022 since Last Open Forum

CoE	Economy	Program	Format	Date
SCH	Korea	2022 SCH APEC Medical Device CoE Training	In-Person & Virtual	Nov. 7 - 8 & Nov. 9 - 23
PMDA	Japan	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of / Insight into the IMDRF Documents	Virtual	Nov. 14 - 16
SCU	China	2022 APEC Center of Excellence Training of the Review and Supervision of Implant Medical Devices	Virtual	Dec. 12 - 15

CoE Programs Planned for 2023

CoE	Economy	Planned Program	Format	Date
TFDA	Chinese Taipei	2023 APEC Medical Devices Regulatory Science CoE Workshop	In-Person & Virtual	Sept. 5 - 7
PMDA	Japan	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023	Virtual	Nov. 14-16
USC	United States	(CoE workshop)	In-person	Tentative (May)
SCH	Korea	(CoE workshop)	In-Person & Virtual	Tentative (Oct or Nov)
NEU	United States	(Pilot CoE workshop)	TBC	TBC

Next Steps

- Terms of Reference of APEC LSIF expired at the end of March 2022.
- RHSC is actively seeking a suitable home under APEC to continue regulatory convergence and cooperation efforts for medical products.
- A face-to-face meeting in Oakland, California, on 13-14 April 2023 will review the current work and strategize on the future of RHSC.
- Work is to be continued into 2023 in accordance with Vision 2030 and Strategic Framework.

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Thank you