



IMDRF International Medical
Device Regulators Forum

Update on Medical Device PWA of RHSC



**Asia-Pacific
Economic Cooperation**

APEC Co-Champion Economies:

Japan – MHLW/PMDA

South Korea – MFDS

USA – FDA



Priority Work Areas (PWAs)

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



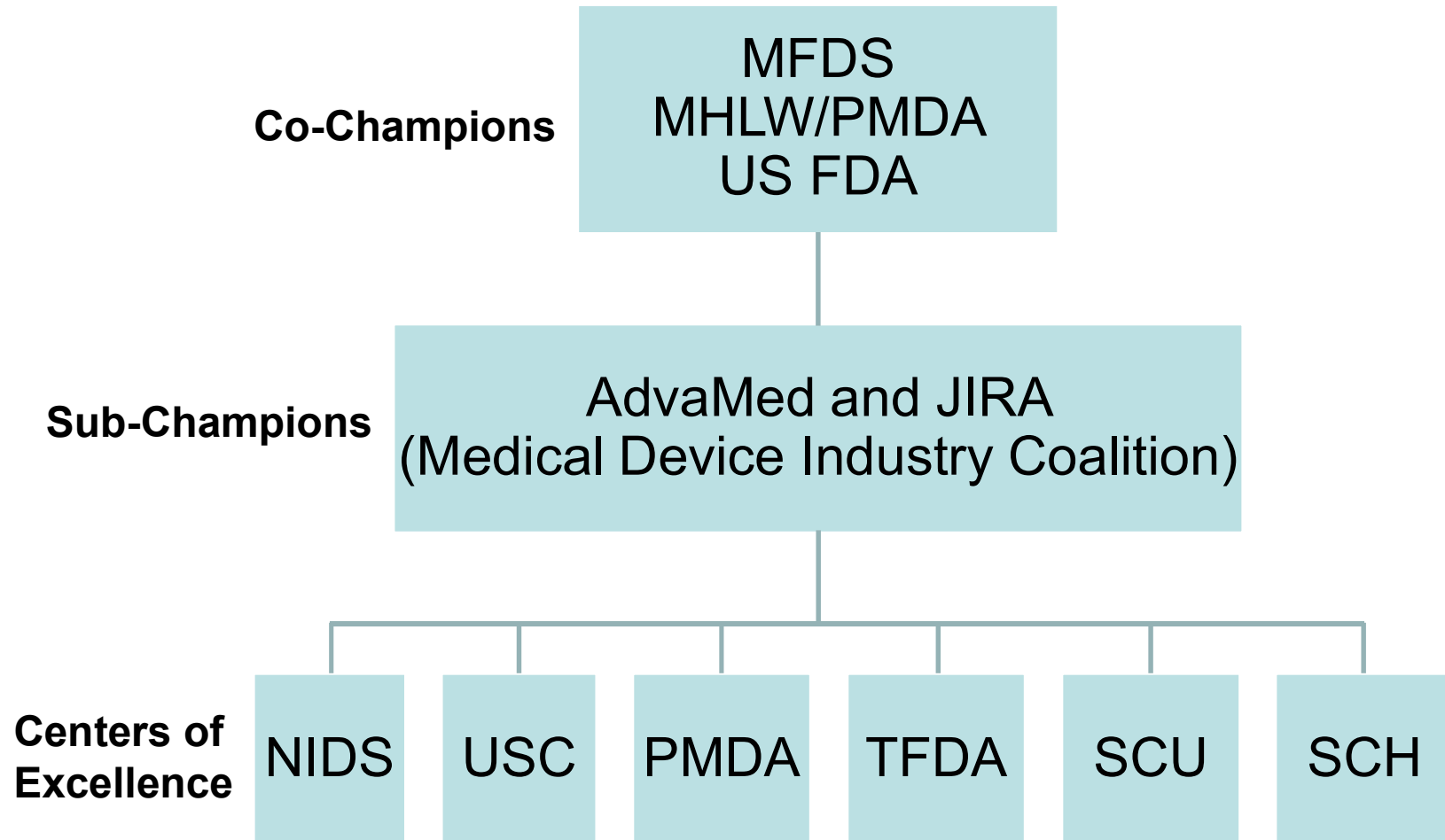
Medical Device PWA

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



Center of Excellence (1/2)

- 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



Center of Excellence (2/2)

- Follows principles in CoE Operating Model
- Ensures quality & consistent training programs via PWA roadmap, Core Curriculum, performance indicators & periodic assessments



CoE Activities in 2020

2020	DEC	APEC Centers of Excellence Established Soonchunhyang University (SCH), Korea
	NOV	APEC CoE Training (Virtual) National Institute of Medical Device Safety Information (NIDS), Korea
	NOV	APEC CoE Training (Virtual) Pharmaceuticals and Medical Devices Agency (PMDA), Japan
	OCT-NOV	APEC Pilot CoE Training (Virtual) Soonchunhyang University (SCH), Korea
	AUG-SEP	APEC CoE Training (Virtual) Taiwan Food and Drug Administration (TFDA), Chinese Taipei
	JUN	APEC Centers of Excellence Established Sichuan University (SCU), China Pharmaceuticals and Medical Devices Agency (PMDA), Japan Taiwan Food and Drug Administration (TFDA), Chinese Taipei
		APEC Pilot Center of Excellence established Soonchunhyang University (SCH), Korea Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School, Singapore



2020 CoE Training Programs

CoE	Economy	Program	Format	Date
TFDA	Chinese Taipei	2020 APEC Medical Devices Regulatory Science Center of Excellence Workshop	Online	Aug. 29 - Sep. 11
SCH	Korea	2020 AHC-SCH Medical Device CoE Pilot Training	Online	Oct. 26 - Nov. 17
PMDA	Japan	PMDA-ATC Medical Devices Webinar 2020	Online	Nov. 16-20
NIDS	Korea	2020 NIDS-APEC Medical Device Vigilance CoE Training	Online	Nov. 18-24



2021 CoE Training Programs

CoE	Economy	Planned Program	Format	Date
SCU	China	The trainings of UDI and Clinical Trial (TBC)	TBA	TBA
PMDA	Japan	PMDA-ATC Medical Devices Webinar 2021	TBA	TBA
NIDS	Korea	2021 NIDS APEC Medical Device Vigilance CoE Training	TBA	Oct.
TFDA	Chinese Taipei	2021 APEC Medical Devices Regulatory Science Center of Excellence Workshop	TBA	Q3
USC	United States	CoE Training by University of Southern California	Online	Apr.
SCH	Korea	2021 SCH APEC Medical Device CoE Training	Online	TBA
CoRE	Singapore			
NEU	United States	Pilot CoE Training by Northeastern University	TBA	2 nd half



Next Steps

- Continue to conduct CoE training programs
- Revise PWA roadmap
 - Initiate the drafting
 - Hold Steering Committee teleconferences or meetings
- Update Core Curriculum as needed



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Thank you