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)

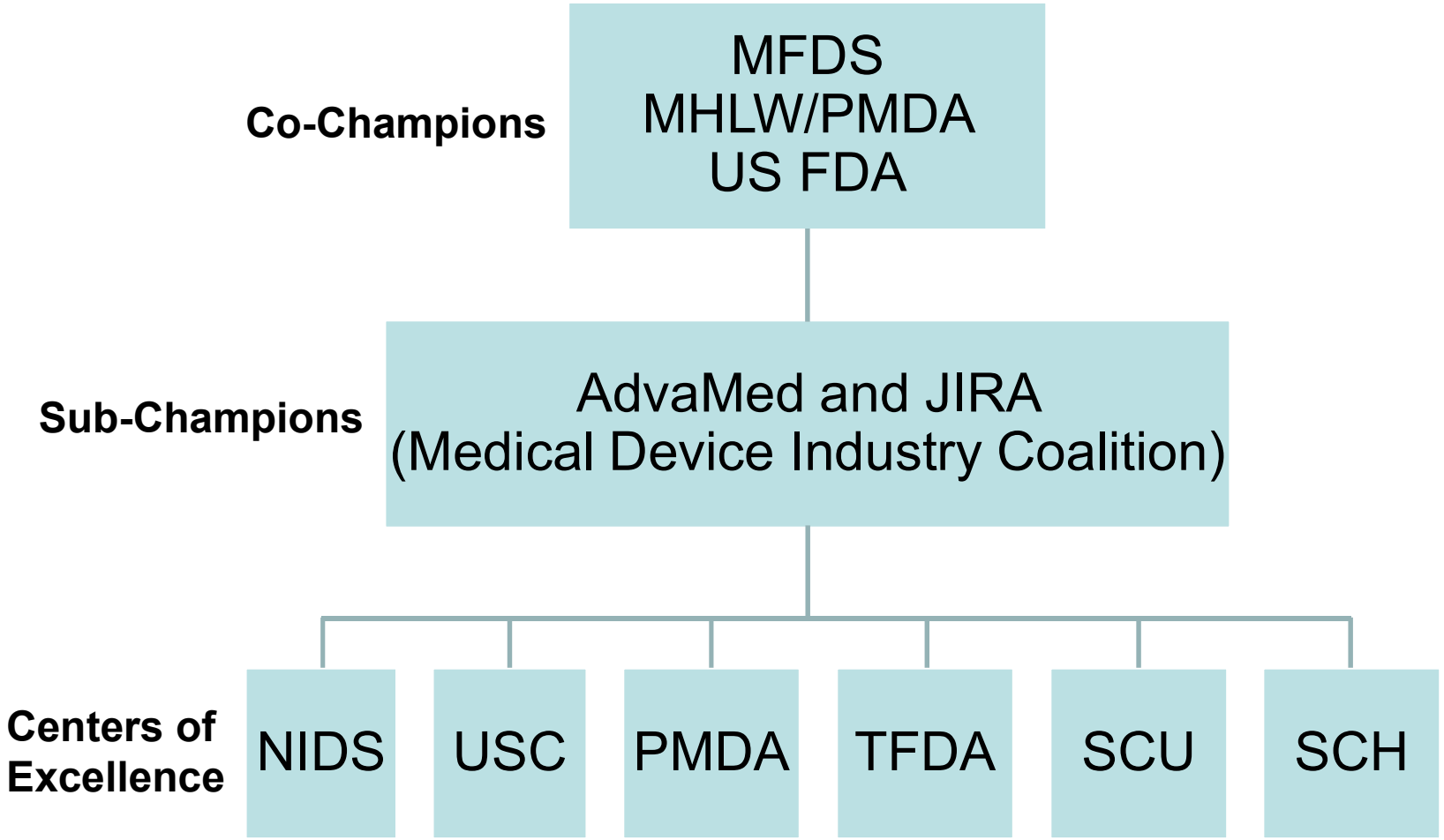
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US, BIO)
- Advanced Therapy Products (Singapore, US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity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

Center of Excellence (1/2)

- The Vision
  - A sustainable platform for promoting regulatory convergence, capacity and cooperation in PWAs relevant to medical product regulation
  - Focus of convergence is on regulatory science and best practices
- 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

2021 CoE Training Programs (1/2)

CoE	Economy	Program	Format	Date
USC	United States	Medical Devices 2021: Regulatory Harmonization of Non-Clinical and Clinical Development	Online	Apr. 6 - 9
SCU	China	2021 APEC Center of Excellence Training of the Labeling for Medical Devices and IVD Medical Devices	Online	May 24 - 28

2021 CoE Training Programs (2/2)

CoE	Economy	Planned Program	Format	Date
TFDA	Chinese Taipei	2021 APEC Medical Devices Regulatory Science Center of Excellence Workshop	Online	Aug. 28 - Sept. 11
NIDS	Korea	2021 NIDS APEC Medical Device Vigilance CoE Training	Online	Sept. 9 - Oct. 1
SCH	Korea	Clinical Performance Evaluation for Regulatory Decision Making	Online	Sept. 1 - 17
PMDA	Japan	PMDA-ATC Medical Devices Webinar 2021	Online	Nov. 15 - 17
CoRE	Singapore			
NEU	United States	Pilot CoE Training by Northeastern University	Online	Q4

Next Steps

- Co/Sub-champions discussed the following on May 17, 2021:
  - No concerns with the current core curriculum but will review it after IMDRF-20 in September
  - Will currently focus on training that adheres to core curriculum when holding RHSC forums
- Will revise PWA roadmap

Asia-Pacific Economic Cooperation

Thank you