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)

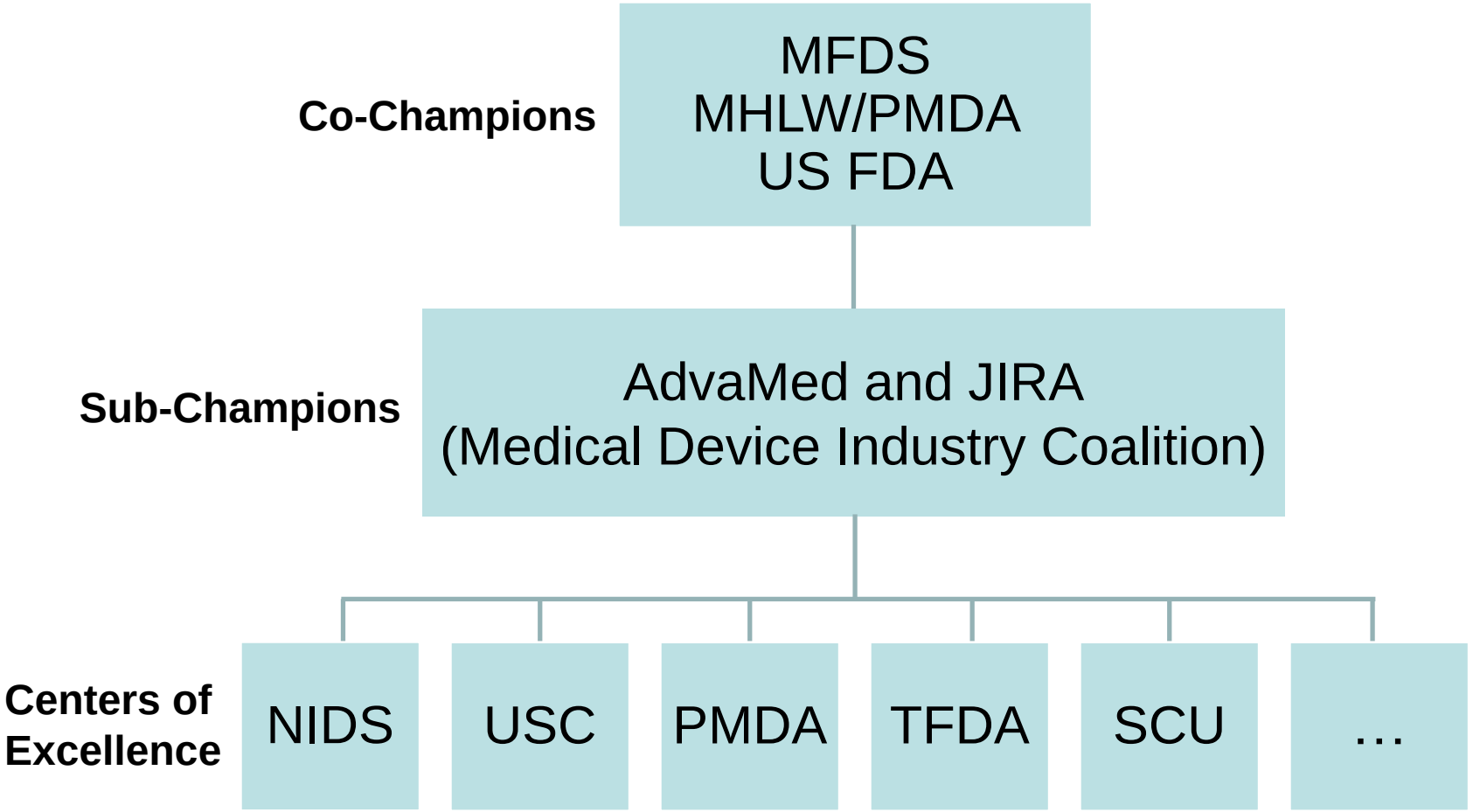
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Korea)
- Advanced Therapy Products (Singapore)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (US)
- **Medical Device**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

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

CoE Training Activities in 2019

Official CoEs	CoE Workshops	Pilot CoE Workshops
• National Institute of Medical Device Safety Information (NIDS) • University of Southern California (USC), Department of Regulatory and Quality Sciences	• NIDS-APEC Medical Device Vigilance CoE Training, Seoul, Korea, November 2019	• Taiwan Food and Drug Administration, Taipei City, Chinese Taipei, October 2019 • PMDA-Asia Training Center, Tokyo, Japan, November 2019 • Sichuan University, Chengdu, China, December 2019

Next Steps

- CoE training workshops to be held in:
  - 2020 Q3 by TFDA
  - 2020 Q4 by NIDS
  - 2020 Q4 by PMDA
- Update of PWA roadmap and Core Curriculum to be continued

Thank you