Update on Medical Device PWA of RHSC

Asia-Pacific Economic Cooperation

APEC Co-Champion Economies:

Japan – PMDA

South Korea – MFDS

USA – FDA

Priority Work Areas (PWAs)

- Multi Regional Clinical Trials and Good Clinical Practices Inspections (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutics (Korea)
- Advanced Therapies (Singapore)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (USA)
- **Medical Devices** (Japan, Korea, USA) – NEW!

Medical Device PWA

Aims to:

- Promote international harmonization initiatives (i.e., IMDRF and former GHTF guidance documents)
- Build regulatory capacity and knowledge
- Support harmonized implementation efforts among APEC economies

Activities since IMDRF-14

- Endorsed Roadmap and Core-Curriculum of Medical Device PWA in Nov. 2018
- Assigned Medical Device Coalitions (AdvaMed and JIRA) as Sub-Champions
- Identified Pilot CoEs
  - CoE pilot program about Medical Device Vigilance conducted by NIDS in Sep. 2018
  - More pilot CoEs been endorsed

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)

Medical Device PWA Roadmap (2)

- Under this roadmap:
  - Co-Champions endorse a Core Curriculum and solicit Sub-Champions
  - Sub-Champions identify potential CoEs, conduct gap analysis, address key performance indicators (KPIs), etc.
  - CoEs conduct training programs and workshops
  - Assessment and feedback are obtained
  - Additional topics of convergence would be identified as needed

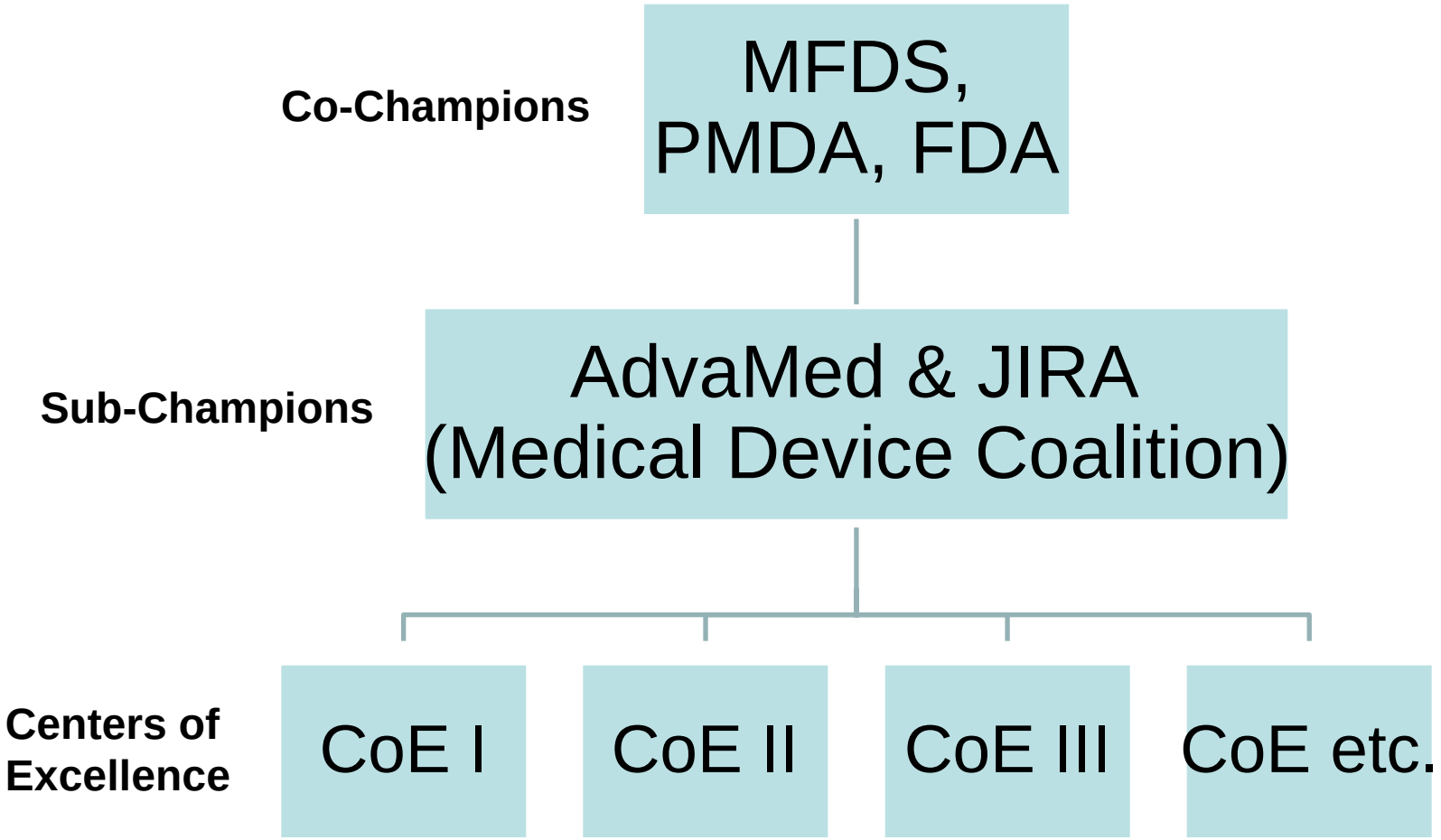
PWA Core Curriculum

- Annex to the PWA roadmap
- “Reference library” of harmonized guidance documents on TPLC topics
- GHTF/IMDRF documents are recognized core harmonized guidance documents in Medical Device PWA

PWA Core Curriculum (2)

- CoEs can select any number of the IMDRF and former GHTF guidance documents from the Core Curriculum to develop training programs and workshops
- Co-Champions continuously update Core Curriculum with intersessional approval
- Both medical devices and in vitro diagnostic (IVD) medical devices are inclusive

Medical Device PWA Structure



Pilot CoE Applicants

Name of institution	Topic		
	Pre market	QMS	Post Market
Duke-NUS	TBC		
NEU			
NIDS			
PMDA			
TFDA			
USC			

Summary and Next Steps

- Sub-Champions assigned and pilot CoEs identified
- Overarching roadmap with core curriculum endorsed
- Pilot CoEs endorsed and training programs to be conducted starting in April
- Launch of RHSC website planned for April 2019

Asia-Pacific Economic Cooperation

Thank you