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)

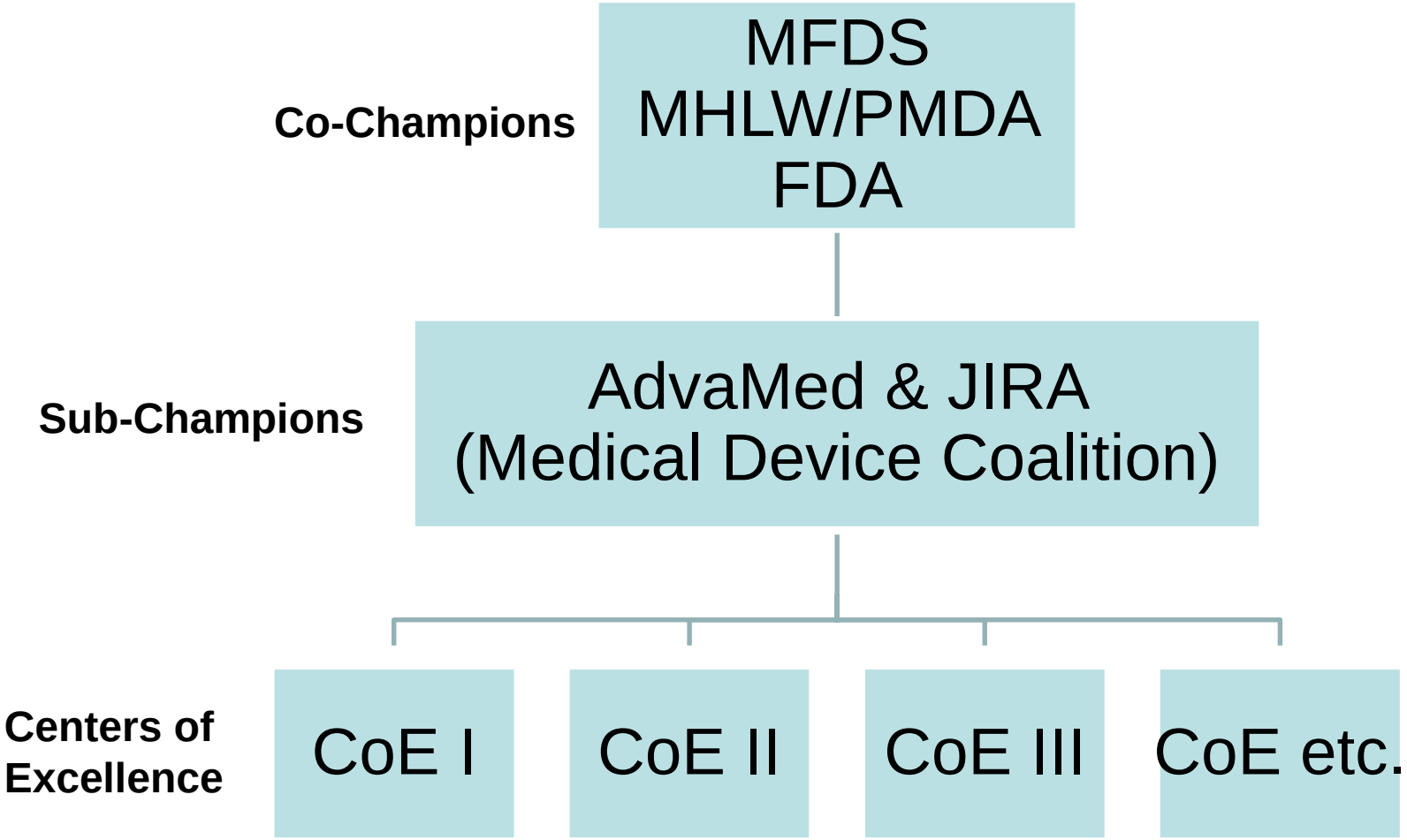
- Multi Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Korea)
- Advanced Therapy Products (Singapore)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (US)
- **Medical Device** (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
- GHTF/IMDRF documents are recognized core harmonized guidance documents in Medical Device PWA

Update of PWA Core Curriculum

Elements	GHTF/IMDRF Documents	GHTF/IMDRF Documents
Essential Principles of Medical Device Safety & Performance	Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (**GHTF**/SG1/N68:**2012**)	Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (**IMDRF**/GRRP WG/N47 FINAL:**2018**)
Role of Standards in the Assessment of Medical Devices	Role of Standards in the Assessment of Medical Devices (**GHTF**/SG1/N044:**2008**)	Role of Standards in the Assessment of Medical Devices (**GHTF**/SG1/N044:**2008**) Optimizing Standards for Regulatory Use (**IMDRF**/Standards WG/N51 FINAL:**2018**)
Principles of Labeling	Label and Instructions for Use for Medical Devices (**GHTF**/SG1/N70:**2011**)	Principles of Labelling for Medical Devices and IVD Medical Devices (**IMDRF**/GRRP WG/N52 FINAL:**2019**)

Center of Excellence (1/3)

- 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 (2/3)

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

Center of Excellence (3/3)

Name of Institution	Topic			Current Status (as of August 2019)
	Pre market	QMS	Post Market	
Duke-NUS				Planning CoE pilot submission
NEU				Planning CoE pilot workshop
NIDS				Formal CoE application endorsed
PMDA				CoE pilot workshop endorsed
TFDA				CoE pilot workshop endorsed
USC				Formal CoE application endorsed
SCU				Planning CoE pilot submission

Activities since IMDRF-15 (1/2)

- Key Performance Indicators (KPIs) of Medical Device PWA established and endorsed:
  - General KPIs
  - PWA KPIs
  - CoE & Pilot CoE KPIs
- RHSC website (www.apec.org/rhsc) launched in July 2019 under the main APEC website

Activities since IMDRF-15 (2/2)

- USC (University of Southern California) conducted a CoE pilot program from April 30 to May 3, 2019, and posted video recordings of the program
- NIDS (National Institute of Medical Device Safety Information) and USC applied to become formal CoE and received endorsement from RHSC on Aug. 15, 2019

Next Steps

- CoE pilot workshops to be held on:
  - 2019.10.22-24 by TFDA
  - 2019.11.25-29 by PMDA
  - 2019 Q4 (November) by NIDS
  - 2019 Q4 or 2020 Q1 by NEU
- Request received from Sichuan University (SCU) to host a CoE pilot workshop in Dec. 2019 with the intention to submit a CoE pilot application for intersessional review by RHSC
- Update of PWA roadmap and Core Curriculum to be continued

Thank you