



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)



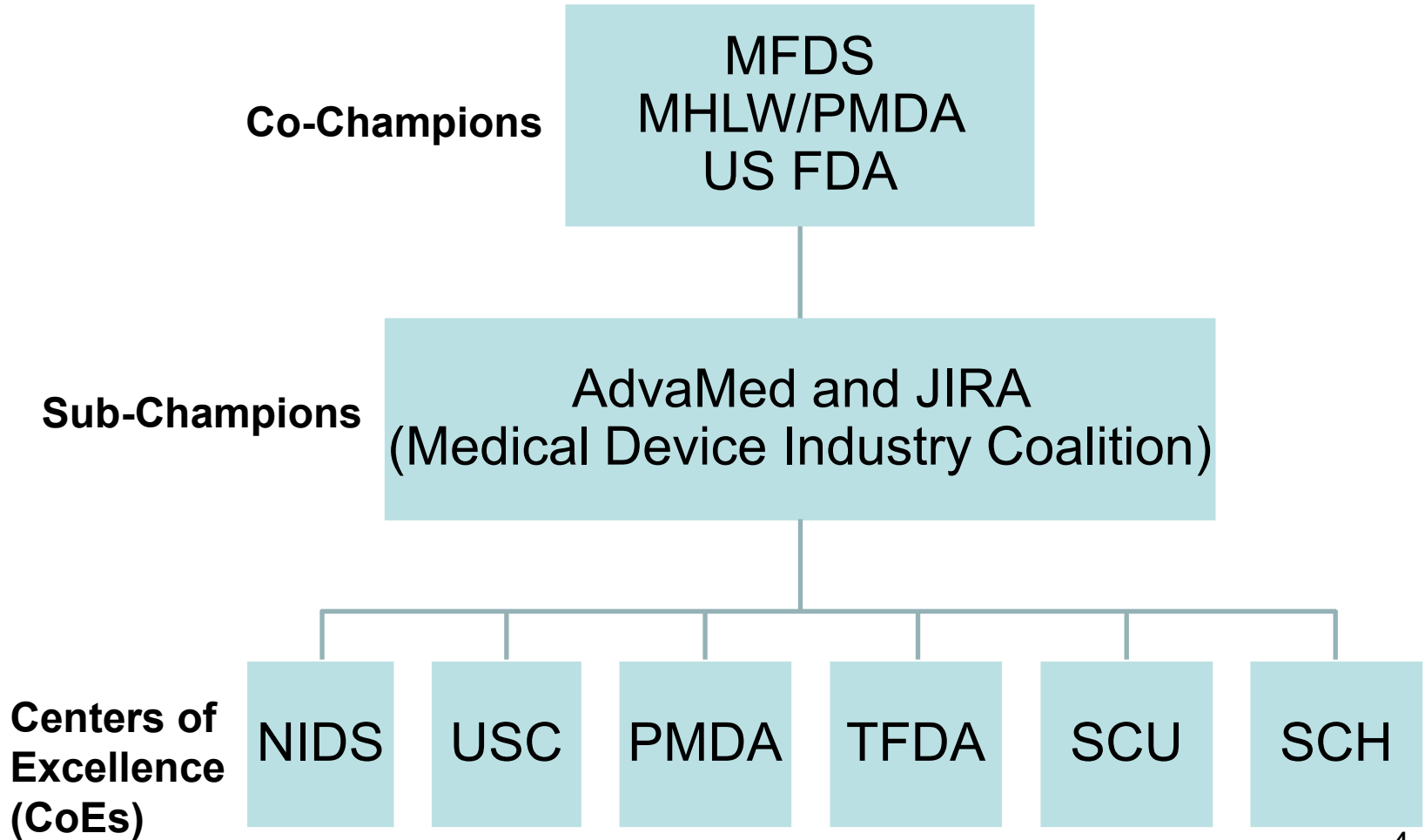
Medical Device PWA

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



CoE Programs Held in 2021 since Last Open Forum

| CoE | Economy | Program | Format | Date |
|------|----------------|---|--------|--------------------|
| TFDA | Chinese Taipei | 2021 APEC Medical Devices Regulatory Science CoE Workshop | Online | Aug. 28 - Sept. 11 |
| SCH | Korea | 2021 SCH Medical Device CoE Training | Online | Sept. 1 - 21 |
| NIDS | Korea | 2021 AHC-NIDS APEC Medical Device Vigilance CoE Training | Online | Sept. 14 - Oct. 15 |
| PMDA | Japan | PMDA-ATC Medical Devices Webinar 2021 | Online | Nov. 15 - 17 |



CoE Programs Planned for 2022

| CoE | Economy | Planned Program | Format | Date |
|------|---------------|--|-----------|------------------|
| NEU | United States | Pilot CoE Training by Northeastern University | In Person | TBA |
| SCU | China | CoE Training by Sichuan University | Online | TBA |
| PMDA | Japan | APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of/Insight into the IMDRF documents - | Online | Nov. 7 & 14 - 16 |



Next Steps

- Terms of Reference of APEC LSIF expired at the end of March 2022.
- RHSC is currently seeking new home forum in APEC to continue regulatory convergence and cooperation efforts for medical products.
- CoEs having workshop plans in 2022 may move forward with activities as planned.
- Work is to be continued in accordance with Vision 2030 and Strategic Framework.



IMDRF

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Thank you