Update on Medical Device PWA of RHSC

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

Co-Champions

MFDS, PMDA, FDA

Sub-Champions

AdvaMed & JIRA
(Medical Device Coalition)

Centers of Excellence

CoE I  CoE II  CoE III  CoE etc.
# Pilot CoE Applicants

<table>
<thead>
<tr>
<th>Name of institution</th>
<th>Topic</th>
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<td></td>
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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
Thank you