Update on Medical Device PWA of RHSC

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

Co-Champions

MFDS
MHLW/PMDA
US FDA

Sub-Champions

AdvaMed and JIRA
(Medical Device Industry Coalition)

Centers of Excellence (CoEs)

NIDS
USC
PMDA
TFDA
SCU
SCH
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

<table>
<thead>
<tr>
<th>CoE</th>
<th>Economy</th>
<th>Program</th>
<th>Format</th>
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<tbody>
<tr>
<td>TFDA</td>
<td>Chinese Taipei</td>
<td>2021 APEC Medical Devices Regulatory Science CoE Workshop</td>
<td>Online</td>
<td>Aug. 28 - Sept. 11</td>
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<tr>
<td>SCH</td>
<td>Korea</td>
<td>2021 SCH Medical Device CoE Training</td>
<td>Online</td>
<td>Sept. 1 - 21</td>
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<tr>
<td>NIDS</td>
<td>Korea</td>
<td>2021 AHC-NIDS APEC Medical Device Vigilance CoE Training</td>
<td>Online</td>
<td>Sept. 14 - Oct. 15</td>
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<tr>
<td>PMDA</td>
<td>Japan</td>
<td>PMDA-ATC Medical Devices Webinar 2021</td>
<td>Online</td>
<td>Nov. 15 - 17</td>
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# CoE Programs Planned for 2022

<table>
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<tr>
<th>CoE</th>
<th>Economy</th>
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<tr>
<td>NEU</td>
<td>United States</td>
<td>Pilot CoE Training by Northeastern University</td>
<td>In Person</td>
<td>TBA</td>
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<tr>
<td>SCU</td>
<td>China</td>
<td>CoE Training by Sichuan University</td>
<td>Online</td>
<td>TBA</td>
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<tr>
<td>PMDA</td>
<td>Japan</td>
<td>APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of/Insight into the IMDRF documents</td>
<td>Online</td>
<td>Nov. 7 &amp; 14 - 16</td>
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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.
Thank you