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 (Korea)
• Advanced Therapy Products (Singapore)
• Good Registration Management (Chinese Taipei, Japan)
• Global Supply Chain Integrity (US)
• Medical Device (Japan, Korea, US)
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
FDA

Sub-Champions

AdvaMed & JIRA
(Medical Device Coalition)

Centers of Excellence

CoE I
CoE II
CoE III
CoE etc.
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

<table>
<thead>
<tr>
<th>Elements</th>
<th>GHTF/IMDRF Documents</th>
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<tbody>
<tr>
<td>Principles of Labeling</td>
<td>Label and Instructions for Use for Medical Devices (GHTF/SG1/N70:2011)</td>
<td>Principles of Labelling for Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N52 FINAL:2019)</td>
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</tbody>
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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)

<table>
<thead>
<tr>
<th>Name of Institution</th>
<th>Topic</th>
<th>Current Status (as of August 2019)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke-NUS</td>
<td>Pre market</td>
<td>Planning CoE pilot submission</td>
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<tr>
<td>NEU</td>
<td>QMS</td>
<td>Planning CoE pilot workshop</td>
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<tr>
<td>NIDS</td>
<td>Post Market</td>
<td>Formal CoE application endorsed</td>
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<tr>
<td>PMDA</td>
<td></td>
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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