



**Asia-Pacific  
Economic Cooperation**

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**2018/LSIF/RHSC2/001**

## **Agenda**

Purpose: Information  
Submitted by: RHSC Secretariat



**Life Sciences Innovation Forum  
Regulatory Harmonization Steering  
Committee Meeting  
Brisbane, Australia  
22-24 August 2018**

## **APEC RHSC 2018 SOM-3 MEETING AGENDA**

22-24 August 2018, Queensland University of Technology (QUT), Brisbane, Australia

<b>Tuesday, August 21: Pre-Meetings</b>
Prep Meetings (by invitation)
<b>Wednesday, August 22</b>
Wednesday August 22, 09:00 – 11:30: RHSC Meeting
<b>1 Welcome and Introductions</b>
<b>2 Review Membership Lists, PWA Leads and new Contact Lists</b>
<b>3 AHC Report</b>
<b>4 RHSC Representatives' Reports</b> 4.1 ICH 4.2 IPRF 4.3 IMDRF
<b>5 APEC Secretariat Management Update</b>
<b>6 Update on Training Activities</b> 6.1 WHO 6.2 ICH Training Subcommittee
<b>7 Update on RHSC website</b>
Wednesday August 22, 13:00 – 17:30 RHSC Meeting (Reports from PWAs)
<b>8 Good Registration Management Roadmap (TFDA- Chinese Taipei and MHLW/PMDA – Japan)</b> 8.1 PWA Update 8.2 Review Revised Roadmap 8.3 CoE update TFDA/RAPS 8.4 Update on PhRMA Special Session on Expedited Pathways
<b>9 Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – MHLW/PMDA and Thailand – TFDA)</b> 9.1 PWA Update (including Steering Committee report) 9.2 Review Revised Roadmap

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- 9.3 CoE Update: PMDA
- 9.4 CoE Update: Singapore Duke/NUS
- 9.5 CoE Update: Peking University
- 9.6 Pilot Program Update: The MRCT Center of Brigham & Women's Hospital & Harvard

### **10 Biotechnological Products Roadmap (Korea –MFDS)**

- 10.1 PWA Update (including Steering Committee report)
- 10.2 Review Revised Roadmap
- 10.3 CoE Update: Northeastern University
- 10.4 Pilot Program Update: Duke NUS

### **11 Global Supply Chain Integrity Roadmap (US –FDA)**

- 11.1 PWA Update (including Steering Committee report)
- 11.2 Review Revised Roadmap
- 11.3 CoE Update: United States Pharmacopeia
- 11.4 Pre-CoE Workshop Update: AHC

### **12 Advanced Therapies Roadmap Update (Singapore - HSA)**

- 12.1 PWA Update (including Steering Committee report)
- 12.2 Review Revised Roadmap
- 12.3 Pilot Program Update: Duke NUS
- 12.4 Pilot Program Application Update: NEU

### **13 Pharmacovigilance Roadmap (Korea – MFDS)**

- 13.1 PWA Update (including Steering Committee report)
- 13.2 Review Revised Roadmap
- 13.3 CoE Update: PMDA
- 13.4 CoE Update: KIDS
- 13.5 Pilot Program Update: MDITAC

### **14 Medical Device PWA Update (Korea – MFDS; Japan-MHLW/PMDA; US FDA)**

- 14.1 PWA Update (including Steering Committee report)
- 14.2 Review Revised Roadmap

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<b>Thursday, August 23</b>
<b>Thursday, August 23, 09:00 – 12:00 CoE Directors’ Meeting</b>
<b>CoE Directors’ Meeting: See separate agenda</b> <b>Invited participants:</b> Formal CoE & Pilot Institutions, PWA Champions, CoE Coalition Leads, AHC, RHSC Leadership [Other interested parties are invited to observe]
<b>Thursday, August 23, 13:30 – 17:00 RHSC Meeting</b>
Reports from PWAs: Continued from August 22 if needed
<b>15 RHSC Review and Discussion of CoE Directors’ Meeting Outcomes</b>
<b>16 Report from CoE Coalition (Incl Q1 training model) and Discussion</b>
RHSC Group Photo
<b>17 Review and Discuss New/Revised CoE Supporting Documents</b>
<b>18 AHC Report on Survey of Regulatory Authorities</b>
<b>19 ICH Implementation Subcommittee Report</b>
<b>20 CIRS Presentation on Implementation</b>
<b>21 RHSC Discussion on Performance Indicators</b>
<b>Friday, August 24</b>
<b>Friday, August 24, 09:00 – 14:00 RHSC Meeting</b>
<b>22 RHSC Members to Review</b> 22.1 Any Proposed CoE Pilot Programs 22.2 Any Formal CoE Applications Submitted 22.3 Finalise and Endorse Any New/Revised RHSC Documents 22.4 Confirm IMDRF APEC representatives and term
<b>23 RHSC Strategic Discussions</b> 23.1 Strategic discussion and conclusion on PIs in RHSC activities 23.2 CIRS presentation on Expedited Pathways

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23.3 Encouraging greater engagement of all 21 APEC economies in RHSC

23.4 To review current PWAs for possible sunseting or maintenance mode, and the potential for taking on new PWAs

23.5 New PWA Proposals:

- Pharmaceutical Quality – PhRMA Coalition

23.6 Promoting & publicity of RHSC activities

**24 Review Decisions and Action Items**

**25 Review Plan for February 2019 Meeting**

**26 Any other Business**