

APEC RHSC Interim Telecon 15 June 2020

Meeting Report

RHSC Welcome

Dr Nobumasa Nakashima and Dr Michelle Limoli, Co-Chairs

***Each Party to email RHSC Secretariat a participant list from your organization for the meeting record.**

***Apologies for telecon acoustical problems. Future RHSC virtual meetings will be held via Webex.**

Remarks by Tan Sri Dr. Rebecca Sta Maria, Executive Director of APEC

Secretariat

Background Documents 1.0-A, 1.0-B

APEC Secretariat Update

Presenter: Mr Johnny LIN

***SOM-3 in-person meetings are cancelled. RHSC will work virtually for remainder 2020.**

***For those interested in applying for APEC funding for projects, Concept Note deadline for Session 2 is June 29, 2020.**

LSIF Secretariat Update

Presenter: Mr Michael SCHMITZ, Ms Patricia WU, and Ambassador Robert HOLLEYMAN, LSIF Secretariat

Background Documents 2.0-A, 2.0-B

***Vision 2030 and Strategic Framework has been circulated for comment and finalized March 17, 2020. No further changes are foreseen. However due to COVID-19 disruptions, email comments are welcomed for the next 2 weeks.**

AHC Update

Presenter: Dr Gi Hyun KIM

Background Document 3.0

RHSC Representatives' Reports

RHSC is invited to note these submitted reports:

ICH /IPRP: Background Document 4.0

IMDRF: Background Document 5.0

RHSC Secretariat Update (5 mins)

Presenter: Ms Serene FOO, RHSC Secretariat

Background Documents 6.0-A, 6.0-B, 6.0-C, 6.0-D, 6.0-E

***RHSC Contact List Management Proposal Endorsed**

***RHSC Document Management System for Final Documents Endorsed**

***Updates to the RHSC Website made (<https://www.apec.org/rhsc>)**

Good Registration Management

Champions: TFDA, Chinese Taipei and MHLW/PMDA, Japan

RHSC is invited to note the submitted reports and background documents:

PWA Update: Background Documents 7.0-A, 7.0-B, 7.1

TFDA, Chinese Taipei/RAPS Taiwan Chapter CoE Update: Background Document 7.2

**** For RHSC Endorsement**

Thai FDA, Thailand: Formal CoE Application: Background Documents 7.3-A, 7.3-B, 7.3-C

Thai FDA Representative: Dr Suchart CHONGPRASERT

***Formal CoE Endorsed**

Multi-regional Clinical Trials and Good Clinical Practices Inspection (5 mins)

Champions: MHLW/PMDA, Japan and Thai FDA, Thailand

RHSC is invited to note the submitted reports and background documents:

PWA Update: Background Documents 8.0-A, 8.0-B, 8.0-C, 8.1

The MRCT Center, Brigham and Women's Hospital & Harvard CoE Update: Document 8.2

PKU CoE Update: Background Document 8.3

PMDA CoE Update: Background Document 8.4

Duke-NUS Medical School (CoRE) CoE

**** For RHSC Endorsement**

KoNECT: Formal CoE Application: Background Documents 8.5-A, 8.5-B, 8.5-C

KoNECT Representative: Ms YoonJae (Natalie) LEE

***Formal CoE Endorsed**

Biotherapeutic Products

Current PWA Management: US FDA and BIO Coalition

*** USFDA and Bio Coalition are serving as interim PWA Managers until an appropriate Champion or Co-Champions can be identified. They are in the process of updating the PWA Roadmap. Will be submitted to the RHSC later in 2020.**

RHSC is invited to note the submitted reports and background documents:

PWA Update: Roadmap Currently being revised: Background Document 9.0

Northeastern University CoE

Duke-NUS Medical School (CoRE) Pilot CoE

**** For RHSC Endorsement**

Kobe University: Formal CoE Application: Background Documents 9.1-A, 9.1-B, 9.1-C

Kobe University Representative: Dr Ineui LEE

***Formal CoE Endorsed**

Global Supply Chain Integrity

Champion: US FDA

RHSC is invited to note the submitted reports and background documents:

PWA Update: Background Documents 10.0, 10.1

USP CoE

University of Tennessee Health Sciences Center CoE

**** For RHSC Endorsement**

Taylor's University: Formal CoE Application: Background Documents 10.2-A, 10.2-B, 10.2-C, 10.2-D

Taylor's University Representative: Prof P.T THOMAS

****Formal CoE Endorsed**

Advanced Therapy Products

Champions: HSA, Singapore and BIO Coalition

RHSC is invited to note the submitted reports and background documents:

PWA update: Background Documents 11.0-A, 11.0-B, 11.0-C

Duke-NUS Medical School (CoRE) CoE

Northeastern University CoE

**** For RHSC Endorsement**

USP: Pilot CoE Application: Background Documents 11.1-A, 11.1-B

USP Representative: Dr Phillip NGUYEN

***Pilot CoE Endorsed**

Pharmacovigilance

Champion: MFDS, Korea

PWA update: Background Documents 12.0-A, 12.0-B, 12.1

PKU CoE Update: Background Document 12.2

KIDS CoE Update: Background Document 12.3

PMDA CoE Update: Background Document 12.4

Medical Devices (10 mins)

Champions: MFDS, Korea and MHLW/PMDA, Japan, and US FDA

Sub-Champions: AdvaMed and JIRA

RHSC is invited to note the submitted reports and background documents:

PWA Update: Background Documents 13.0-A, 13.0-B, 13.0-C, 13.1-A

University of Southern California CoE
NIDS CoE Update: Background Document 13.2
Northeastern University Pilot CoE

**** For RHSC Endorsement at SOM-3**

RHSC Endorsement of Revised Core Curriculum: Background Document 13.1-B
Champion Representative: Dr Ryan HOSHI, US FDA

*** The Medical Device Co-Champions wish to postpone endorsement of the core curriculum since it needs to be further updated to reflect recent outcomes of the IMDRF March meeting and subsequent telecons. They will bring this topic back to the RHSC once updating is complete. This may also involve revision to the KPIs.**

**** For RHSC Endorsement**

Sichuan University: Formal CoE Application: Background Documents 13.3-A, 13.3-B, 13.3-C
Sichuan University Representative: Dr Anyu LEE

***Formal CoE Endorsed**

**** For RHSC Endorsement**

TFDA, Chinese Taipei: Formal CoE Application: Background Documents 13.4-A, 13.4-B
TFDA Representative: Ms Yueh-Tzu HUNG

***Formal CoE Endorsed**

**** For RHSC Endorsement**

PMDA: Formal CoE Application: Background Documents 13.5-A, 13.5-B
PMDA Representative: Dr Yoshimasa YOKOYAMA

***Formal CoE Endorsed**

**** For RHSC Endorsement**

Duke-NUS Medical School (CoRE): Pilot CoE Application: Background Documents 13.6-A, 13.6-B, 13.6-C

Duke NUS Representative: Mr Ananda Padmanabhan MUTHALAGU

***Pilot CoE Endorsed**

**** For RHSC Endorsement**

Soonchunhyang University: Pilot CoE Application: Background Documents 13.7-A, 13.7-B
Soonchunhyang University Representative: Dr You Kyoung LEE

***Pilot CoE Endorsed**

**** For RHSC Endorsement**

Medical Device Authority, MOH Malaysia: Pilot CoE Application: Background Documents 13.8-A, 13.8-B, 13.8-C, 13.8-D, 13.8-E, 13.8-F

Medical Device Authority, MOH Malaysia Representative: Mrs Ir. Sasikala Devi THANGAVELU

***Endorsed in Principle contingent upon future communications with the Medical Device PWA Co-Champions to confirm that the topic(s) chosen for the Pilot Program is in accordance with the core curriculum.**

Updated CoE Operating Model

Background Document 14.0

**** For RHSC Endorsement**

Partnerships/Collaborations with APEC Centers of Excellence

In order to promote outreach on RHSC activities and regulatory convergence globally, formal APEC Centers of Excellence may partner with organizations outside of the APEC region in the delivery of training programs in any of the existing priority work areas. These organizations will be bound by the same operating rules as APEC CoEs, but the APEC CoE will act as advisor in the development and conduct of the training program. Plans and outcomes of these programs should be reported to the RHSC at biannual RHSC meetings.

***Endorsed**

**** For RHSC Endorsement**

To become a formal CoE, the applying CoE Host Institution submits a Formal CoE application form to the RHSC Secretariat, indicating its successful completion of at least three pilot programs. The requirement of three pilot programs will be effective for any applications received after June 1, 2020, and will only apply to new organizations or institutions that are not already a formal APEC CoE in another PWA.

***Endorsed with revision of June 1, 2020 to December 31, 2020.**

Actions Items for SOM-3

- **Each PWA Champion(s) to convene at least one PWA Steering Committee telecon prior to SOM-3**

- **CoE Coalition to develop:**
 - **Proposed mechanisms to assess Pilot Programs held virtually**
 - **Assessment Tool and criteria for periodic evaluations of CoEs**

- **Co-Chairs to review Roadmap Template (“4 Phases”) for possible proposal that are reflective of our current operations.**

Update on ICH Implementation Survey Results/PhRMA

Background Document 15.0

Presenter: Dr Janet VESSOTSKIE

WHO Update on Reliance Survey/Good Reliance Practices

Background Document 16.0

Presenter: Dr Samvel AZATYAN

* For the working document on *Good Reliance Practices in Regulatory Decision-Making: High-level Principles and Recommendations* that is currently in public consultation, please send any comments to Marie Valentin (valentinm@who.int) and Carolyn Doucelin (doucelinc@who.int) no later than 24 July.

Any other Business

Adjourn