

APEC RHSC Meeting Agenda (version 7/28/17)

Rex Hotel – Ho Chi Minh City, Vietnam

Meeting Room TBC

RHSC Meeting Friday, August 18, 2017: 10:00-18:00

Welcome and Introductions

New Membership Lists

AHC Report and Presentation on Draft Role of AHC in CoE Coordination

RHSC Representatives' Reports: **ICH**
 IPRF
 IMDRF

Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – PMDA and Thailand – TFDA)

Reference Documents:

Roadmap to Promote Multi Regional Clinical Trials and Good Clinical Practice Inspection (GCP Inspection)

- **Update on Roadmap**
- **CoE Update: MHLW/PMDA**
- **CoE Update: Singapore Duke/NUS**
- **CoE Update: Peking University**
- **CoE Update: The MRCT Center of Brigham & Women's Hospital & Harvard**

Global Supply Chain Integrity Roadmap (US –FDA)

Reference Documents:

Roadmap to Promote Global Medical Product Quality and Supply Chain Security

- **Update on Roadmap**
- **CoE Update: University of Tennessee Health Sciences Center**
- **CoE Update: United States Pharmacopeia**

Cellular Therapies Roadmap Update (Singapore - HSA)

Reference Documents:

Roadmap to Promote Prospective Regulatory Convergence in Cell- and Tissue-based Therapeutic Products

- **Update on Roadmap**
- **CoE Update: Duke NUS/CoRE**

Biotechnological Products Roadmap (Korea –MFDS)

Reference Documents:

APEC Biotherapeutic Products Roadmap: To reach a high level of regulatory convergence by 2020

- **Update on Roadmap**
- **CoE Update: Northeastern University**

Good Registration Management Roadmap (TFDA- Chinese Taipei and PMDA –Japan)

Reference Documents:

Roadmap to Promote Good Registration Management (GRM)

- **Update on Roadmap**
- **CoE Update: TFDA**
- **CoE Update: COFEPRIS**

Pharmacovigilance and Medical Device Vigilance Roadmap (Korea – MFDS)

Reference Documents:

Roadmap to Promote Pharmacovigilance and Medical Device Vigilance

- **Update on Roadmap**
- **CoE Update: MHLW/PMDA**
- **CoE Update: KIDS**
- **CoE Update: MDITAC**

Proposal for New PWA on Medical Devices

CoE Director's Meeting Saturday, August 19: 10:00-12:15

CoE Directors' Meeting: see separate agenda

Invited Participants: Formal CoE Institutions, Pilot CoE Institutions, PWA Champions, AHC, RHSC Leadership

[Other interested parties are invited to observe]

Welcome and Adoption of the Agenda

Objective and expectations of the Meeting

Discuss AHC's Draft Paper on CoE Coordinator's Role

Report out from each CoE & Pilot Institution (5 min per each institution)

Strengthening CoE collaborations within and across PWAs

Open Discussion:

- Difficulties encountered and potential solutions
- Intellectual property rights and sharing training materials
- Benefits of being an APEC CoE hosting institution
- Funding issues and handling travel grants

Develop Potential Path forward for Future Meetings

Action Items and Summary of the Meeting

RHSC Meeting Saturday, August 19: 13:45-18:00

RHSC Review and Discussion of CoE Directors' Meeting Outcomes

Review and Discuss Proposal for Performance Indicators

Review and Discuss New Template/Paradigm for RHSC Roadmaps

Review and Discuss New/Revised CoE Supporting Documents

Reference Documents:

CoE Operating Model and Guidelines

How to Conduct an APEC CoE Pilot Program

RHSC Members to Review (Regulators & Industry Coalitions Members):

- Any Proposed CoE Pilot Programs
- Any Formal CoE Applications Submitted
- AHC Concept Paper
- Finalize and Endorse New/Revised CoE Documents
- Confirm IMDRF APEC representatives and term

Review Decisions and Action Items

Any other Business

