



APEC LIFE SCIENCES INNOVATION FORUM REGULATORY HARMONIZATION STEERING
COMMITTEE

APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee Meeting

Decisions and Action Items - FINAL

February 28 – March 1, 2019

Santiago, Chile

* Please refer to relevant Priority Work Area (PWA) roadmaps and slides presented at the RHSC meeting as background to the following items.

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

Reference documents: 6.1, 6.2, 6.3, 6.4, 6.4-B

- TFDA/RAPS Taiwan Chapter plans to host CoE program Q3 2019
- Action item: GRM PWA Champions to continue developing a survey on the impact of GRevP and GSubP for possible intersessional circulation or at SOM-3 2019
- RHSC endorsed CoE Pilot application submitted by Thai FDA to host a GRM pilot CoE program in November 2019

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

Reference documents: 7A, 7B, 7C, 7D, 7.1, 7.2, 7.3, 7.4

- The RHSC can expect a pilot MRCT/GCP CoE application from KoNECT for intersessional consideration and possible endorsement
- PMDA held a CoE workshop from 21-24 Jan 2019 and plans to conduct a workshop in January 2020
- PKU plans to conduct a CoE workshop in September 2019
- Harvard MRCT Center will conduct a CoE workshop in Canada, 26-28 Feb 2019
- Duke-NUS will conduct a CoE workshop in Singapore, 11-12 July 2019

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Biotechnological Products Roadmap (Korea –MFDS)

Reference slides: 8.1, 8.2, 8.3

- Action item: PWA Champion plan to update Biotechnological Products Roadmap and Core Curriculum by May 2019 for circulation to the RHSC
- AHC plans to hold a workshop in September 2019, Seoul
- Northeastern University plans to hold a CoE workshop in Boston, 16-20 September 2019
- Northeastern University is planning in-country training in collaboration with the University of Chile in Santiago from 11-13 March for regulators/academia and 14-15 March 2019 for industry
- Duke-NUS is considering a 2nd pilot CoE workshop in November 2020. RHSC concluded that a pilot application is not required for the 2nd pilot program.

Global Supply Chain Integrity Roadmap (US –FDA)

Reference slides: 9, 9.1, 9.2, 9.3-A, 9.3-B, 9.3-C

- USP CoE is planning a Regulators Roundtable in Santiago, June 2019 and consultation visits to individual economies in Latin American, Q4 2019
- RHSC endorsed Taylor's University in cooperation with NPRA Pilot Program application to host a training program in September 2019, Malaysia

Advanced Therapies Roadmap Update (Singapore – HSA, BIO)

Reference slides: 10A, 10.2, 10.3, 10.4

- RHSC endorsed the PWA core curriculum
- Northeastern University to conduct a pilot program in July 2019

Pharmacovigilance Roadmap (Korea – MFDS)

Reference documents: 11-A, 11-B, 11-C, 11.1, 11.2, 11.3

- PWA Champions are revising the core curriculum and will circulate for RHSC consideration and possible endorsement at 2019 SOM-3
- PMDA hosted a CoE program in Japan, 4-7 February 2019
- PKU is planning a pilot CoE program in China, April 2019
- KIDS is planning a CoE program in Korea, September 2019
- RHSC will request WHO to provide an update on the UMC activities relevant to the APEC region at 2019 SOM-3



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

Reference documents: 12-A, 12-B, 12-C, 12.1, 12.2, 12.3-A, 12.3-B, 12.4-A, 12.4-B, 12.5-A, 12.5-B, 12.6-A, 12.6-B

- NIDS CoE Pilot conducted in September 2018. They plan to submit a formal CoE application intersessionally for RHSC consideration and possible endorsement
- RHSC endorsed USC pilot application to host a CoE pilot program from 30 April – 3 May 2019
- RHSC endorsed PMDA pilot application to host a CoE pilot program in Nov 2019
- TFDA pilot application to host a CoE pilot program in Q4 2019 will be considered intersessionally for endorsement
- RHSC endorsed Northeastern University pilot application to host a CoE pilot program in Fall 2019 or Spring 2020

LSIF Secretariat Update

Reference documents: 4, 4.1

- RHSC requested to provide any comments on the draft of the Policy Dialogue agenda by 28 February 2019 in anticipation of presenting a draft to LSIF Planning Group on 2 March 2019

Report from CoE Coalition and Discussion

Reference documents: 13.1

- RHSC to provide any comments to the CoE coalition lead on the 5 points below by 1 April 2019
 - CoEs(approved) notify the RHSC of their training plans but do not have to obtain permission to train
 - Remove descriptions on who can be co-champions from CoE Operating Model and insert in RHSC Terms of Reference (ToR)
 - CoE directors meeting to be held in SOM1 and SOM3 and coordinated by the CoE Coalition
 - Develop a template to use for 'basic' CoE reports
 - Number of CoEs for each PWA should be addressed on a case by case basis by the PWA Champion and relevant steering committee

RHSC Website

Reference document: 5

- Action items:
 - PWA Champions and CoE Coalition to provide feedback on their landing pages to the RHSC Secretariat by mid-March 2019



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- Launch of website planned for April 2019

IMDRF

- The RHSC agreed to having one Observer seat for a one-year term be given to an interested non-IMDRF member economy, and allowing any of the APEC Medical Device Co-Champion Regulatory Authorities who are IMDRF members, the ability to speak on behalf of APEC at the IMDRF table.

Pharmaceutical Quality PWA Update

- **Action items:**
 - Economies who are interested in becoming Co-Champions of the Pharmaceutical Quality PWA to contact PhRMA

GMP Inspection Training Course

- **Action items:**
 - MHLW to consider an appropriate PWA on this course

Performance Indicators

- Action item: PWA Champions expressed a desire to conduct a survey to measure Key Performance Indicators. Next steps will be proposed intersessionally or at SOM-3.

Review Plan for August 2019 Meeting

- RHSC meeting will be tentatively held from 15-16 August 2019, the LSIF PG meeting on 17 August, and the LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence on 18 August 2019 in Puerto Varas, Chile