**RHSC Oct 2021 Virtual Meeting Agenda**

**26 Oct 2021, 07:00 – 09:00 Washington DC (GMT-4) / 20:00 – 22:00 Tokyo (GMT+9)**

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| RHSC Oct 2021 Virtual Meeting **26 Oct 2021, 07:00 – 09:00 Washington DC (GMT-4) / 20:00 – 22:00 Tokyo (GMT+9)** | **Documents** |
| RHSC Welcome and Introductory Remarks (5 mins) Speakers: Dr Nobumasa NAKASHIMA and Dr Michelle LIMOLI, RHSC Co-Chairs |  |
| LSIF Advisor’s Office Update (10 mins) Speakers: Ms Patricia WU  Background Document 1.0 |  |
| AHC Update (5 mins) Speaker: Dr. Young-Ju CHOI  Background Document 2.0 |  |
| Update from RHSC Co-Chairs (10 mins) Speakers: Dr Nobumasa NAKASHIMA and Dr Michelle LIMOLI, RHSC Co-Chairs  Background Documents 3.0-A, 3.0-B, 3.0-C, 3.0-D |  |
| Good Registration Management (10 mins total)(Co-Champions: Chinese Taipei – TFDA and Japan – MHLW/PMDA) Background Documents 4.0-A, 4.0-B |  |
| PWA Update Speaker: Ms Chyn-Liang HUANG, TFDA  Background Document 4.1 |  |
| CoE Update: TFDA with RAPS Taiwan Chapter Speaker: Ms Chyn-Liang HUANG  Background Document 4.1 |  |
| CoE Update: Food & Food Drug Administration, Thailand (Thai FDA) Speaker: Ms Unsanee RATTANACHEEVAKUL  Background Document 4.1 |  |
| Multi-regional Clinical Trials and Good Clinical Practices Inspection (5 mins total)(Champions: Japan – MHLW/PMDA and Thailand – Thai FDA) Background Documents 5.0-A, 5.0-B, 5.0-C |  |
| PWA Update Speaker: Mr Hayato ISHIDA, PMDA  Background Document 5.1 |  |
| Global Supply Chain Integrity (5 mins total)(Champion: US – FDA) Background Document 6.0 |  |
| PWA Update & CoE Update: United States Pharmacopeia (USP) Speakers: Dr Leigh VERBOIS, US FDA & Mr Michael SCHMITZ, USP  Background Document 6.1 |  |
| Advanced Therapy Products (5 mins total)(Champions: Singapore – HSA and US – FDA;Sub-Champion: BIO) Background Documents 7.0-A, 7.0-B |  |
| PWA update Speaker: Dr Srinivasan KELLATHUR, HSA  Background Document 7.1 |  |
| CoE Update: United States Pharmacopeia (USP) Speaker: Dr Maura KIBBEY  Background Document 7.2 |  |
| Biotherapeutic Products (5 mins total)(Current PWA Management: US FDA and BIO Coalition) Background Document 8.0 |  |
| PWA Update Speaker: Dr Michelle LIMOLI, US FDA  Background Document 8.1 |  |
| CoE Update: Northeastern University (NEU) (updates for both Biotherapeutic Products and Advanced Therapy Products PWAs) Speaker: A/Prof Jared AUCLAIR  Background Document 8.2 |  |
| Pharmacovigilance (5 mins total)(Champion: Korea – MFDS) Background Documents 9.0-A, 9.0-B |  |
| PWA Update Speaker: Ms In Sun LEE  Background Document 9.1 |  |
| Medical Devices (5 mins total)(Champions: Korea – MFDS, Japan – MHLW/PMDA and US FDA;Sub-Champions: AdvaMed and JIRA) Background Documents 10.0-A, 10.0-B |  |
| PWA Update Speaker: Ms Michelle NOONAN, US FDA  Background Document 10.1 |  |
| WHO Update (5 mins) Speaker: Dr Samvel AZATYAN  Background Document 11.0 |  |
| APEC LSIF Rare Disease Network (5 mins) Speaker: Mr Eric OBSCHERNING, LSIF Advisor’s Office  Background Document 12.0 |  |
| Review Decisions and Action Items (5 mins) Lead by RHSC Co-Chairs |  |
| Concluding Remarks and Adjourn (2 mins) Lead by RHSC Co-Chairs |  |