Agenda of 2021 APEC Medical Devices CoE Workshop

Version of June 9, 2021

August 28 to September 11
Online Course 1 • Opening Remarks • Roadmap and Core Curriculum of Medical Device PWA • CoE Training Program
Online Course 2 • Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: MD Session
Online Course 3 • Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’ (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N045&N046) • Summary of Essential Principles for In Vitro Diagnostic (IVD) Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: IVD Session
Online Course 4 • Introduction of Clinical Evaluation (IMDRF/MDCE WG/N55&N56&N57 FINAL:2019)
Online Course 5 Current harmonization status of pre-market regulation in APEC member economies

item	Time length	Topic	Speaker
Introduction Session (Online Course)			
1	N/A	Introductory Remarks	Letters from MOH Minister & TFDA Director General
	10 minutes	Roadmap and Core Curriculum of Medical Device PWA	APEC LSIF RHSC MD PWA Co-Champion: Dr. Maeda Yuta Coordinator, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
	10 minutes	CoE Training Program	Division of Medical Devices and Cosmetics, TFDA, MOHW
Medical Device Session (Online Course)			
2	40 minutes	• Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: MD Session Product: Soft Contact Lens	Dr. Jai-Yen Chen Senior Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE)
In Vitro Diagnostic Medical Device Session (Online Course)			

3	40 minutes	• Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Basic Scheme of Conformity Assessment Procedure and Classification for Medical Devices (GHTF/SG1/N77&N78) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: IVD Session Product: Pregnancy Rapid Test	Dr. Te-Hsuen Chen Senior Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW
Clinical Evaluation Session (Online Course)			
4	40 minutes	• Clinical Investigation (IMDRF/MDCE WG/N57FINAL:2019) • Clinical Evaluation (IMDRF/MDCE WG/N56FINAL:2019) • Clinical Evidence (IMDRF/MDCE WG/N55FINAL:2019)	Dr. Mami Ho Senior Scientist for Clinical Medicine, Medical Device Unit, Office of Medical Devices I, PMDA, Japan
Current harmonization status of pre-market regulation in APEC member economies (Online Course)			
5	10 minutes/each	The sharing of current harmonization status of pre-market regulation in APEC member economies will be pre-recorded. Regulators who participate in the workshop will be invited to pre-record their presentation.	Representatives from regulatory authorities of each participating member economy
Digital Health (Optional Online Course)			
6	40 minutes	Cybersecurity Case Sharing of Korea	Ms. Eun-Hee Cho RA Director, Abbott Medical Devices, Korea