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
	5 minutes	Opening Remarks	TFDA Director General
	10 minutes	Roadmap and Core Curriculum of Medical Device PWA	APEC LSIF RHSC MD PWA Co-Champion: Dr. Yuta Maeda Coordinator, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
	10 minutes	CoE Training Program	Ms. Cheng-Ning Wu, Section Chief, 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