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