2020 AHC SCH Medical Device CoE Pilot Training

October 26 – November 17, 2020 | On-line training (Available for 3 weeks, total 9.3 hours)

(Version updated on September 22, 2020)

Method	Time	Topic	Speaker
Subject 1. Clinical Evaluation (2.8hrs courses) *Objectives: 1) To understand the requirement of clinical evaluation for IVD based on IMDRF guidance* *2) Discuss clinical trial design to secure IVD clinical evidence through virtual scenarios* *Core curriculums: 1) Clinical Investigation (IMDRF MDCE WG/N57FINAL:2019)* *2) Clinical Evaluation (IMDRF MDCE WG/N56FINAL:2019)* *3) Clinical Evidence (IMDRF MDCE WG/N55 FINAL:2019)* *Additional Documents: 1) GHTF/SG5/N6:2012 Clinical evidence for IVDs-Key Concepts* *2) GHTF/SG5/N7:2012 Clinical evidence for IVDs-Scientific Validity* *3) GHTF/SG5/N8:2012 Clinical evidence for IVDs-Clinical Performance Studies*			
VOD lectures	40 mins	Clinical Evaluation and Evidence for Medical Devices - Focused on IMDRF MDCE WG/N55, 56, 57 FINAL:2019	TBD
	40 mins	Clinical Evaluation and Evidence for IVD Medical Devices - Focused on GHTF/SG5/N6,7,8:2012	TBD
Online activity	30 mins	Case study – Clinical Trial for COVID-19 real-time PCR	
		Survey: 3~4 close-ended questions	
		Comment and Feedbacks	
Untact Conference	60 mins	***Live Video Conference 1*** Practical Application of Clinical Evaluation in COVID-19 Regulatory Approval (including EUA)	Presenter: Hyeonho Kim (MFDS) Moderator: TBD
Subject 2. Quality Management System (3.7hrs courses) *Objectives: 1) Introduce of ISO 13485 and MDSAP among QMS in VID* *2) To share the best practices on ISO 13485 and MDSAP in IVD* *Core curriculums: 1) ISO13485/2016* *2) Medical Device Regulatory Audit Reports (MDSAP WG/N24:2015)* *Additional Documents: 1) Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes (SG3/N18: 2010)*			
VOD lectures	40 mins	Overview of ISO 13485:2016	Yong Ho Lee (SGS Korea)
	40 mins	General Understanding of Medical Device Single Audit Program	TBD
	40 mins	MDV-QMS Intersection	Eric Woo (ECRI)

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		- Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes (SG3/N18: 2010)	
	20 mins 20 mins	Sharing Best practices - Medical Device Manufacturer Perspectives - ISO 13485 - MDSAP	Sun Young Jeong (SD Biosensor) TBD
Untact Conference	60 mins	***Live Video Conference 2*** Practical Application of QMS in COVID-19 real-time PCR Manufacture	Presenter: Seong-Youl Kim (SEEGENE) Moderator: TBD
Subject 3. Medical Device Vigilance (2.8hrs courses) *Objectives: Building the ability to analyze the medical device adverse event occurring in the healthcare practice and express them using IMDRF terms & codes* *Core curriculum: 1) Terminologies for Categorized Adverse Event Reporting: Terms, Terminology Structure and Codes (IMDRF/AE WG/N43 (Edition 4.1) FINAL:2020) & Updated Annexes (Edition 4.1)* *Additional Document: 1) Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006)*			
VOD lectures	40 mins	Introduction to Medical Device Adverse Events	Naoki Morooka (JIRA)
	30 mins	IMDRF Terms & Codes	Ishikawa Hiroshi (PMDA)
	10 mins	Exploration of IMDRF Adverse Event Terminology Web Browser	Ishikawa Hiroshi (PMDA)
Online activity	30 mins	Case study – BST	
		Survey: 3~4 close-ended questions	
		Comment and Feedbacks	
Untact Conference	60 mins	***Live Video Conference 3*** In Vitro Diagnostic Device in Laboratory Practice; Experience for COVID-19 real-time PCR	Presenter: Hyuk Min Lee (Yonsei University) Moderator: TBD