Full Agenda of 2022 TFDA Medical Devices Regulatory Science Center of Excellence Workshop
1st Part (August 26 to September 11)

Item	Time length	Topic	Speaker
Online Learning Session			
Medical Device Session			
1	30 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: Fingertip Pulse Oximeter	Dr. Shang-Lung Dong Reviewer, Division of Medical Devices and Cosmetics, TFDA, MOHW
In Vitro Diagnostic Medical Device Session			
2	30 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 In Vitro Diagnostic Medical Devices (GHTF/SG1/N45&N46) • Summary of Essential Principles for Medical Devices (IMDRF/GRRP WG/N47) • Introduction of Case Study: Dengue Virus Antigen Assay	Mr. Shang-Ching Lin Assistant Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW
Optimizing Standards Session			
3	30 minutes	• Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51 FINAL:2018)	Mr. Naoki Morooka Senior Manager, Quality Assurance Dept., Medical Systems Division,

			Shimadzu Corporation, Japan
Digital Health Session			
4	30 minutes	• Trends & Challenges of AI Technology in Digital Health	Mr. Varun Veigas Leader - Policy and Strategic Partnership, Health Policy and Patient Access Value Stream, Roche Diagnostics Asia Pacific Pte. Ltd
Medical Device Manufacturing Video			
5	13 minutes	• Continuous Positive Airway Pressure (CPAP) Device	APEX Corp.

2nd Part (September 2 to September 8)

Item	Time length	Topic		Speaker
Videoconference Session				
1st	09:00-11:00 TST September 2	• Current Harmonization Status of Pre-Market Regulation in Medical Devices		• Opening: TFDA • Moderator: Grace Huang, Coordinator, GIS Group • Speakers: Representatives from each participating regulatory authority • Q&A for speakers

2	09:00-10:30 TST
	September 6
		Case Study: In Vitro Diagnostics (IVD) Session
		• Introduction of Product (20 minutes)
			• Group A
			Discussion (70 minutes)
				• Moderator: Grace Huang
				• Speaker: Mr. Shang-Ching Lin, Assistant Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW
				• Facilitators of Group A:
				  • Dr. Shao Chang, Assistant Professor, Program of Biotechnology Management, National Taiwan University;
				  • Eli (Shuwei) Hsu, Regulatory Affairs Associate, Regulatory Affairs and Drug Development Solutions, IQVIA
				  • Grace Huang, Coordinator, GIS Group

3	14:00-15:30 TST September 6	Case Study: In Vitro Diagnostics (MD) Session	• Group B Discussion (70 minutes)	• Moderator: Grace Huang • Speaker: Mr. Shang-Lung Dong, Reviewer,

		• Introduction of Product (20 minutes)	• Group C
			Discussion (70 minutes)
				Division of Medical Devices and Cosmetics, TFDA, MOHW
				• Facilitators of Group B:
				  • Teresa Huang, GA, Market Access & RA Associate Director, TW&HK, Alcon Services AG, Taiwan Branch
				  • Grace Huang, Coordinator, GIS Group
				• Facilitators of Group C:
				  • Nicole Kuo, Engineer, Office of Medical Device Evaluation, ITRI
				  • Serena Lin, Coordinator, GIS Group

4	09:00-10:30 TST
	September 8
		• Opening Remarks (5 minutes)
		• IVD Case Study Presentation (15 minutes/Group and 5 minutes for answer explanation)
		• MD Case Study Presentation (10 minutes/Group and 5 minutes for answer explanation)
		• Q&A of Online Courses (30 minutes)
		• Closing Remarks (5 minutes)
				• Opening:
				  • Ms. Pei-Weng Tu
				Director, Division of Medical Devices and Cosmetics, TFDA, MOHW
				• IVD: Representative from Group A
				• MD: Representatives from Groups B&C
				• Q&A: Dr. Shang-Lung Dong, Dr. Shang-Ching Lin, Mr. Naoki Morooka, Mr. Varun Veigas
				• Closing:
				  • Ms. Cheng-Ning Wu,

			Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW