

Short Agenda of 2023 APEC Medical Devices CoE Workshop

2023.06.21 V1

Time	Day 1 - Aug. 29 (Tue.)	Day 2 - Aug. 30 (Wed.)	Day 3 - Aug. 31 (Thu.)
Morning (3 hours)	Registration	Registration	Registration
	<ul style="list-style-type: none"> ● Introduction of Workshop <ul style="list-style-type: none"> • Introduction of APEC Medical Device PWA • Introduction of CoE 	<ul style="list-style-type: none"> ● Medical Device Session <ul style="list-style-type: none"> • Principles of Conformity Assessment for Medical Devices • Essential Principles of Medical Device Safety & Performance • Case Study 1: Infusion set 	<ul style="list-style-type: none"> ● Optimizing Standards for Regulatory Use <ul style="list-style-type: none"> • Q&A
	Coffee Break	Coffee Break	Coffee Break
	<ul style="list-style-type: none"> ● Current Harmonization Status of Pre-Market Regulation in Each Economy <ul style="list-style-type: none"> • Panel Discussion (Q&A) 	<ul style="list-style-type: none"> • Group Discussion • Group Presentation 	<ul style="list-style-type: none"> ● Expectations from the Workshop and Next Steps <ul style="list-style-type: none"> • Stakeholder Presentations • Certificate Award Ceremony
Noon	Lunch	Lunch	Lunch
Afternoon (3 hours)	<ul style="list-style-type: none"> ● Icebreaker Activities 	<ul style="list-style-type: none"> ● In Vitro Diagnostic Device Session <ul style="list-style-type: none"> • Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices • Essential Principles of Safety and Performance of IVD Medical Devices • Case Study 2: Influenza Virus Antigen Detection Test System 	(Optional – only for regulators) <ul style="list-style-type: none"> ● Manufacturing site visit (Device firm)
	<ul style="list-style-type: none"> ● Definition & Classification Session <ul style="list-style-type: none"> • Medical Device & In Vitro Diagnostic Device Classification 		
	Coffee Break	Coffee Break	
	<ul style="list-style-type: none"> • Definition and Classification Practice 	<ul style="list-style-type: none"> • Group Discussion • Group Presentation 	
Evening	Welcome Reception		