衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

工業技術研究院 Industrial Technology Research Institute

2023 國際醫療器材法規研討會

Conference on International Medical Device Regulations

研討會議程 Agenda

Time	Topic	Speaker
08:30~09:30	Registration	
09:30~09:40	Welcoming Remarks	Taiwan Food and Drug Administration (TFDA) (TBD)
09:40~09:50	Souvenir Presentation and Photo Session	
09:50~10:20	Update on Medical Device Regulations in Australia	**Tracey Duffy** First Assistant Secretary, Medical Devices and Product Quality Division, Health Products Regulation Group, Therapeutic Goods Administration, Australia (on-line)
10:20~10:50	Update on Medical Device Regulations in European Union	**Erik Hansson** Senior Expert, EU
10:50~11:10	Coffee Break	
11:10~11:40	Update on Medical Device Regulations in Vietnam	**May Ng** Global Director Global Regulatory & Quality Consultant, ARQon Pte Ltd, Singapore
11:40~13:30	Lunch	
13:30~14:00	Australia Experience on Reviewing a Medical Device Conformity Assessment Application	**John Jamieson** Assistant Secretary, Medical Devices Authorisation Branch, Medical Devices and Product Quality Division, Therapeutic Goods Administration, Australia (on-line)

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Time	Topic	Speaker
14:00~14:30	Update on ASEAN Medical Device Directive (AMDD) Status and Implementation	**May Ng** Global Director Global Regulatory & Quality Consultant, ARQon Pte Ltd, Singapore
14:30~14:45	Coffee Break	
14:45~15:35	EU Experience on Reviewing a Medical Device Conformity Assessment Application	**Hailey Chu** Regulatory Lead of Global Oversight (Medical Devices), British Standard Institution (on-line) **Michael Bothe** Head of active medical devices DQS Medizinprodukte GmbH (on-line)
15:35~15:55	Q&A	Moderator: TFDA
15:55~16:00	Closing Remarks	TFDA