DAY 1: 18 Mar 2024 (Day 1 of IMDS)

MEDICAL DEVICE REGULATORY & INNOVATION **Chairperson:** May Ng, ARQon			**Speaker Status**
Time (KST)	**Time (SGT)**	**Topics**	
900 - 0915	0800 -0815	**Registration**	
915 - 0930	0815 - 0830	**Opening & Welcome Remarks**	Temasek poly May NG, CEO of ARQon Group Jack Wong , ARPA Dae Hee Hong, CEO of Mediguide Gabriel Sim, APACMED
0930 - 1015	0830 - 0915	**Role of Trade Associations – Driving access, innovation & collaboration** · The effective network of industry associations across the ASEAN, ASIA, EU, US, GLOBAL · The importance of association's role for its stakeholders i.e. local industry and the national authorities/agencies	Gabriel Sim, APACMed May Ng, ARQon & ATTOPOLIS Dae Hee Hong, CEO of Mediguide
1015 -1040	0915- 09:40	**EU Regulatory Requirements & Strategy** • Brief Overview of Regulation & Strategy • Case studies	Hana Na, Tuv Rheinland
1040 - 1105	09:40 - 10:05	**US Regulatory Requirements & Strategy** • Brief Overview of Regulation & Strategy • Case studies	CY Won, Mediguide and ARQon Korea
1105 - 1130	1005 - 1030	**Innovation vs Regulation: Friend or foe?**	Kim Dong Woo, TODOC
1130 - 1145	1030 - 1045	**Tea Break**	
1145 - 1215	1045 - 1115	**Medical software – Regulation & Strategy**	Sujeong Yoo, MDREX
1215 - 1240	1115 - 1140	**APAC regulatory Requirements - Korea**	Dae Hee Hong, Mediguide and ARQon Korea
1240 - 1300	1140 - 1200	**Medical Device reimbursement in Korea – A MedTech company's worst nightmare?**	Lee Sang-Soo, Medtronic
1300 - 1400	1200 - 1300	**Lunch**	
1400 - 1445	1300 - 1345	**Clinical Investigation for the registration of Medical Devices in Korea**	Park Ducklyul, WIKICRO
1445 - 1530	1345 - 1430	**Global Harmonization of the medical device regulations - Jack** · Overall regulations, directives, guidelines IMDRF, AHWP, ASEAN MDD, EU, US, Canada, Japan, Australia · Definition and Risk classification of Medical Device, IVD, and Combination product	Jack Wong, Asia Regulatory and Professional Association (ARPA)
1530 - 1545	1430 - 1445	**Tea Break**	
1545 - 1615	1445 - 1515	**MedTech in Korea – Where is it heading?**	Dae Hee Hong, CEO of Mediguide
1615-1645	1515- 1545	**The Startup Journey – From Concept to Commercialization and Adoption**	Hoseok Lee, Business Developer of WAYCEN
1645 - 1715	1545 - 1615	**Startup Funding – Tips for landing it**	Bert Lee (Lee Jong Mu) , KitsCorp
1715	1615	**End of IMDS KR/SG DAY 1**	

DAY 2: 19 Mar 2024

MEDICAL DEVICE DESIGN & DEVELOPMENT, QUALITY MANAGEMENT & STANDARDS **Chairperson:** May Ng, ARQon & Jack , ARPA			
	Time	**Topics**	
	0900 - 0930	**Registration**	
	0930 - 0950	**Design Thinking of Medical Device Innovation**	Dr Sean Chia, Singapore Biodesign Alumni
	0950 - 1005	**Tea Break**	
	1000 - 1200	**Design Thinking Workshop:** · Concept brainstorming & Value proposition · Design requirements, Feasibility vs validation discussion · Project Management	Dr Sean Chia, Singapore Biodesign Alumni
	1200 - 1300	**Lunch**	
	1300 - 1330	**Quality Management System - Importance of QMS, Design to Production, Risk management, Design Control** · What are the key QMS: ISO 13485, MDSAP, QSR, MDR, IVDR · Design to production requirements · Design control requirements · Elements in Design History File · Risk management in product lifecycle: ISO 14971	Shaun Kho, MedtechBOSS
	1330 - 1350	**Standards Adoption for Medical Device**	Wong Siow Kay, CoRE-SDO
	1350 - 1410	**Electrical and Electromagnetic testing** · IEC60601, IEC61010	Mr Yeoh Wei Yee , TUV SUD
	1410 - 1430	**Software validation, Usability, Software** · IEC62304, IEC62366	Dr Sheng Hui Liao, Industrial Technology Research Institute (ITRI)
	1430 - 1450	**Biocompatibility** · ISO10993	Chen Jia Yi, TUV SUD
	1450 - 1510	**Sterilization & Packaging**	Ng Xi Yun, invoX Pharma & Head of Consulting, MedRationale.
	1510 - 1535	**Health safety compliance** · Equipment registration requirements for Wireless Medical Devices ·Packaging reporting & Radiation	Lim Chee Gee, IMDA May Ng, ARQon
	1535-1600	**Tea Break**	
	1600 - 1800	**Workshop Regulatory Strategy** · Start-ups getting first approval in US, CE, or local country · Regulatory strategy compliance for Technical, Clinical, Key requirements for Global approval · Content of Technical documentation, Clinical Evaluation Report, Country Submission Dossier	May Ng & Saw Kai Li, ARQon & MedtechBOSS
	1820	**End of Day 2**	

DAY 3: 20 Mar 2024

MARKET & SUPPLY CHAIN STRATEGY **Chairperson:** May Ng, ARQon & Jack , ARPA			
	Time	**Topics**	
	0830 - 0900	**Registration**	
	0900 - 0930	**Market trend and opportunities in Medtech**	Devanathan Raghunathan, PWC
	0930 - 1000	**Medtech Marketing Approaches** · Sales Model: Subsidiary, Direct Sales or Distributor · Product licence holding rights	Ivan Goh,QuantumTX Jane Wang , Roceso
	1000 - 1030	**UDI Barcode** •What is UDI and benefit of UDI for traceability •Global landscape on UDI regulatory requirements	Andy Siow, GS1
	1030 - 1100	**Labelling** · Labelling requirements: Product label, IFU, eIFU, Brochure · Promotion and Advertisement · Challenges	Victor Tan,SMF MTIG
	1100 - 1115	**Tea Break**	
	1115 - 1145	**Intellectual Property: Patents, Trademarks, Liability** · Patenting strategies; timing and geographical · Product trademark · Product liability/risk after sales	Jonathan Agmon, Soroker Agmon Nordman
	1145 -1215	**Distributor GDP/SS620 and Post market** · When you need GDP certification · What are the steps for GDP set-up · Common challenges for GDP set-up in ASEAN · GDP differences between device and pharmaceutical · Complaint and Vigilance handling · Expectations of the certification body	Shaun Kho, MedtechBOSS
	1215 - 12:35	**Due Diligence and Valuation for Startups**	Cairan He, Venture Blick
	1235 - 1335	**Lunch**	
	1335 - 1355	**Hospital procurement** · Medical device procurement policy in hospital	Jessica Lee, DNA Medic

	1355 - 1415	**Code of Ethics for Medical Device Industry** · Good Ethics for Professionals in Medtech Industry	May Ng, ARQon
	1415 - 1500	**Fund raising** Value proposition Pitching dos and don't	Bhargav Sosale, Mediostech
	1500 - 1530	**IVD Performance Evaluation studies (Online)**	Pinar Nebol, Adviqual
	1530 - 1545	**Tea break**	
	1545 - 1800	Commercialization and Distribution strategy Workshop · Strategy and Considerations for Product Launch · Investor & Collaborator approach · Determine distribution channel	Dev Jashani
	1800	**End of Day 3**	
DAY 4: 21 Mar 2024			
Product Research & Development and Application Technology (R&D, Engineering) **Chairperson:** Adrian Danker, TP			
	Time	**Topics**	
	830	**Registration**	
	900-1100	**Laboratory Practices & Medical Biochemistry** • Introduction to Laboratory Management System • Innovating Lab Practices : A roadmap to sustainability digitalization and ISO 17025 Alignment.	Cathy Sagun (2hr) Temasek Poly
	1100-1130	**Tea Break**	
	1130- 1300	Tour of TP , TP AMC, 3D Printing, HEC & Innovation Learning Lab	Dr Wong Yee Shan (2Hrs) Temasek Poly
	1300-1330	**Lunch**	
	1330 -1630	**Microfluidics Technologies and Point of Care Systems** Microfluidic-based point-of-care systems have multiple advantages over traditional diagnostic platforms such as cost-effectiveness and shorter turnaround time. They have been increasingly used in medical and healthcare sectors. • Fundamentals of microfluidic theories, design principles, fabrication methods and key applications. • The technologies help in curbing COVID-19 pandemic will be introduced. Practical session will also be conducted for the participants to produce and test a simple microfluidic device.	Dr Fu Yi (4hrs) Temasek Poly
	1630-1700	**Tea Break**	
	1700	**Workshop Summary**	Panelists (1hr) May Ng Jack Wong Adrian Danker
	1800	**Mandatory Assessment**	
	1830	**End of Day 4 MDS SG**	