Date: 27 March 2023 (Monday)
Venue: Korea University Medicine

MEDICAL DEVICE REGULATORY

Time (SGT)	**Time (KST)**	Sub-Topic	**Speakers**
0800	0900	Registration	
0830	0930	Opening	• IL-HO PARK, Director for office of Clinical Trials of Korea University Medicine • Song Kwok Yuen , Director, School of Engineering, Temasek Polytechnic. • May Ng , CEO of ARQon Group • Dae Hee Hong, CEO of Mediguide
0900	1000	The role of Industry Associations and partners in regulatory convergence and healthcare innovation • 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 • Marc Perut, Swiss Ventures • Hakan, Requalite Europe • Dae Hee Hong, CEO of Mediguide
0945	10:45	Clinical trial for Innovation Products • What are funding available and criteria • Single or Multi-centre trial • Plan and conduct of Clinical trial • Differences between Clinical trial vs clinical evaluation	• Dong Ho, Hong, Mediguide
1030	1130	Tea Break	
1045	1145	The trends of Medical Device Industry in Korea	• Dae Hee Hong, CEO of Mediguide
1115	1215	APAC regulatory requirements - South Korea	• Chan Yo (CY) Won, Mediguide and ARQon Korea
1140	1240	APAC regulatory requirements - ASEAN, Greater China	• May Ng, ARQon Group
1200	1300	Lunch	
1300	1400	MDR & IVDR CE mark regulatory requirements – Introduction & Conformity assessment Routes • MDD and the New MDR, Other related Directives eg Combination products • IVDD and the New IVDR • Conformity assessment routes for CE Marking • Post Market: Vigilance, PMPF, PMCF, PSUR • Further changes eg Eudamed, Clinical Evaluation	• Hakan, Requalite Europe
1345	1445	Korea Q&A	
1400	1500	End of IMDS KR	
1345	-	Global Harmonization of the medical device regulations • 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)
1430		Tea Break	
1445		UDI Barcode • What is UDI and benefit of UDI for traceability • Global landscape on UDI regulatory requirements	• Andy Siow, Singapore Manufacturing Federation's GS1 (SMF's GS1)
1600		**SG Q&A** & Quiz (IMDS SG)	
1700		**End of IMDS SG DAY 1**	

DAY 2		
Date: 28 March 2023 (Tuesday) **Venue: Temasek Polytechnic, Singapore**		
MEDICAL DEVICE DESIGN & DEVELOPMENT, QUALITY MANAGEMENT & STANDARDS		
Time	**Sub-Topic**	
0900	Registration	
0930	**Design Thinking of Medical Device Innovation**	• Alex Choh Agency for Science, Technology and Research (A*STAR) 's Singapore Biodesign
1000	**Design Thinking Workshop:** • Concept brainstorming & Value proposition • Design requirements, Feasibility vs validation discussion • Project Management	• Joel Tan MedtechBOSS
1200	**Lunch**	
1300	**Quality Management System - Importance of QMS, Design to Production, Risk management** • What are the key QMS: ISO 13485, MDSAP, QSR, MDR, IVDR • Design to production requirements • Risk management in product lifecycle: ISO 14971	• Shaun Kho MedtechBOSS
1330	**Standards Adoption for Medical Device**	• Celine Tan Enterprise Singapore
1350	**Electrical and Electromagnetic testing** • IEC60601, IEC61010	• Zhuo Guo Ping Underwater Laboratories (UL)
1410	**Software validation, Usability, Software** • IEC62304, IEC62366	• Dr Sheng Hui Liao, Industrial Technology Research Institute (ITRI)
1430	**Biocompatibility** • ISO10993	• Chen Jia Yi, TUV SUD
1450	**Sterilization & Packaging**	• Jimmy Li , OliverHCP • Shaun Kho, MedtechBOSS
1510	**Health safety compliance** • Equipment registration requirements for Wireless Medical Devices • Others (i.e. Packaging reporting, Radiation, etc.)	• Cavin Wang, IMDA • Wong Xue Wen, MedtechBOSS
1530	**Tea break**	
1550	**Collaboration Opportunities in Europe** • Sharing on different type of collaboration opportunities in Europe for MedTech companies	• Ian Lee, Enterprise European Network (EEN)
1605	**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	• Joel Tan, MedtechBOSS
1750	**Quiz**	
1805	**End of Day 2**	

DAY 3		
Date: 29 March 2023 (Wednesday) **Venue: Temasek Polytechnic, Singapore**		
MARKET & SUPPLY CHAIN STRATEGY		
Time	**Sub-Topic**	**Speakers**
0830	Registration	
0900	**Market trend and opportunities in Medtech**	• Devanathan Raghunathan, PWC
0940	**Medtech Marketing Approaches** • Sales Model: Subsidiary, Direct Sales or Distributor • Product licence holding rights	• Nilesh Wadhwa, Life science industry professional
1000	**IVD Case Study - GASTROClear: The Journey from Lab to Clinic**	• Teo Cher Hwa, Mirxes
1040	**Labelling** • Labelling requirements: Product label, IFU, eIFU, Brochure • Promotion and Advertisement • Challenges	• Victor Tan, SMF MTIG
1100	**Tea Break**	
1115	**Intellectual Property: Patents, Trademarks, Liability** • Patenting strategies; timing and geographical • Product trademark • Product liability/risk after sales	• PATRICK CHOW CHOW NG PARTNERSHIP
1135	**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	• May Ng, ARQon Group
1205	**Profession job roles in Medtech Industry** • Sharing different Medtech roles • How to select the right candidate. What is their skillset? • Managing resources need	• Cheong Yee Yin, Integrity
1220	**Fund raising** • Value proposition • Pitching dos and don't	• Bhargav Sosale, Remidio
1300	**Lunch**	
1415	**Hospital procurement** • Medical device procurement policy in hospital	• Gjan Lim, Healthcare Essentials
1445	**Code of Ethics for Medical Device Industry** • Good Ethics for Professionals in Medtech Industry	• Gjan Lim, Healthcare Essentials
1545	**US FDA regulatory requirements** • 510(k), PMA and other submissions	• Eamonn Hoxey, Association for the Advancement of Medical Instrumentation (AAMI)
1615	**Tea break**	
1630	**Commercialization and Distribution strategy Workshop** • Strategy and Considerations for Product Launch • Investor & Collaborator approach • Determine distribution channel	• Ashvanni, iMedrix
1815	**Quiz**	
1830	**End of Day 3**	

DAY 4		
Date: 30 March 2023 (Thursday) **Venue: Temasek Poly**		
Main Header: Product Research & Development and Application Technology (R&D, Engineering) (Moderator: Adrian Danker)		
Time	**Sub-Topic**	**Speakers**
0830	Registration	
0900	Medical Devices Development • Function and characteristics of Electrodes and Transducers • Design amplifiers and filters for medical applications. • Relate the various methods of noise and Electromagnetic Interference (EMI) suppression. • Build a Medical Device prototype of a physiological signal measurement system.	Kwok Siew Loong (0.5hr) Temasek Poly Qian Xi Jun (0.5hr) Temasek Poly
1000	Tea Break	
1030	Laboratory Practices & Medical Biochemistry • Introduction to Laboratory Management System • Medical Biochemistry Fundamentals	Cathy Sagun (0.5 hr) Temasek Poly Dr Raja (0.5 hr) Temasek Poly
1130	Smart Wearable Healthcare Devices The advancement of smart wearable technology and growing demand from consumers to take control of their own health has influenced the medical industry and technology companies to develop more smart wearable devices. This lecture will cover the following topics: • What are smart wearable healthcare devices? • Examples of smart wearable healthcare devices Technology roadmap: accessory type, textile integrated, skin patchable, body implantable.	Dr Sun Ling Ling (1 hr) Temasek Poly
1230	**Lunch**	
1330	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 (2 hr) Temasek Poly
1530	Tea Break	
1600	Workshop Summary	Panelists (2 hr) May Ng Jack Wong Adrian Danker
1800	End of Day 4 MDS SG	