Asia Regulatory & Quality Consultancy
Medical Device & Drug

Temasek POLYTECHNIC

MEDICAL DEVICE SCHOOL

Programme Outline

DAY 1

Location: Temasek Polytechnic

CUSTOMER LANDSCAPE & GO-TO-MARKET STRATEGY FOR MEDTECH INDUSTRY

Time	Topic	Speaker
0830	Registration	
0900	Opening and Welcome Speech	• Cheah Swee Hock, Temasek Poly • May Ng, ARQon
0915	Opening remarks by the instructor to set the scene/agenda + Poll 1.	
0930	The sustainability of our health systems, and implications for medtech companies + Poll 2	• Chris L. Hardesty, KPMG
1000	DSTM approach for aligning to the "job to be done" principles in successful medtech ventures.	• Mark Chong, Singapore Biodesign
1045	Break	
1100	How to know who your real "customer" is, and the variety of ways to reach them.	• Arun Sethuraman, Crely
1145	Open discussion, morning wrap-up + Poll 3	
1200	Lunch Break	
1300	Scaling up – how to evolve your concept into a sustainable and profitable business.	• Andrew Frye, Baxter
1345	Launching your product/service to market with an intentional manufacturing & supply strategy.	• David Lee, MedtechBOSS • Andy Siow, GS1 Singapore
1430	Break	
1500	OTHERS: Bringing it all together to reflect on the above and other items like funding, support, human capital (panel format) • Panel to cover off some of the themes not already covered (e.g. investment, IP, talent, government support, reimbursement)	• Christopher Laing, Duke-NUS Medical School Innovation & Entrepreneurship • Mark Wang, Pureland Group • Ran Wang, EVYD
1600	Open discussion, afternoon wrap-up + Quiz	
1700	End of Day 1	

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1800	**IMDS Networking: ASIA** Virtual Medtech Exchange Networking **Global Medtech Market Entry, Avoiding Commercialisation Hurdles, EU Regulatory System Changes and Impacts on Industry** **Breakout Sessions for Networking** **Time:** 6pm to 7:30pm **Venue:** Zoom platform **Complimentary. Prior registration required**

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DAY 2

Location: Temasek Polytechnic

PRODUCT DESIGN AND DEVELOPMENT, STANDARDS, MANUFACTURING, QMS, CLINICAL EVIDENCE

Time	Topic	Speaker
0830	Registration	
0900	Singapore Biodesign Introduction	• Dr. Lee Phin Peng, Agency for Science, Technology and Research (A*STAR)'s Singapore Biodesign
0920	Design Thinking Process • Concept brainstorming & Value proposition • Early validation through feasibility • Project management	• Dr. Lee Phin Peng, Agency for Science, Technology and Research (A*STAR)'s Singapore Biodesign
0935	MedTech International Collaboration opportunities • Sharing on manufacturing and collaboration opportunities	• Katherine Heng, Enterprise Europe Network (EEN) • May Ng, ARQon
1045	Break	
1100	Standards Development Organization • Introduction • Why Adoption of Singapore Standards (SS) and if different from ISO • Standards	• Kevin Tan, Singapore Manufacturing Federation (SMF)
1120	Electrical, Electromagnetic testing, Usability • IEC 60601, IEC 61010, IEC 62366	• Zhuo Guoping, Underwriters Laboratory (UL)
1140	Software validation & Cybersecurity • IEC 62304	• May Ng, ARQon
1200	Sterilization & Packaging validation	• Santosh Madival Oliver Healthcare Packaging. • May Ng, ARQon
1220	IVD safety and effectiveness requirements RNA standards Singapore	• Jeremiah De Costa, Mirxes
1240	Lunch Break	
1340	CE mark regulatory requirements – Technical Documentation • Contents of a Technical documentation • Key challenges in CE approval	• May Ng, ARQon

1410	M"edtech Manufacturing Set-up & Challenges • Bill of Material • Production Floor • Lean Cost-Effective manufacturing • Contract Manufacturing Sourcing • Vendor selection criteria and considerations • Expectations of the certification body	• Lim Sing Wee, ARQon
1440	Medtech Quality Assurance in Product Release and Supply chain • Cleanroom, Production and Validation • Product release and Quality Assurance • Supply chain management • Expectations of the certification body	• Heidi Goh, Edward Lifesciences
1510	Break	
1525	National Health Innovation Centre Introduction (Subject to Change)	• Teo Cher Hwa, National Health • Innovation Centre, Singapore (NHIC)
1545	Developing a clinical strategy • What is clinical investigation/research • When this is needed for medical devices • How to plan and conduct clinical investigation properly • What are the differences between clinical investigations and clinical evaluation? • What are the differences for medical device, IVD and pharmaceutical clinical • Investigation	• Anthony Lie, HistoIndex
1615	Panel discussion: Clinical needs, plan, approval and conduct	Moderator: • Teo Cher Hwa, National Health Innovation Centre, Singapore (NHIC) Panelists: • Dr. Angela Renayanti Dharmawan, Sing Health • Dr. Henry Ho, Sing Health
1655	Quiz	
1800	End of Day 2	

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DAY 3

Location: Temasek Polytechnic

REGULATORY IN PRODUCT LIFECYCLE

Time	Topic	Speaker
0830	Registration	
0900	Global development and 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, Drug and Combination product • Product lifecycle from research to commercialization	• Jack Wong, Asia Regulatory and Professional Association (ARPA)
0930	ASEAN medical device regulatory requirements • Establishment registration: Manufacturer, Importer, Distributor, Authorised Representative • Product registration & Other access routes • ASEAN/SG Common Submission Dossier Template (CSDT)	• Duc Duong, Edwards Life Science
1045	Tea Break	
1100	Medical Device vs IVD • Key highlights differences between Medical Device and IVD registration	• May Ng, ARQon
1130	Panel discussion: The role of Industry Associations and partners in regulatory convergence and healthcare improvement • The effective network of industry associations across the ASEAN, ASIA, EU, US, GLOBAL • The importance of association's role for its stakeholder i.e. local industry and the national authorities/agencies.	Moderator: • May Ng, ARQon Panelists: • Duc Duong, Edwards Life Science • Dr. Aishwarya Bandla, Institute of Electrical and Electronics Engineers (IEEE)
1200	Lunch	
1300	Asia regulatory requirements • Greater China, Japan, Korea	• Jack Wong, Asia Regulatory and Professional Association (ARPA)
1320	Panel discussion: Regulatory barriers and strategies, Sharing of investment Policies. • Case studies and sharing by MNC Case studies and sharing by SME	Moderator: • Jack Wong, Asia Regulatory and Professional Association (ARPA)

		Panelists: • Steven Ang, EyRIS. • Kim Kangwook, Dahai Korea • May Ng, ARQon
1350	Post-market surveillance overview • What is Post Market Surveillance • What to report and timeline for Vigilance Reporting • Post-Market Clinical Follow up (PMCF) • Handling Complaints, Adverse Event and Field Safety Corrective Action/Recall	• Jack Wong, ARPA
1410	Product/Process/Label Changes • Managing changes and Impact • Regulatory intelligence news updates	• Yenny Anggoro, Stryker
1430	Reimbursement Australia & NZ, Korea • What is Reimbursement & technology coding being paid of	• May Ng, ARQon • Kim Kang Wook, Dahai Korea
1450	Global Regulatory strategy & FAQs • Start-ups getting first approval: What to do? • What is Medical Device File, Technical File, and Design History File? • Which country first: US, EU or SG? • Is it a must to certify to ISO 13485? • Can we use literature paper vs Clinical trial? • How to transit MDD/IVDD to CE MDR/IVR	• May Ng, ARQon
1520	Tea Break	
1535	MDR CE mark regulatory requirements – Introduction & Conformity assessment Routes • MDD and the New MDR, Other related Directives e.g. Combination products • Conformity assessment routes for CE Marking • Post Market: Vigilance, PMCF, PSUR • Further changes e.g. Eudamed, Clinical Evaluation	• Tatiana Vignudelli, ECM
1555	IVDR CE mark regulatory requirements – Introduction & Conformity assessment Routes • IVDD and the New IVDR - most important changes • Timelines of IVD Regulation • Conformity assessment procedures • Challenges for Manufacturers • Guidance documents CE process & Timeline	• Dr. Ooi Xi Jia, Tuv Sud
1615	Quality Management System - Importance of QMS in Design, Development, Manufacturing, Storage, Distribution (ISO13485:2016, MDSAP, USQSR, SS620 GDPMDS) • Why need QMS? • What are the key QMS and differences: ISO/EN ISO 13485:2016, MDSAP, US QSR, EU MDR/IVDR • Common industry challenges for QMS set-up and maintenance • How is risk management use in product lifecycle	• Dr. Eamonn Hoxey , AAMI
1635	US FDA regulatory requirements • 510(k), PMA and other submissions • Key challenges in US approval	• Dr. Eamonn Hoxey , AAMI

1655	Regulatory Controls on • Wireless Medical Devices	• Salamah Hashim, Infocomm Media Development Authority (IMDA)
1715	Regulatory Controls on • Radiation (Ionizing and Non-Ionizing) Medical Devices	• May Ng, ARQon
1735	Quiz	
1800	End of Day 3	

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DAY 4

Location: Temasek Polytechnic

PRODUCT RESEARCH & DEVELOPMENT AND APPLICATION TECHNOLOGY (R&D, ENGINEERING)

Time	Topic	Speaker
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, Temasek Polytechnic. • Qian Xi Jun, Temasek Polytechnic
1100	Tea Break	
1030	Laboratory Practices & Medical Biochemistry • Introduction to Laboratory Management System • Medical Biochemistry Fundamentals	• Cathy P. Sagun, Temasek Polytechnic • Dr. Raja Rangaswamy, Temasek Polytechnic
1315	Lunch	
1400	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, Temasek Polytechnic
1530	Tea Break	
1545	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	• Dr Sun Ling Ling, Temasek Polytechnic

	Technology roadmap: accessory type, textile integrated, skin patchable, body implantable.	
1715	Centre of Excellence Tour (HRG & AMC)	• Ng Kee Wee, Temasek Polytechnic
1800	End of Day 4	