Asia Regulatory & Quality Consultancy
Medical Device & Drug

Temasek POLYTECHNIC

MEDICAL DEVICE SCHOOL

Programme Schedule

DAY 1
01 OCT 19

MEDICAL DEVICE REGULATORY AFFAIRS
VENUE: ASPIRATION ROOM, LEVEL 2M, MATRIX BUILDING (BIOPOLIS), 30 Biopolis Street, Singapore 138671
CHAIRPERSON: Jack Wong, Asia Regulatory and Professional Association (ARPA)

Time	Topics	Speakers
0830	**Registration**	
0900	**Opening**	• Wong Kia Ngee, Temasek Polytechnic • May Ng, ARQon
0915	**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) /Allergan
0945	**ASEAN medical device regulatory requirements** • Establishment registration: Manufacturer, Importer, Distributor, Authorised Representative • Product registration & Other access routes	• May Ng, ARQon • ASEAN Regulators
1045	**Tea Break**	
1100	**Panel discussion: ASEAN regulators**	Moderator: • Audrey Lee, Invisalign Singapore / Singapore Manufacturing Federation's Medtech Industry Group (SMF's MTIG) • ASEAN Regulators
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 stakeholders i.e. local industry and the national authorities/agencies.	Moderator: • Duc Duong, Edward LifeSciences / Singapore Manufacturing Federation's Medtech Industry Group (SMF's MTIG) • Jacqueline Monteiro, Regulatory Affairs Professionals Society (RAPS) • May Ng, ASEANMed • Ruth Shennan, Medical Technology of Australia (MTAA)
1200	**Lunch**	
1300	**Asia regulatory requirements** • China **Asia regulatory requirements** • Taiwan ROC	• Dazhi (ex-CFDA/NMPA), ARQon China • Albert Li, Industrial Technology Research Institute (ITRI)

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1345	**Asia regulatory requirements** • India	• Sreenu Babu, Cardinal Health
1405	**Asia regulatory requirements** • Japan	• Jack Wong, Asia Regulatory and Professional Association (ARPA) /Allergan
1430	**Asia Pacific regulatory requirements & Reimbursement** • Australia & NZ • What is Reimbursement & technology coding being paid of	• Ruth Shennan, Device Technologies
1500	**Product/Process Changes** • Managing changes and Impact	• Yenny Anggoro, Stryker
1520	**Asia regulatory requirements - Differences Medical Device, IVD** Key highlights differences between Medical Device and IVD registration	• Nashata Isa, Qiagen
1540	**Tea Break**	
1555	**MDR CE mark regulatory requirements – Introduction & Conformity assessment Routes** • MDD and the New MDR, Other related Directives eg Combination products • Conformity assessment routes for CE Marking • Post Market: Vigilance, PMCF, PSUR • Further changes eg Eudamed, Clinical Evaluation	• Moira Lim, TUV SUD
1615	**IVDR CE mark regulatory requirements – Introduction & Conformity assessment Routes** • IVDD and the New IVDR • Conformity assessment routes for CE Marking • Post Market: Vigilance, PMPF, PSUR • Further changes in EU eg Companion diagnostic	• Ooi Xi Jia, TUV SUD
1635	**CE mark regulatory requirements – Technical Documentation** • Contents of a Technical documentation • Reviewing the Essential requirements • The use of relevant standards	• May Ng, ARQon
1655	**US FDA regulatory requirements** • 510(k), PMA and other submissions • US QSR Quality system and inspections • Warning letters and key lookout	• Albert Li, Industrial Technology Research Institute (ITRI) • Michael Bjornstad, ARQon US
1725	**Regulatory Controls on** • Wireless medical device • Radiation medical device	• Salamah Hashim, Infocomm Media Development Authority (IMDA) • May Ng, ARQon
1745	**Global Regulatory strategy & FAQs** • Start-ups getting first approval • Manufacturer penetrating Asia • Manufacturer transitions to CE MDR/IVR	• May Ng, ARQon • Heikki Pitkanen, Lean Entries Finland
1815	**Quiz**	
1830	**End of Day 1**	

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MEDICAL DEVICE DESIGN & DEVELOPMENT, STANDARDS & QUALITY MANAGEMENT, CLINICAL
VENUE: LT301 ROOM, LEVEL 3, NTU ALUMNI CLUB (NTU@ONE NORTH), 11 Slim Barracks Rise, S138664
CHAIRPERSON:
Mark Chong, Agency for Science, Technology and Research (A*STAR)'s Singapore Biodesign
Choi Kwok Keong, Standards Development Organisation (SDO)
Teo Cher Hwa, National Health Innovation Centre (NHIC)

DAY 2
02 OCT 19

Time	Topics	Speakers
0900	**Singapore Biodesign Introduction**	• Mark Chong, Agency for Science, Technology and Research (A*STAR)'s Singapore Biodesign
0915	**Quality Management System - Importance of QMS and Risk management** • Why need QMS? • What are the key QMS: ISO/EN ISO 13485:2016, MDSAP, US QSR, EU Conformity • How risk management fits with the product lifecycle, ISO 14971:2012	• Eamonn Hoxey, Association for the Advancement of Medical Instrumentation (AAMI)
0945	**Quality Management System - Design Control** • Design control requirements • Elements in Design History File • Expectation of the certification body	• May Ng, ARQon
1015	**Design Thinking Process** • Concept brainstorming & Value proposition • Early validation through feasibility • Project management	• Mark Chong, Agency for Science, Technology and Research (A*STAR) 's Singapore Biodesign
1045	**Tea Break**	
1100	**Standards Development Organization Introduction**	• Choi Kwok Keong, Standards Development Organisation (SDO)
1115	**Electrical and Electromagnetic testing** • IEC60601, IEC61010	• Zhuo Guoping, Underwriters Laboratory (UL)
1135	**Software validation and Usability** • IEC62304, IEC62366	• Wang Jen-Chieh, Industrial Technology Research Institute (ITRI)
1155	**Cybersecurity & Data Protection**	• May Ng , ARQon
1215	**Biocompatibility ISO10993**	• Li Yang, TUV SUD
1235	**Sterilization & Packaging validation**	• Eamonn Hoxey, Association for the Advancement of Medical Instrumentation (AAMI)

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1255	**Lunch**	
1355	**Quality Management System - Production, Warehousing & Distribution** • Cleanroom, Production and Validation • Product release and Quality Assurance • Supply chain management • Expectations of the certification body	• Heidi Goh, Edward Lifesciences
1425	**Medtech Manufacturer's Quality Management System Set-up** (ISO13485:2016, MDSAP, USQSR) • When you need QMS certification • What are the Steps for QMS set-up • Common industry challenges for QMS set-up	• Teo Siow Thing, ARQon
1455	**Medtech Manufacturing Set-up & Challenges** • Bill of Material • Production Floor • Lean Cost-Effective manufacturing • Other key considerations • Process Validation IQ/OQ/PPQ	• Colin Chong, ARQon US • Michael Bjornstad, ARQon US
1525	**Medtech Outsourcing Contract Manufacturing** • Contract Manufacturing Sourcing • Vendor selection criteria and considerations • Factor for success collaboration	• Colin Chong, ARQon US
1545	**Medtech Manufacturing and Collaboration opportunities** • Sharing on manufacturing and collaboration opportunities • Sharing on investment policy & business/manufacturing setup	• Katherine Heng, Enterprise Europe Network (EEN) • Daniela Radrizzani, Fidinam
1625	**Tea Break**	
1640	**National Health Innovation Centre Introduction**	• Teo Cher Hwa, National Health Innovation Centre, Singapore (NHIC)
1655	**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	• Ivanus Manopo, Singapore Clinical Research Institute (SCRI) • Emily Tan, Paraxel International
1725	**Panel discussion: Clinical needs, plan, approval and conduct**	Moderator: • Teo Cher Hwa, National Health, Innovation Centre, Singapore (NHIC) • Ivanus Manopo, Singapore Clinical Research Institute (SCRI) • Emily Tan, Paraxel International
1815	**Quiz**	
1830	**End of Day 2**	

Asia Regulatory & Quality Consultancy
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Temasek POLYTECHNIC

MEDICAL DEVICE SCHOOL

Programme Schedule

DAY 3
03 OCT 19

MARKET & SUPPLY CHAIN STRATEGY
VENUE: ASPIRATION ROOM, LEVEL 2M, MATRIX BUILDING (BIOPOLIS), 30 Biopolis Street, Singapore 138671
CHAIRPERSON: May Ng, ARQon (Asia Regulatory & Quality Consultancy)

Time	Topics	Speakers
0900	**Market trend and opportunities in Medtech**	• Howard Chai, Deloitte
0920	**Medtech Market Access: Barriers & strategies** • Market strategy and Considerations for Product Launch	• Alok Mishra, Value Addition
0940	**Medtech Marketing Approaches** • Sales Model: Subsidiary, Direct Sales or Distributor • Product license holding rights **Medtech Business One-Stop Service platform** • MedtechBOSS Network	• Shikharesh Das, Ontogenix • David Lee, MedtechBOSS
1010	**Healthcare software/apps & E-commerce** • HealthTech Regulatory Sandbox • Are these product/service and its provider being controlled? Software/Apps for clinical service, Software for healthcare lifestyle, Online sales of medical device for commercial or personal use • SMA eMarket	• Ministry of Health (MOH) • Jasmine Tan, Bizzmann and Singapore Medical Association (SMA)
1040	**Labelling** • Labelling requirements: Product label, IFU (eIFU), brochure • Promotion and Advertisement • Challenges	• Kelvin Koh, Terumo
1100	**Tea Break**	
1115	**Intellectual Property: Patents, Trademarks & Liability** • Patenting strategies; timing and geographical coverage • Product trademark • Product liability/risk after sales	• Ong Siew Hwa, Acumen
1135	**Code of Ethics for Medical Device Industry** • Key points in Code of Ethics policy for a Medtech company	• Fiona Goh, Zimmer Biomet

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1155	**Profession job roles in Medtech Industry** • Sharing different Medtech roles • How to select the right candidate. What is their skillset? • Managing resources need	• Colin Tan, Endomaster
1215	**Fund raising** • Value proposition • Pitching dos and don't	• Mark Wang, Pureland Global Venture
1235	**Awareness on Government Funds & Support for Medtech Industry & Industry 4.0**	• Gerald Wong, Singapore Manufacturing Federation's Centre for Corporate Learning (SMF's CCL) Singapore Manufacturing Federation's SME Centre (SMF's SME Centre)
1255	**Lunch**	
1355	**Hospital procurement** • Medical device procurement policy in hospital - Singapore - Indonesia i.e. E-catalogue, manufacturing capabilities and investment policy	• Christopher Tay, Association for Persons with Special Needs (APSN), ex-COO Tan Tock Seng Hospital Singapore • Kevin Widjaja, DEMKA Sakti / GAKESLAB / ASPAKI Indonesia
1330	**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)
1350	**Post-market surveillance overview** • What is Post Market Surveilance • What to report and timeline for Vigilance Reporting • Post-Market Clinical Follow up (PMCF) • Handling Complaints, Adverse Event and FSCA	• Joanna Koh, MDNet
1410	**Quality Management System Set-up & Challenges for Importer & Distributor SS620, GDPMD in ASEAN** • 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	• Terry Song, Boston Scientific • Stephen Hsu, Boehringer Ingelheim
1440	**Quiz**	
1500	**End of Day 3**	
1600	**MEDTECH EXCHANGE NETWORKING EVENT (COMPLIMENTARY OPEN TO ALL MEDTECH INDUSTRY)** **VENUE:** AUDITORIUM, LEVEL 2, MATRIX BUILDING (BIOPOLIS), 30 Biopolis Street, Singapore 138671 **ORGANISED BY:** ARQON, ASEANMed, SG INNOVATE, TEMASEK POLYTECHNIC	

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DAY 4
04 OCT 19

PRODUCT RESEARCH & DEVELOPMENT AND APPLICATION TECHNOLOGY
VENUE: LT16 ROOM, LEVEL 1-UNIT 4, BLOCK 7, SCHOOL OF INFORMATIC & IT (TEMASEK POLYTECHNIC), 21 Tampines Avenue 1, Singapore 529757
CHAIRPERSON: Adrian Noel Danker, Temasek Polytechnic

Time	Topics	Speakers
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.	• Mr Siew Loong, Temasek Polytechnic • Mr Qian Xijun, Temasek Polytechnic
1015	**Tea Break**	
1030	**Genetic Engineering & Tissue Engineering** • Methods to produce different genetically modified organisms (GMOs) • Applications of genetic engineering in biotechnology • Laboratory management, quality assurance, laboratory automation, statistical methods and safety regulations practised in laboratories Stem Cells and Tissue Engineering • Concepts of tissue engineering, stem cells, biomaterials and a review on extracellular matrix, topics on cell-cell and cell-matrix interactions at both the theoretical and experimental levels **Clinical Chemistry** • Pathophysiological changes in disease and the application of clinical chemistry concepts for the diagnosis, prognosis, monitoring and screening of diseases	• Dr. Ismail Muhamad Hanif, Temasek Polytechnic
1145	**Lunch**	
1245	**3D Printing Technologies and Applications**	• Mr Lee Khim Yong, Temasek Polytechnic
1345	**Microfluidics Technologies and Applications**	• Dr Fu Yi, Temasek Polytechnic
1445	**Quiz**	
1500	**Travel to Manufacturing site / Tea Break** JTC MedTech Hub, 2 Tukang Innovation Grove, S619624	
1600	**Visit to JTC MedTech Hub's manufacturing sites:** • Medical device: Implant and 3D printing	• Jurong Town Corporation (JTC) • Osteopore
1800	**Travel back to MRT train station**	
1830	**Course completion**	

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