IMDS MALAYSIA

23-25 Mar 2022

MD School
International Medical Device School

INTRODUCTION

Register now at:
http://www.mddev.com.my/ or https://forms.gle/KnJ8yw7ZYeFLN4FM8

ABOUT

This course will provide MedTech (Medical Technology) industry professionals a chance to receive a quick yet comprehensive overview of the medical devices including IVDs product lifecycle, starting from research and development stage to commercialization in Malaysia. It will also include opportunities and challenges in the manufacturing and post market handling of medical devices. Participants will gain valuable insight on medical devices with regulators, industry experts and academicians joining hands to share the global regulatory landscape and latest updates including the Malaysian MDR, Halal Medical Devices, New CE MDR and the latest innovation in Medtech. The course would also provide opportunities for like-minded MedTech professionals in exploring potential business collaboration.

KEY BENEFITS

- Gain valuable insights and experiences from the key respected speakers in the field to apply to your work/decision and preventing common mistakes.
- Gain a comprehensive understanding on global regulatory landscape and latest updates including the new CE MDR.
- Discover the design, testing and standards requirements for product safety.
- To explore the innovation and advanced technologies in medical device.
- To hear about the opportunities and challenges in the manufacturing and post market handling.
- Networking with Medtech partners and industries, for potential collaboration.

DETAIL

Date: 23-25 Mar 2022
Venue: Online Platform

Cost:	Early Bird*	Standard
Students (Malaysian)	RM 450	RM 500
Students (International)	USD 140	USD 150
Malaysian	RM 1,400	RM 1,500
International	USD 750	USD 850

* Early Bird will end on 14 March 2022

CONTACT US

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ORGANIZERS

UNIVERSITI MALAYSIA PERLIS (UniMAP)
TUSB – TECHNOPRENEUR UNIMAP SDN. BHD.
UNIVERSITI MALAYSIA PERLIS SERO – SPORTS ENGINEERING RESEARCH CENTRE
MdDev – MedTech Consultancy
ARQon – Asia Regulatory & Quality Consultancy – Medical Device & Drug
ARPA – Asia Regulatory Professionals Association
MedtechBOSS – Business One Stop Service –
ASEANMed – ASEAN Federation of Medical Device Industry

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AGENDA Day 1: 23 March 2022

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Day 1: 23 March 2022
Medical Device Regulatory & Innovation
Moderator: Ir. Sasikala Devi

08:30 – 09:00 AM
Registration

09:00 – 09:15 AM
Opening Speech
Minister of Science

09:15 – 09:45 AM
KEYNOTE SPEECH: Introduction to Healthcare & Challenges Malaysia
MOH/ MOSTI

09:45 – 10:15 AM
Update on MD Registration and challenges in Malaysia on second stage of registration
Mariammah A/P Krishnasamy
Chief Assistant Director under Licensing and Registration Branch, MDA

10:15 – 10:30 AM
Tea Break

10:30 – 11:00 AM
MALAYSIA: Introduction to Post Market Surveillance (PMS) regulation in Malaysia
MDA

11:00 – 11:30 AM
Medical Device Advertisement, Labelling & FAQ
MDA

11:30 – 12:00 PM
MALAYSIA: Halal compliance and the challenges in medical device industry
Salbiah Bt Yaakop
Director of policy, code & standards Division, MDA

12:00 – 12:30 PM
MALAYSIA: Inter agency compliance for medical devices Radiation/MCMC
MEDTECH INDUSTRY

12:30 – 13:00 PM
Medtech Support & Challenges from Medtech Industry, INDUSTRY & ACADEMIC & GOVERNMENT: TOWARDS MEDTECH COLLABORATION, Panel Discussion - Wrap up of Launching Panel Discussion
Sherulanuar Abd. Karim
Deputy Director of Life Sciences & Medical Technology Division, MIDA

13:00 – 14:00 PM
Lunch Break

14:00 – 14:30 PM
Implant Commercialisation Experience (Tissue/SIRIM)
SIRIM

14:30 – 15:00 PM
Young entrepreneur
KHAIRUL MUSTAQIM RIDWAN WONG
Founder & CEO of Kinikio Dialysis Technologies

15:00 – 15:30 PM
New Trend in Innovation, IOT and Big Data
UniMAP/ University Malaya

15:30 – 16:00 PM
Innovation in MD I
B.Braun

16:00 PM
End of Day 1

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AGENDA Day 2: 24 March 2022

Register now at:
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Day 2: 24 March 2022
Medical Device Design & Development, Standards & Clinical
Moderator: UNIMAP

09:00 - 09:30 AM
Product lifecycle from research to commercialization
University Malaya

09:30 - 10:00 AM
Medical device clinical Investigation research requirements for medical devices
Clinical Research Malaysia (CRM)

10:00 - 10:30 AM
Clinical Trials/ Clinical Investigation requirements for medical devices
Clinical Research Centre (CRC)

10:30 - 11:00 AM
Break

11:00 - 11:30 AM
Performance Evaluation Methodology for Infectious Diseases/ Covid 19
Institute For Medical Research; IMR

11:30 - 12:00 PM
Physical Testing & Validation on the safety and performance for PPEs i.e. Surgical mask and Medical face mask
3M

12:00 - 12:30 PM
Testing & Calibration for medical device in accordance with international requirement
SIRIM

12:30 - 13:00 PM
Software Validation As Medical Device (SAMD) & standards in software, Usability, Cybersecurity (ISO IEC 62304, IEC62366)
Pan Asiatic Technologies

13:00 - 14:00 PM
Lunch Break

14:00 - 14:30 PM
Biocompatibility testing for medical device in accordance with ISO10993
UNIMAP

14:30 - 15:00 PM
IVD: Covid 19 test kit
UNIMAP

15:00 - 15:30 PM
Research and Innovation in Medical Device Technology
UNIMAP/ UTM

15:30 - 16:00 PM
Research and Innovation in Medical Device Technology II
UTM/ Segi /UNITAR/Cyberjaya/UniKL

16:00 PM
End of Day 2

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AGENDA Day 3: 25 March 2022

Register now at:
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Day 3: 25 March 2022
Medical Device Regulatory, Manufacturing & Collaboration
Moderator: **May Ng**

08:30 – 09:00 AM
Registration

09:00 – 09:30 AM
Opening Speech

09:30 – 9:50 AM
Journey of Medical Device:
R&D/Design/Manufacturing/Sterilization/Logistic/Commercial/Industry 4.0

09:50 – 10:20 AM
MedTech International Collaboration Opportunities
Katherine Heng
Enterprise Europe Network (EEN)

Jacqueline Thacker
MedtechBOSS

10:20 – 10:40 AM
Global Regulatory Strategy & FAQs
May Ng
ARQon/MedtechBOSS

10:40 – 10:50 AM
Break

10:50 - 11:30
ASEAN Medical Device Regulatory Requirements
Sasikala
ex-MDA/AHWP

11:30 – 12:00 PM
Asia Regulatory Requirements

12:00 – 13:00 PM
Lunch

13:00 – 13:45 PM
Global Development and Harmonization of the Medical Device Regulations
Jack Wong
Asia Regulatory and Professionals Association (ARPA)

13:45 – 14:30 PM
Quality Management System - Importance of QMS in Design, Development, Manufacturing, Storage, Distribution (ISO13485:2016, MDSAP, USQSR, SS620 GDPMDS)
Shaun Kho
MedtechBOSS

14:30 – 15:15 PM
Supply chain and traceability of medical device in hospital
Andy Siow
GS1 Singapore

15:15 – 16:00 PM
MDR CE mark regulatory requirements – Introduction & Conformity assessment Routes
Wu Yu Long
ECM

16:00 – 16:45 PM
US FDA regulatory requirements, Key challenges in US approval
Dr. Eamonn Hoxey
AAMI

16:45 – 17:00 PM
Quiz

17:00 PM
End of Day 3 IMDS MY