

# IMDS MALAYSIA



23-25 Mar 2022

# IMD 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.

## 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

## 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.

## CONTACT US

MdDeV Sdn. Bhd

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Website: [www.imdsgroup.com](http://www.imdsgroup.com)

## ORGANIZERS



# IMDS MALAYSIA



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## AGENDA

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Day 1: 23 March 2022

Medical Device Regulatory & Innovation

Moderator: UniMAP

09:00 – 09:15 AM

Registration

09:15 – 09:40 AM

Opening Ceremony

University Malaysia Perlis (UniMAP)

09:40 – 10:15 AM

KEYNOTE SPEECH: Research & Innovation in the Medical Device Technology; Malaysia

**Assoc. Prof. Ts. Dr. Nashrul Fazli Mohd Nasir**

Division of Medical Science and Instrument

School of Mechatronic Engineering

University Malaysia Perlis (UniMAP)

10:15 – 10:30 AM

Break

10:30 – 11:00 AM

Update on MD Registration and challenges in Malaysia on second stage of registration

**Mariamamah A/P Krishnasamy**

Chief Assistant Director, Medical Device Registration Division

Medical Device Authority (MDA)

11:00 – 11:30 AM

Updates on Regulatory Requirements (PMS Regulation & Code of Advertisements)

**Salbiah Bt Yaakop**

Director

Policy, International Relations & Industrial Facilitation Division

Medical Device Authority (MDA)

11:30 – 12:00 PM

Malaysia: Halal Standards and the challenges in medical device industry

**Dato' Zamane Abdul Rahman**

Former Chief Executive Officer

Medical Device Authority

12:00 – 12:30 PM

MALAYSIA: Radiation requirements for medical device under atomic energy licencing act 1984 (Act 304)

**Nurmazaina Binti Md Ariffin**

Senior Principal Assistant Director

Division of Medical Radiation Regulatory

Code and Standards Section

Ministry of Health Malaysia (MOH)

12:30 – 13:00 PM

Medtech Support & Challenges from Medtech Industry

(INDUSTRY & ACADEMIC & GOVERNMENT):

Towards Medtech Collaboration, Panel Discussion Highlights

**Ahmad Mohsein Azman**

Assistant Director

Life Sciences & Medical Technology Division

Malaysian Investment Development Authority (MIDA)

13:00 – 14:00 PM

Lunch Break

14:00 – 14:30 PM

Implant Commercialization Experience (Tissue/SIRIM)

**Dr. Rosdi Bin Ibrahim**

Director

Industrial Centre Innovation in Bio-Medical

Standard And Industrial Research Institute of Malaysia

(SIRIM)

14:30 – 15:00 PM

Young entrepreneur

**Khairul Mustaqim Ridwan Wong**

Founder & Ceo

Kinikio Dialysis Technologies

15:00 – 15:30 PM

New Trend in Innovation, IOT and Big Data

**Assoc. Prof. Ir. Ts. Dr. Muzammil Bin Jusoh**

Director

Student Development & Services Center & Research Fellow of

Advanced Communication Engineering (ACE)

Centre of Excellence (CoE)

University Malaysia Perlis (UniMAP)

15:30PM

End of Day 1

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Day 2: 24 March 2022

Medical Device Design & Development, Standards & Clinical

**Moderator:** UniMAP

09:00 – 09:30 AM

Registration

09:30 – 10:00 AM

Performance Evaluation Methodology for Infectious Diseases/  
Covid 19

**Dr. Teoh Boon Teong**

Senior Lecturer

Tropical Infectious Diseases Research & Education Centre

University Malaya

10:00 – 10:30 AM

Respiratory protection during a pandemic

**Sherlyn Voon**

Application Engineering Specialist, 3M Malaysia

10:30 – 11:00 AM

Testing & Calibration for medical device in accordance with  
international requirement

**Dr Samsulida Abd Rahman**

Researcher at Industriail Biotechnology Research Centre

Standard And Industrial Research Institute of Malaysia (SIRIM)

11:00 – 11:30 AM

Break

11:30 – 12:00 PM

Software Validation as Medical Device (SAMD) & standards in  
software, Usability, Cybersecurity (ISO IEC 62304, IEC62366)

**Dr. Haikal**

Research And Development Manager

Pan Asiatic Technologies Sdn Bhd

12:00 – 12:30 PM

Biocompatibility testing for medical device in accordance with  
ISO10993

**Dr. Nur Farahiyah Mohammad**

Division of Medical Science and Instrument

School of Mechatronic Engineering

University Malaysia Perlis (UniMAP)

12:30 – 13:00 PM

IVD: Covid 19 test kit

**YBhg.Prof. Ts. Dr. Uda Hashim**

Deputy Vice Chancellor Research and Innovation

University Malaysia Perlis (UNIMAP)

13:00 – 14:00 PM

Lunch Break

14:00 – 14:30 PM

Supporting Clinical Research for Medical Devices in Malaysia

**Asha Thanabalan**

Manager, Business Development

Clinical Research Malaysia (CRM)

14:30 – 15:00 PM

Research and Innovation in Medical Device Technology by  
Universiti Tunku Abdul Rahman (UTAR)

**Dr. Chee Pei Song**

Chairperson

Center of Healthcare Science and Technology (CHST)

Universiti Tunku Abdul Rahman

15:00 – 15:30 PM

Research and Innovation in Medical Device Technology by University  
Teknologi Malaysia (UTM)

**Assoc. Prof. Ir. Dr. Malarvili Balakrishnan**

Faculty of Engineering

School of Biomedical and Health Science Engineering.

Universiti Teknologi Malaysia

15:30 – 16:00 PM

Research and Innovation in Medical Device Technology by  
University Malaya (UM)

**Associate Prof. Dr. Nahrizul Adib Bin Kadri**

Senior Lecturer

Department Of Biomedical Engineering

Faculty of Engineering

University Malaya

16:00 PM

End of Day 2

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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

**Ng Kee Wee**

Temasek Poly

09:30 – 9:50 AM

Journey of Medical Device:

Medical Device innovation in Malaysia

**Dr Hyzan Mohd Yusof**

CEO of OSA Technologies

(Representative from PERANTIM)

09:50 – 10:20 AM

MedTech International Collaboration Opportunities

**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

**Ir. Sasikala Devi A/P Thangavelu**

Ex-MDA/AHWP

11:30 – 12:00 PM

Asia Regulatory Requirements

**Kelvin Koh**

Arthrex

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**

Ente Certificazione Macchine (ECM)

16:00 – 16:45 PM

US FDA regulatory requirements, Key challenges in US Approval

**Dr. Eamonn Hoxey**

Association for the Advancement of Medical Instrumentation (AAMI)

16:45 – 17:00 PM

Quiz

17:00 PM

End of Day 3 IMDS MY