



INTERNATIONAL MEDICAL DEVICE CONFERENCE 2019

DATE : 15-17 OCTOBER 2019

VENUE : MALAYSIA INTERNATIONAL TRADE & EXHIBITION CENTRE (MITEC),
KL

THEME : ADVANCED MEDICAL DEVICE INNOVATION FOR IMPROVED
HEALTHCARE

OBJECTIVES :

- i. To provide updates on global regulatory requirements for medical devices.
- ii. To facilitate the advancement of global healthcare
- iii. To promote research into quality and safety improvement
- iv. To foster effective medical innovation & solutions
- v. To create a connection between the leaders and players of the medical industry

OVERVIEW : This conference-cum-exhibition will provide a forum for discussion on updates in medical device regulatory control as well as communications and sharing of relevant information such as new inventions and innovations, research and development in medical technology and industry. In addition, it gives industry players the opportunity to promote and showcase their innovations and inventions in medical technology, particularly to the Malaysian consumers. It also provides them with the opportunity to organize and run spin-off activities, such as exchange of ideas, creation of collaborative network and business dealings and promotions. IMDC2019 and MyMEDEX2019 promise an exciting forum as we target all relevant stakeholders, such as medical device industry, medical professional and clinicians, academicians, researchers, service providers and relevant government agencies, and any other interested parties to participate in this 3-day event. It is envisaged that this event will further enhance the visibility of the industry, especially our local SMEs and start-up companies, and hopefully it will boost the performance of this industry to a higher level. MDA cordially invites all stakeholders and any other interested parties to participate in this exciting 3-day conference-cum-exhibition event.



CONFERENCE OUTLINE

| TIME | DAY 1: 15 OCTOBER 2019 (TUESDAY) | | |
|-------------------|--|--|--|
| 08.00am - 09.00am | Registration / Networking Break & Exhibition Area Visit | | |
| 09.00am - 09.45am | ASIAN Harmonization on Medical Device <i>Speaker: Mr Ali M.Al-Dalaan, Executive Director, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia</i> | | |
| 09.45am - 11.30am | Opening Ceremony by Tun Dr Mahathir, YAB PM Signing MoU with Saudi Food & Drug Authority (SFDA) Press Conference | | |
| 11.30am - 12.15pm | Top Global Research Trends in Medical Devices <i>Speaker: Dr. Eng. Nazeeh Shuja Alothmany, World Health Organization (WHO) Medical Devices Expert</i> | | |
| 12.15pm - 01.00pm | Regulatory Updates on Medical Device Directive in European Community <i>Speaker: TBC by B.Braun Malaysia</i> | | |
| 01.00pm - 02.15pm | Networking Break & Exhibition Area Visit | | |
| 02.15pm - 02.45pm | TRACK 1: REGULATORY REQUIREMENTS | TRACK 2: MEDICAL DEVICE RESEARCH ENVIRONMENT | TRACK 3: STATE OF THE ARTS |
| | Towards Implementation of ASEAN Directive in Malaysia <i>Speaker: Madam Ir. Sasikala Devi a/p Thangavelu, Director, Policy, Code & Standard Division, Medical Device Authority, MoH</i> | Delivery Clinical Research within Speed, Reliability and Quality <i>Speaker: Dr Akhmal Yusof Chief Executive, Clinical Research Malaysia (CRM)</i> | Robotics in Healthcare: Trends and Possibilities <i>Speaker: Dr Ogan Gurel, Invited Professor at DGIST as well as Founder & CEO of NovumWaves</i> |
| 02.45pm - 03.15pm | Harmonization of Standards in Medical Device Regulatory Requirement in ASIAN <i>Speaker: Mdm Salbiah Binti Yaakop, Head of Policy & Industrial Support Branch, Medical Device Authority, Ministry of Health Malaysia</i> | Clinical Data for Medical Device to Meet Medical Device Authority Regulatory Requirements <i>Speaker: Dr. Lim Teck Onn, former Clinical Research Centre (CRC) Director</i> | Retrofit Magnetic resonance imaging (MRI) <i>Speaker: TBC by Engineering Services Division, Ministry of Health Malaysia</i> |
| 03.15pm - 03.45pm | To Implement ASEAN Medical Device Directive (AMDD) Requirements in ASEAN Countries <i>Speaker: TBC</i> | Ethical Requirement in Doing Health Technology Research <i>Speaker: Dr HjH Salina Abdul Aziz, Chairperson of Medical Research Ethics Committee (MREC)</i> | Advances in Diagnostic Imaging Devices <i>Speaker: Prof. Dr. Ng Kwan Hoong, Senior Professor at the Department of Biomedical Imaging, University of Malaya</i> |

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| 03.45pm - 04.15pm | Change Management for Medical Devices <i>Speaker: Dr Adelheid Schneider, Regional Head Regulatory Affairs & Quality Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd</i> | Regulatory Control on Safety and Performance of Medical Device Research <i>Speaker: Mdm Aidahwaty M.Olaybal, Director of Technical Evaluation, Medical Device Authority, Ministry of Health Malaysia</i> | IEC PAS 63077 “Good Refurbishment Practice of Medical Imaging Equipment” & Regulations for Refurbished Medical Devices in the USA, EU, Japan and ASEAN countries <i>Speaker: Mdm Patricia Gehrlein, Vice Chair, DITTA Good Refurbishment Practice Working Group</i> |
| 04.15pm - 04.45pm | Panels Discussion <i>Moderator: Dr. Vincent Lam Chee Choong, Senior QMS Lead Auditor / Head of Medical Device Certification Scheme, TUV SUD Malaysia Sdn. Bhd. (TBC)</i> | Panels Discussion <i>Moderator: Dr. Lim Teck Onn, former Clinical Research Centre (CRC) Director (TBC)</i> | Panels Discussion <i>Moderator: Mr Ahmad Shariff Bin Hambali, Chief Executive, Medical Device Authority Malaysia</i> |
| 04.45pm - 05.00pm | Networking Break & Exhibition Area Visit | | |

| TIME | DAY 2: 16 OCTOBER 2019 (WEDNESDAY) | | |
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| 08.00am - 09.00am | Registration | | |
| 09.00am - 09.45am | Global Strategy for Digital Health <i>Speaker: YBhg. Datuk Dr. Noor Hisham Bin Abdullah, Director General, Ministry of Health Malaysia</i> | | |
| 09.45am - 10.00am | Networking Break & Exhibition Area Visit | | |
| 10.00am - 10.45am | The Future of Digital Health: Exploring New Regulatory Paradigms <i>Speaker: Mr Varun Veigas, Regional Manager (Asia Pacific)-Regulatory Affairs Roche Diagnostics Asia Pacific Pte Ltd</i> | | |
| 10.45am - 11.30am | Spearheading Healthcare Innovation with Internet of Things and Big Data <i>Speaker: Mr Jaffri Ibrahim, Chief Executive Officer of CREST</i> | | |
| 11.30am - 12.15pm | TBC by Asia Pacific Medical Technology Association (APACMed) | | |
| 12.15pm - 01.00pm | Supporting Innovation and Faster Access to Safe Medical Devices <i>Speaker: TBC by Health Science Authority, Singapore</i> | | |
| 01.00pm - 02.00pm | Networking Break & Exhibition Area Visit | | |
| | TRACK 4: DIGITAL HEALTH | TRACK 5: SAFETY & PERFORMANCE DATA FOR MEDICAL DEVICE | TRACK 6: TRADE FACILITATION |
| 02.15pm - 02.45pm | Digitalization of Healthcare: Key Trends In Healthcare <i>Speaker: Mr Rod Frazer, Managing Director, Siemens Healthineers</i> | Good Laboratory Practice based on OECD for Medical Device <i>Speaker: Dr Jahangir Kamaldin, Senior Lecturer & Lead Advisor Bioassay for Chemical Safety and Quality Assurance, University Sains Malaysia (USM)</i> | Topic TBC <i>Speaker: TBC by Malaysia External Trade Development Corporation (MATRADE)</i> |
| 02.45pm - 03.15pm | Electronic Medical Record in Healthcare | Biocompatibility Report Submission for Regulatory Approval | Topic TBC |

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| | <i>Speaker: Dr Fazilah bt Shaik Allaudin, Deputy Director of eHealth Planning Unit, Planning Division, Ministry of Health Malaysia</i> | <i>Speaker: Dr. T.S. Kumaravel, American Board Certified &UK Registered Toxicologist; Chairman, GLR Laboratories Pvt Ltd</i> | <i>Speaker: TBC by Malaysian Investment Development Authority (MIDA)</i> |
| 03.15pm - 03.45pm | Topic TBC <i>Speaker: Mr Dinesh Sampath Rangaraj, Vice President, Business Unit Leader, Frost & Sullivan</i> | Test Available for Biocompatibility in Accordance with ISO10993 <i>Speaker: Prof. Dr. Nor Fadilah Rajab, Laboratory Director Makmal Bioserasi, University Kebangsaan Malaysia</i> | Topic TBC <i>Speaker: Dr. Mohd Nor Azman bin Hassan, Deputy Secretary General at Ministry of Energy, Science, Technology, Environment and Climate Change (MESTECC)</i> |
| 03.45pm - 04.15pm | Big Data, Data Protection and Cyber Security in Healthcare <i>Speaker: TBC</i> | Screening Test Evaluation for Infectious Diseases <i>Speaker: Dr Ravindran Thayan, Unit Head of Virology, Institute for Medical Research</i> | Topic TBC <i>Speaker: TBC by Ministry of International Trade and Industry (MITI)</i> |
| 04.15pm - 4.45pm | Panels Discussion <i>Moderator: Dr Aida binti Basri, Program Director, Digital Healthcare, CREST</i> | Panels Discussion <i>Moderator: En. Yusuf Mohd Johari, Director of Registration, Licensing and Enforcement Division, Medical Device Authority, Ministry of Health Malaysia</i> | Panels Discussion <i>Moderator: Dr Hyzan Mohd Yusof, Chief Executive Officer, OSA Technology Sdn Bhd</i> |
| 04.45pm - 5.00pm | Networking Break & Exhibition Area Visit | | |

| TIME | DAY 3: 17 OCTOBER 2019 | | |
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| 09.00am - 09.45am | Healthcare Management in Malaysia, The Way Forward <i>Speaker: YBhg. Dato' Seri Dr. Chen Chaw Min, Secretary General, Ministry of Health Malaysia</i> | | |
| 09.45am - 10.00am | Networking Break & Exhibition Area Visit | | |
| 10.00am - 10.45am | Health Technology Assessment (HTA) 101 – Applying HTA Data for Medical Device Innovations <i>Speaker: Mr. Eric Woo, Regional Director, Asia Pacific ECRI</i> | | |
| 10.45am - 11.30am | Adverse Events Terminology <i>Speaker: Mr Hiroshi Ishikawa, Chair of IMDRF & Adverse Events Terminology Working Group</i> | | |
| 11.30am - 12.15pm | Single Window Concept <i>Speaker: TBC by Ministry of Health, Republic of Indonesia</i> | | |
| 12.15pm - 01.00pm | Point-of-Care Medical Devices in Malaysia <i>Speaker: Professor Ir. Dr. Fatimah binti Ibrahim, Lecturer / Researcher, Biomedical Engineering in University of Malaya</i> | | |
| 01.00pm - 02.00pm | Networking Break & Exhibition Area Visit | | |
| | TRACK 7: COMBINATION PRODUCTS | TRACK 8: MEDICAL PROCEDURES & SAFETY DATA | TRACK 11: RESEARCH PAPER PRESENTATION COMPETITION |

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| 02.15pm - 2.45pm | An Overview of Malaysian Requirement for Drug-Device Combination Product <i>Speaker: Mdm Mariammah a/p Krishnasamy, Head of Registration Unit, Medical Device Authority, Ministry of Health Malaysia</i> | Topic TBC <i>Speaker: Ir. Dharmesh R Doshi, Associate Director, Asia Pacific ECRI</i> | [Collaboration with Medical Devices And Technology Center (Meditec), University Technology Malaysia (UTM)] |
| 02.45pm - 3.15pm | An Overview of the Global Regulatory Landscape for Drug-Device Combination Product <i>Speaker: Mr Tim Chesworth, Senior Director Medical Devices and Combination Products, AstraZeneca United Kingdom</i> | Assessing the Value of Innovative Medical Device <i>Speaker: Dr Izzuna Mudla Mohamed Ghazali, Public Health Physician/Head of Unit, Horizon Scanning, Communication and Information Unit, Malaysian Health Technology Assessment Section (MaHTAS), Medical Development Division, Ministry of Health Malaysia</i> | |
| 03.15pm - 03.30pm | Panels Discussion <i>Moderator: TBC by Pharmaceutical Association of Malaysia (PhAMA)</i> | Challenges to Implement the Regulatory Requirements based on Conformity Assessment Body Perspectives (TBC) <i>Speaker: Mr Kenny Chong Khin Khen</i> | |
| 03.30pm - 03.45pm | Networking Break & Exhibition Area Visit | | |
| | TRACK 9: CAPACITY BUILDING | | |
| 03.45pm - 04.15pm | Centre of Regulatory Excellent (CoRE) <i>Speaker: Madam Ir. Sasikala Devi a/p Thangavelu, Director, Policy, Code & Standard Division, Medical Device Authority, MoH</i> | Minimally Invasive Thoraic Surgery on Endoscopic Thoraic Sympathectomy <i>Speaker: Dato' Dr Ahmad Farouk Musa, Former Surgeon at Institute Jantung Negara, A lecturer/researcher at Monash University</i> | |
| 04.15pm - 04.45pm | Maximize Learning Experiences with An Innovative E-Learning Solution <i>Speaker: Mdm Angeline Tay, Application & Education Manager (DX), Siemens Healthcare Sdn Bhd</i> | Aesthetics Medical Device and Non-Medical Aesthetics Devices: Differences and Similarities in Relation to Medical Device Act 737 <i>Speaker: Dr. Ungku Mohd Shahrin Bin Mohd Zaman, Member of Aesthetics Medical Practice Committee (AMPC)</i> | |
| 04.45pm - 05.00pm | Panels Discussion <i>Moderator: TBC</i> | Q&A Session | |