Medtec
Southeast Asia

16-18 July 2025

MITEC, Kuala Lumpur, Malaysia

DRIVING INNOVATION & MANUFACTURING EXCELLENCE IN MEDTECH ECOSYSTEM

Conference Programme

Join us at Medtec Southeast Asia
to unlock opportunities and foster innovation

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MATRADE

DRIVING INNOVATION & MANUFACTURING EXCELLENCE IN MEDTECH ECOSYSTEM

Conference Programme

Part of International Healthcare Week | Kuala Lumpur, Malaysia

Medtec Southeast Asia 2025 is the region's leading conference and exhibition dedicated to advancing medical technology through innovation, regulatory harmonisation, and industrial growth. As ASEAN's healthcare sector evolves, the event serves as a vital platform for medical device manufacturers, regulators, conformity assessment bodies, maintenance, testing and validation services providers, researchers, and investors to engage in meaningful dialogue, share technical know-how, and drive ecosystem development.

Held in conjunction with International Healthcare Week, the 3-day conference will spotlight strategic themes— Innovation, Compliance, and Industrial Scaling—and explore how Southeast Asia can lead in medical device R&D, emerging technologies, maintenance, testing and validation, halal compliance, regulatory readiness, and smart manufacturing.

Concurrent sessions

- **Main Conference**
- **ASEAN MedTech Nexus**: Bridging Innovation with Global .

Conference Objectives

- To highlight emerging trends and technologies in medical device design and development
- To bridge innovation and regulation through real-world testing and global compliance strategies
- To showcase the ASEAN manufacturing ecosystem, supply chain readiness, and investment opportunities
- To foster collaboration among OEMs, regulators, innovators, academia, and government agencies
- To elevate Malaysia and the ASEAN region as a competitive global hub for MedTech manufacturing

Target Participants

- Manufacturers : Medical device OEMs, EMS, contract manufacturers
- Service Providers: Sterilisation, maintenance, testing, calibration, packaging, CAB/Notified bodies
- Government & Regulators: MDA, NPRA, MITI, MIDA, ASEAN regulatory bodies
- Technology Providers : AI, 3D printing, digital health, electronics integrators
- Educational Institutions: Universities, training centres, R&D institutions
- Investors & Trade Agencies: VCs, PE firms, international trade & investment agencies
- Regulatory Affairs officers, QA/QC officers, Engineers & Clinician

OVERVIEW

Day 1: Driving Innovation& Manufacturing Excellence in Medtech Ecosystem

Designing the Future – Innovation in Medical Device R&D and Advanced Materials

Key Topics:

- Advanced Biomaterials: Smart polymers, nanomaterials, biodegradable and bioactive compounds
- Digital Design & Simulation: AI-assisted prototyping and predictive modelling
- Human Factors Engineering: Safety and usability in device design
- 3D Printing in MedTech: From prototyping to personalised implants
- Smart Wearables & Implantables: Development and integration strategies
- SaMD: Innovation trends, early compliance challenges
- University–Industry Collaboration: Innovation-to-prototype frameworks
- ASEAN Start-up Showcase: Spotlight on regional disruptors

Day 2: Manufacturing Ecosystem, Smart Technology & Industrial Growth

Scaling Innovation – Building a Future-Ready MedTech Industry

Key Topics:

- Medical Device Design, Development & Manufacturing Raw Materials
- Moulding Services & Equipment
- Tubing & Extrusion
- Pumps & Valves
- Smart Factories in Healthcare
- 3D Printing at Scale
- Smart & Halal-Compliant Manufacturing
- Ethical and Sustainable Manufacturing: ESG-aligned practices for global markets
- Cleanroom Validation (ISO 14644): Environmental and sterility control
- Workforce & Investment Ecosystem
- Public-Private Collaboration Models: Facilitating trade, R&D, and infrastructure

Day 3: Emerging Technologies , Testing & Regulatory Pathways

Innovation Meets Regulation – Ensuring Safety, Compliance & Market Access

Key Topics:

- Electrical Safety & IEC 60601: Ensuring compliance for electrical medical equipment
- EMC Testing : Performance risk mitigation and integration into design
- Sterilisation Masterclass: Choosing and validating gamma, EO, and steam sterilisation
- Biocompatibility Testing: Deep dive into ISO 10993 and advanced applications
- SaMD & IoT Devices: Risk categorisation, cybersecurity & Validation strategies
- Regulatory Intelligence: AMDD implementation, ISO 13485 updates, EU MDR & USFDA
- Robotics in MedTech: From surgical assistance to autonomous rehabilitation devices
- Cybersecurity in Connected Devices: AI-driven systems and risk controls
- Regulatory Convergence: ASEAN-wide harmonisation strategies

Sponsorship Prospectus

Tier	Platinum	Gold	Silver	Bronze
Price (USD)	18,000	13,000	6,000	7,000
Special Price (USD) until 24 June 2025	10,800	7,800	5,400	4,200
Exhibition booth, standard package (sqm)	21	15	12	9
Delegate passes	5	3	2	1
Main conference speaking slot (min)	60	45	30	30
Technical presentation (min)	30	30	30	30
Business matching (face-to-face) with international manufacturers	Yes	Yes	Yes	Yes
Logo placement online C offline of exhibition C conference (tiered)	Yes	Yes	Yes	Yes
Logo placement in electronic direct mail	Yes	-	-	-
Dedicated electronic direct mail blast	1	-	-	-
Electronic direct mail scoop in conference highlight (shared)	-	1	1	1
Brochure in delegate kit	Yes	Yes	-	-

Delegate Pass

3 Day Pass	Early bird	Standard	ONSITE
	Now-23 Jun	24 Jun-15 Jul	16-18 Jul
USD	650	700	750

Remark: *Group discount of 3 eligible for 5% discount*
Government department/university eligible for 5% discount

MAIN CONFERENCE 16 July 2025

Designing the Future – Innovation in Medical Device R&D, Advanced Materials and emerging technologies in medical devices manufacturing

11:00 – 11:30

ASEAN as a Global MedTech Innovation Hub
Datuk Sikh Shamsul Ibrahim Sikh Abdul Majid,
CEO of the Malaysian Investment Development Authority (MIDA)

11.30-12.00

Malaysia's MedTech Transformation:
A Decade of Growth and the Roadmap to Global Innovation Leadership
YBRS. DR. MURALITHARAN PARAMASUA.
CHIEF EXECUTIVE OFFICER, Medical Devices Authorit

12:00 – 12:30

The Next Frontier in Biomaterials: Smart, Biodegradable & Bioactive
Prof. Dr. Hazizan Md Akil
Professor of Materials Engineering, Universiti Sains Malaysia (USM)

12:30 – 13:00

Building a Secure and Standards-Driven IoMT Ecosystem:Pathways to Safe, Smart, and Connected Medical Devices
Enabling Smart, Safe & Connected MedTech: MIMOS's Role in Advancing IoMT Innovation
Dr.Pannirselvam Kanagaratnam
Chief Technology Officer, MIMOS

14.00-14.30

Human Factors Engineering: Safe & Intuitive Device Design
TBC

14.00-14.30

SaMD and Connected Device Interface Design
Dr. Muhammad Haikal Satria
Senior Lecturer at Universitas Nasional Jakarta, Indonesia,
Chief Finance Officer at PT Visi global teknologi, Indonesia

15.00 – 15.30

Driving Digital Transformation for Future Operations for Medical Devices
Yukti Rastogi
Life Sciences & Nutrition Manager, Rovisys Singapore

15.30 – 16.00

Smart Wearables & Implantable: Design, Integration & Market Insights
Dr. Maheshwara Rao a/l Appannan,
Director, Digital Health Division, Ministry of Health Malaysia

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MAIN CONFERENCE 16 July 2025

Designing the Future – Innovation in Medical Device R&D, Advanced Materials and emerging technologies in medical devices manufacturing

16:00 – 16:30

Augmented Reality (AR) / Virtual Reality (VR) / Mixed Reality (MR) in MedTech: Regulatory and Technical Requirements for Immersive Technologies

Mr. Sandeepraj Ratnasabhapathy, CEO, OmniHabits

16:30 – 17:00

Collaborative Prototyping Models: University–Industry Design Hubs

Prof. Ir. Dr. Fatimah Ibrahim

Department of Biomedical Engineering, Universiti Malaya

MAIN CONFERENCE 17 July 2025

Manufacturing Ecosystem & Smart Technologies

10:00 – 10:30

Emerging technologies in MedTech manufacturing – Global Perspectives & ASEAN Readiness on SaMD and AI.Navigating the Evolving Regulatory Landscape and Compliance Requirements Singapore

Lin Anle
Health Sciences Authority (HSA)

10.30 - 11.00

Malaysia's MedTech Manufacturing Advantage: Strengthening Industrial Capabilities and Export Competitiveness in the Era of AI and SaMD

Abdul Halim Bin Mohamed Shariff
Deputy Director, Exports Promotion & Market Access Division
Lifestyle & Life Sciences Section

11.00 - 11.30

Emerging Technologies in Medical Devices: Additive Manufacturing, Smart Implants, and Wearables

11.30 – 12:00

New Insight into Biomaterial in Woundcare

12.00 - 12:30

3D Printing at Scale: Manufacturing, Post-Processing & Material Choices

Jaffri Ibrahim
Chief Executive Office
Collaborative Research in Engineering, Science and Technology

11.30 – 12:00

Verification & Validation of SaMD: Principles, Challenges, and Best Practices IEC 62304 Software lifecycle & Clinical evaluation of SaMD outputs

14:00 – 14:30

Cybersecurity in SaMD and Connected Devices: Safeguarding Patient Safety and System Integrity.ISO 81001-1, IEC 81001-5-1

Dr. Muhammad Haikal Satria
Universitas Nasional Jakarta / PT Visi Global Teknologi

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MAIN CONFERENCE 17 July 2025

Manufacturing Ecosystem & Smart Technologies

14:30 – 15:00

Quality 4.0 in MedTech: Driving Innovation and Compliance with ISO 13485

15:00 – 15:30

Advancing ASEAN IVD Innovation for In-Vitro Diagnostic (IVD) Testing and Calibration: From Lab Bench to Regulatory Approval

Dr. Ami Fazlin Syed Mohamed
Director, Institute for Medical Research

15.30 – 16.00

Strengthening ASEAN Testing Ecosystems: Advancing Safety and Performance Testing Infrastructure

Dato' Indera Ir. Dr. Ahmad Sabirin Arshad
President and Group CEO, SIRIM Berhad

16:00 – 16:30

Biocompatibility Testing Requirements: Standards, Process, and Compliance

Dr. Siew Ee Ling
Senior Lecturer, Associate Lecturer,
Laboratory Director,
Biocompatibility Laboratory (Makmal Bioserasi),
Centre for Natural and Physical Laboratory Management (ALAF)
Universiti Kebangsaan Malaysia

16:30 – 17:00

Halal-Compliant Manufacturing: Medical Device Certification

YBhg. Tuan Muhyidin Bin Aziz @ Saari
Director, Halal Management Division, JAKIM

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MAIN CONFERENCE 18 July 2025

Emerging Technologies, & Regulatory Pathways
Theme: Innovation Meets Regulation – Ensuring Safety, Compliance & Market Access

10:00 – 10:30

Keynote Global Regulatory Trends: The New Era of Convergence and Divergence - Harmonising Regulation & Tech

Alfred Kwek
General Manager of Tigermed Asia Pacific Limited, Talon Labortaries Pte Ltd, Professor, GHWP Academy

10.30 - 11.00

MOH (KSU)
Procurement Trends in Malaysia's Healthcare System: What Local Manufacturers Should Know

YBhg. Datuk Mohd Fauzee bin Abd Majid
Setiausaha Bahagian Perolehan Dan Penswastaan

11:00 – 11.30

ASEAN Regulatory Harmonization: Navigating Progress, Challenges & The Path Forward in AMDD Implementation

Ir.Dr.Sasikala Thangavelu
Medical Device Consultant, CEO MdDev, Regulatory with WHO, Adjunct Professor at University Malaya, Former Director of Policy Code & Standard, Medical Device Authority, MOH

11.30 - 12.00

Vietnam Market Spotlight – Decree 98 and Local Compliance Challenges
Product registration pathways, dossier requirements, and import controls

12.00 - 12.30

Indonesia Market Spotlight – Risk Classification, SIPNAP, and Post-Market Enforcement - Key documentation requirements and role of local representative

12.30 - 13.00

Thailand Market Spotlight – Regulatory Evolution and Local Testing Framework
Fast-track registration, IVD classification, and alignment with AMDD

14:00 – 14:30

Malaysia Market Spotlight: REGULATORY & Compliance Services Hub

Mariammah Krishnasamy
Deputy Director Of Policy Coordination
Medical Device Authority

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MAIN CONFERENCE 18 July 2025

Emerging Technologies, & Regulatory Pathways
Theme: Innovation Meets Regulation – Ensuring Safety, Compliance & Market Access

14:30 – 15:00

Malaysian Device Authority (MDA) Insights on MDA Innovation, emerging Technology and Compliance

Mariammah Krishnasamy
Deputy Director Of Policy Coordination , Medical Device Authority

15:00 – 15:30

From MDD to IVDR: Strategic Transitions and Compliance Readiness for ASEAN Manufacturers

Vincent Lam
Manager of Medical Health Services at TUV SUD PSB Malaysia

15.30 – 16.00

USFDA Market Access Pathways: 510(k), De Novo, and PMA Explained- Practical steps for ASEAN manufacturers

Dr. Pierre Hoerner
IneoTech Sdn Bhd, Company Director

16:00 – 16:30

Navigating the EU MDR, IVDR and US FDA Regulatory Pathways: Lessons for ASEAN Manufacturers (Key milestones, documentation, and evidence generation requirements)

TBC

16:30 – 17:00

Ask Me Anything: Building Robust Technical Documentation for EU MDR/IVDR and USFDA Compliance

Vincent Lam
Manager of Medical Health Services at TUV SUD PSB Malaysia

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Bridging Innovation with
Global Sessions Market Access

Hall 5

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Emerging Technologies & Disruptive Trends in MedTech

14.00-14.30

Harnessing Industry 4.0 in MedTech: Robotics, Smart Manufacturing & Digital Infrastructure for the Next Generation of medical devices

Ir. Dr. Mohd Nor Azman Hassan
Deputy Secretary General (Technology Development), Ministry of Science, Technology and Innovation (MOSTI), Malaysia

14.30-15.00

3D Printing in MedTech: Regulatory and Technical Requirements for Safe Manufacturing

Jaffri Ibrahim
Chief Executive Office
Collaborative Research in Engineering, Science and Technology (CREST)

15.00 – 15.30

Smart Implants and Bio-Integrated Sensors: Engineering the Future of Connected, Responsive, and Personalised Healthcare

15.30 – 16.00

Biomaterials in Medical Devices: Regulatory, Safety, and Performance Requirements for implants

Dr. Hyzan Mohd Yusof
CEO
OSA TECHNOLOGY SDN BHD

16:00 – 16:30

Integrating AI & Simulation in Concept Development of medical devices

Assoc. Prof. Ts. Dr. Mohd Ibrahim Shapiai
Director, Centre for Artificial Intelligence & Robotics (CAIRO), Universiti Teknologi Malaysia (UTM)

16:30 – 17:00

Technologies in MedTech
Optimizing Quality: MES Execution Strategy for Medical Device Manufacturing

Lois Loh
Critical Manufacturing, SEA Director
Rovisys

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Regulatory Science & Safety Testing

11:00 – 11:30

Regulatory Compliance for Ionising Medical Devices in Healthcare: Ensuring Safety, Performance, and Compliance with National Regulations and IAEA Standards

- Puan Nurmazaina Binti Md Ariffin
- Ketua Penolong Pengarah Kanan
- Bahagian Bahagian Kawalselia Radiasi Perubatan
- Seksyen Seksyen Pendakwaan

11.30-12.00

Quality Assurance and Annual Quality Control: Ensuring Performance of the Radiation Equipment Nurmaizaina MOH

- Puan Nurmazaina Binti Md Ariffin
- Ketua Penolong Pengarah Kanan
- Bahagian Bahagian Kawalselia Radiasi Perubatan
- Seksyen Seksyen Pendakwaan

12:00 – 12:30

From Reactive to Proactive: Transforming Medical Equipment Maintenance in Government Hospitals : Panel session

Ir. Jeffry Bin Mohamad Noor
Division Engineering Services Division

12:30 – 13:00

OSHA in MedTech: Legal Duties of Directors & Manufacturers – Avoid Liability, Prevent Lawsuits

Vimala Raghawan
Director at National Institute of Occupational Safety & Health

14.00-14.30

Risk Management to Legal Action: Mandatory OSH Compliance in Medical Device Manufacturing & Healthcare Institutions

Vimala Raghawan
Director at National Institute of Occupational Safety & Health

14.30-15.00

Quality in MedTech: Ensuring Safety, Traceability, and Compliance through Good Distribution Practices

Seenu Suntharamurthy
Technical Personnel, Amdtext Sdn Bhd

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ASEAN MedTech Nexus 17 July 2025

Regulatory Science & Safety Testing

15.00 – 15.30	**Beyond Clean: Integrating ISO 14644 with Smart Environmental Monitoring for MedTech Manufacturing Excellence**
15.30 – 16.00	**Sterilisation : Gamma, EO, Steam – What & When to Use**
16:00 – 16:30	**Navigating Clinical Translation of Innovative Medical Devices Through Strategic Design, Testing & Regulatory Compliance** Li Zhao Hui, PhD CEO Kezhuo Shenzhen Scientific & Excellent Medical Testing Co., Ltd
16:30 – 17:00	**Clinical Trials:** **Ensuring Ethical, Scientific, and Regulatory Integrity in Medical Device Clinical Investigations Aligned with ISO 14155:2011 and Good Clinical Practice (GCP) Guidelines** Dr. Akhmal Yusof CEO, Clinical Research Malaysia

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Manufacturing Technology & Industry Development

11:00 – 11:30

Accelerating MedTech Commercialisation in Malaysia Opportunities for Innovators, Startups & Industry Players

Mohd Safuan Mohd Zairi
Chief Ecosystem Officer, MRANTI

11.30-12.00

Positioning Malaysia as a Regional Innovation Hub in ASEAN: Opportunities for Local and Foreign Innovators

Ir. Dr. Mohd Nor Azman Hassan
Deputy Secretary General (Technology Development), Ministry of Science, Technology and Innovation (MOSTI), Malaysia

12:00 – 12:30

Strategic Investment & Industry Linkages
Invest Selangor / Invest Penang / Invest Johor Invest Sabah Berhad (ISB) Invest Sarawak

12:30 – 13:00

MANUFACTURING HUB:
Sarawak: The Emerging Medical Devices Manufacturing Hub – Unlocking Investment Opportunities in Southeast Asia's Next MedTech Frontier

14.00-14.30

Navigating the Medical Device Commercialisation Journey

Assoc. Prof. Ir. Ts. Dr. Nashrul Fazli Bin Mohd Nasir
B.Biomed. Eng. (Malaya), M.Sc. (Keele), PhD. (RMIT University), P.Eng. Ptech., SMIEEE, MIET.
Deputy Dean (Academic and Research),
Faculty of Electronic Engineering Technology (FTKEN),
Universiti Malaysia Perlis (UniMAP), Malaysia

14.30-15.00

Vietnam Medical Device Market Authorisation: Case Study 1

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ASEAN MedTech Nexus 18 July 2025

Manufacturing Technology & Industry Development

15.00 – 15.30

Navigating Regulatory Pathways in Vietnam — A Practical Case Study on Medical Device Registration and Approval

15.30 – 16.00

Indonesia Medical Device Market Authorisation: Case Study : Case Study 1

16:00 – 16:30

Thailand Medical Device Market Authorisation: Case study Understanding the Thai FDA Pathway — A Case Study on Medical Device Registration and Licensing Procedures

16:30 – 17:00

Conformity Assessment in Malaysia: Ensuring Safety, Quality, Performance, and Efficacy for Successful Market Authorisation

Seenu Suntharamurthy
Technical Personnel, Amdtext Sdn Bhd

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Contact Us!

mtsea2025conference@gmail.com

Marketing Team

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