UNLOCKING MARKETS: NAVIGATING MEDICAL DEVICE REGULATIONS IN EU & ASEAN (INDONESIA, MALAYSIA, VIETNAM, THAILAND)

24 & 25 APRIL 2024
AC HOTEL BY MARRIOTT, PENANG

Seminar Brief

- Guide to regulatory pathways for medical device approval in key markets: Indonesia, Vietnam, Thailand, Malaysia, and the European Union (EU)
- Focus on the latest updates on regulatory requirements, particularly the new requirements in Malaysia & EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR)
- Valuable insights and practical knowledge regarding expedited registration pathways

We will also look into key areas:

- Challenges in Software as a Medical Device (SAMD), Artificial Intelligence (AI), and cybersecurity within medical devices while diving into the latest regulatory updates in SAMD, AI, and cybersecurity for medical devices.
- Strategic planning to navigate challenges and opportunities in Malaysia's healthcare landscape

Don't miss out our networking session with ASEAN regulators, JAKIM(Halal Medical device), MOH, MDA, MIDA & MATRADE

Who Should Join

- Regulatory affairs professionals, healthcare professionals, quality assurance managers, consultants
- Local manufacturers, authorised representative & distributors
- Entrepreneurs and startups
- Industry players seeking investment opportunities in ASEAN countries & Europe

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DAY 1 : ASEAN EMERGING MEDICAL DEVICE MARKET : MANAGING NEW HARMONISED AMDD REQUIREMENTS

9.00 Navigating Harmonization Challenges: Assessing AMDD Implementation Across ASEAN Member States :Ir.Dr.Sasikala, MDDEV,Malaysia

9.30 New regulatory updates, policies and innovative device assessment pathways in Malaysia : Mdm Mariammah Krishnasamy, MDA.MOH,Malaysia

10.45 Break

11.00 Single window and market authorisation of medical devices in Indonesia ,Kemenkes, Indonesia Ibu Pritha Elisa

12.00 Medical Device Regulatory Landscape in Vietnam by Mr.Doan Minh, MOH,Vietnam

13.00 Lunch

14.00 Market authorization of medical devices in Thailand by Thai FDA,Thailand

15.00 Strategic Healthcare Technology Management: Navigating Regulation, Innovation, and Maintenance in Malaysia's Healthcare Sector by Ir.Ts.Dr.Aizat Hilmi Bin Zamzam, Engineering Services Division, MOH, Malaysia

16.00 Networking Session with ASEAN Regulators ,MDA, JAKIM (Halal Medical device) Mida ,MDA, Matrade & MOH Officials

17.00 Opening Ceremony

18.00 End of Day 1

DAY 2 : MANAGING NEW CHALLENGES: SOFTWARE &AI IN MEDICAL DEVICES,COMPLIANCE TO THE NEW EU MEDICAL DEVICE REGULATION & AMDD

9.00 Ensuring Compliance: Navigating Standards and Documentation for Software, AI, and Cybersecurity in Medical Devices by HSA, Singapore

10.30 Break

11.00 Implementation of EU MDR & IVDR: a way forward by Dr.Vincent Lam (TUV SUD)

12.00 Comprehensive guide to clinical evaluation reports (CERS) & Post Market Surveillance & Vigilance: Understanding PMS requirements in EU by Dr.Vincent Lam (TUV SUD)

13.00 Lunch

14.00 IVD & GMD Case Study:Technical Documentation for EU Compliance by Dr.Vincent Lam

15.30 Break

15.45 Managing new challenges: GMD & IVD Registration Case Studies in Malaysia by Mdm Mariammah Krishnasamy, MDA.MOH

17.30 End of Day 2

FOR FURTHER ENQUIRIES : 012-2683818 (Ms. Kirubaleni) kiru.mddev@gmail.com