MARKET AUTHORISATION OF MEDICAL DEVICES IN EUROPEAN UNION

7 MARCH 2024
PENANG

Who should join

Regulatory affairs officers and industry players keen to understand medical devices market authorisation requirements based on CE marking. Local manufacturer's are encouraged to participate.

EUROPE

CE Marking for EU

CPD POINTS FROM BEMS AVAILABLE & HRDF CLAIMABLE

Fees: RM1200/ pax.

Please get in touch with us for a Group Discount.

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

MARKET AUTHORISATION OF MEDICAL DEVICES IN EUROPEAN UNION

- We will offer you a comprehensive guide to the regulatory pathways of obtaining approval and clearance for medical devices in European Union (EU)s.
- We will focus on CE marking, and the overarching process outlined by the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).
- Practical case studies are integrated throughout the training to give you an insight on submissions and guide for marketing submission.

THE SPEAKERS

DR VINCENT LAM CHEE CHOONG

Vincent Lam is Senior Lead Auditor and Product Specialist for the Notified Body TÜV SÜD Product Service. In this role, he is responsible to establish and maintain device test programs for the assessment of specific medical devices to facilitate review of pre market regulatory requirements including the requirements of the European Notified Body conformity assessment scheme

DR IR SASIKALA DEVI A/P THANGAVELU

A professional Biomedical Engineer, consultant and HRDF trainer backed with 36 years of service in Malaysian public sector. She spent 21 years in the Ministry of Health. She was a Director of Policy, Code and Standard, Medical Device Authority of the Ministry of Health and was involved in the development of medical device regulatory program, drafting of Medical Device Act 2012 and its subsidiary legislation in Malaysia. She was involved in the development of the ASEAN Medical Device Directive (AMDD),medical device standards, guidance documents, code of practice and guidelines and subsequently appointed as a consultant for WHO. She is currently an independent trainer and subject expert in medical technology and regulatory requirements for Malaysia and ASEAN (AMDD).

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BEM Pre-Approved CPD Hours

For HRDF claimable process, kindly liaise before 29 February **2024** **at kiru.mddev@gmail.com**

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