SPECIALISED MARKET BRIEFING

Updates and Changes in the EU Medical Device Regulations 2020

The new Medical Device Regulations (MDR) entered into force on May 25, 2020. This means that the market access framework for all member countries of the European single market (28 EU member states including the UK, the members of the EEA – Iceland, Lichtenstein and Norway, and through bilateral treaties Switzerland) will change significantly. The aim of the new MDR is to address some inherent weaknesses in the old directives as well as the swift evolution of science and technology in the field of medical devices. The briefing will highlight the key improvements, requirements, concepts and the overall processes of the MDR, the essential knowledge of Regulatory Affairs and the basic implementation of CE marking projects.

Programme

8.30am	Registration of Participants
9.00am	* MDR (EU 2017/745) and European Database on Medical Devices (EUDAMED) * Unique Device Identification (UDI) * Clinical Evaluation Requirements in MDR
1.00pm	Lunch
2.00pm	* Technical Documentation Expectation from MDR * MDR Compliance Timeline and Conformity Assessment
5.00pm	End of Session

Speaker - Kenny Chong Khin Khen

Lead Auditor and specialising in Management Systems - ISO 9001, 14001, 45001, 13485, Process Validation, Risk Management for Medical Devices and country specific medical devices regulatory requirements with a career spanning over 12 years in management systems implementation.

7 NOVEMBER 2019

9am - 5pm

MREPC Seminar Hall

Unit 36-01, Level 36,
West Wing, Q Sentral,
50470 Kuala Lumpur

Registration Fee

Only **RM60 nett**
per participant

Hurry and register online now at www.mrepc.com as seats are limited

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