KEMENTERIAN PERLADANGAN DAN KOMODITI

MALAYSIAN RUBBER COUNCIL

Updates on EU Medical Device Regulations (EU MDR) and Medical Device Single Audit Programme (MDSAP)

26 March 2024 | **9 am - 5 pm** | **Via Microsoft Teams**

Technological advancement such as artificial intelligence (AI) and remote monitoring capabilities upsurges the medical device sales in the EU with expectation of exceeding €170 billion by 2027. Since European Medical Device Regulations (EU MDR) came into force on 26 May 2021, medical device manufacturers can navigate the intricate landscape of compliance and contribute to safer and smooth functioning of the internal market. While with a comprehensive insight of MDSAP, medical device exporters will be able to maintain compliance to quality management system (ISO 13485) and jurisdiction requirements more transparent with a single audit. Optimise the regulatory resources and market your medical devices with high safety and surveillance in the 5 member countries.

Learn the essentials of EU MDR 2017/745 and stay update with the changes in the new regulation of medical device in European market. Uncover the reporting mechanism and identification of the medical devices as per new EU MDR regulations as well as the role of European Database on Medical Devices (EUDAMED) in providing transparency and coordination of information regarding medical devices available on the EU market.

Click **HERE** to register

Receive e-Certificate of Participation upon completion

About Speaker

Captain Rajkumar Arokiasamy (Capt Rajkumar) holds a degree in Physics and Computer Science and advanced diploma in applied sciences. He is a certified Master Mariner in the merchant marine with a career at sea spanning over 16 years and has assisted medical device manufacturers in achieving compliances to MDD, FDA and CE marking and certifications for ISO 13485 standard for a decade.

Capt Rajkumar was one of the first trainers to be certified to ISO 31000 risk management standard and is a certified trainer for SGS, BSI and BVQI certification bodies on risk management. He is also the appointed trainer for ISO 13485, lead auditor and train-the-trainer for FDA; lead trainer and auditor in ISO 9001, OSHAS, EMS, ISO 27001 for SGS; ISO 20000, ISO 9000 and 14000 standards and TUV STAR® program; and a qualified consultant for ISO 28000, a standard for supply chain security and PCI DSS standard, for credit card security.

In his career, he has trained and qualified over 200 candidates as lead auditors for ISO 13485. Currently, Capt Rajkumar is the founder and current chairman of Supply Chain Security Forum of Malaysia that is dedicated in providing a secure framework for transportation and storage of high value cargo transiting and being shipped from Malaysian ports.

Who Should Attend

- **Quality Management Department**
- **Internal Auditors for Medical Devices**
- **Medical Devices Marketing Department**

WEBINAR FEE

- **RM60/pax** *(MRC Member)*
- **RM150/pax** *(Non-Cess & Non-Member Companies)*

Programme Details

8.30 am	– Online registration of participants
9.00 am	– Welcoming remarks by MRC
9.15 am	– Introduction to European Regulations on Medical Devices
	– Essential Components of the European Medical Device Regulations (EU MDR) and Documentation
1.00 pm	– Lunch Break
2.00 pm	– MDSAP and Auditing Method & Reporting Requirements and Identification
	– European Database on Medical Devices (EUDAMED)
4.45 pm	– Q & A session
5.00 pm	– End of programme

For more information, Please contact
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