Updates on Global Medical Device Registration and Regulation Processes

Registration Fee RM60

Dear Members of the Rubber Industry,
Warm greetings from the Malaysian Rubber Council (MRC)!

MRC is pleased to extend an invitation to participate in our webinar titled ***Updates on Global Medical Device Registration and Regulation Processes***. The event will be held on 26 August 2021 from 9am to 5pm.

The webinar is aimed to create awareness of various types of medical devices, their risk based categories and classifications based on FDA and Medical Device Directives (MDD). Participants will also be exposed to standards like ISO 13485, ISO 14971 and 21 CFR Part 820 including GDPMD Act 737 and will acquire recent developments and updates on the standards.

For more details or any query, you may contact us at 03-2782 2100 or via email and mobile,
Nurhaiza Abdul Hamid (nurhaiza@myrubbercouncil.com, 012-2114496)
Muhammad Alif Afiq (alif@myrubbercouncil.com, 013-4497818).

About the Webinar

Compliance with the Medical Device Directives is mandatory for organizations supplying devices to the European market. Likewise, for those supplying to US, the need to comply with 21 CFR Part 820 is imperative. ISO 13485 is the best benchmark for quality and regulatory compliance. The standard offers significant additional benefits to management, quality assurance and production. It is accepted as best practice by the 148 member countries of ISO representing all the world's major trading blocks including Europe, USA, Japan, Canada and Australia. This webinar is designed to create a deeper understanding of the regulatory requirements in addition to the quality management system that is common practice. This session is aimed to create awareness and provide updates amongst the medical device manufacturers with regards to compliances and regulations imposed on by the authorities of various countries including Malaysia.

The Speaker

Captain 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 spanning over 16 years. After his retirement from Sea Career, he has implemented and trained several companies in various standards and assisted medical device manufacturers in achieving compliances to MDD, FDA, CE marking and certifications for ISO 13485 standard for a decade. He has worked with companies such as Flextronics, Celestica, Top Glove, Kossan Rubber, WRP, Frazer Medicals, Cryocord, BD Medicals in FDA, MDD ,CE markings and ISO 13485. He has worked with Class 3 devices such as Injecting Gels, Strut Rods and Screws, Surgical Gloves amongst other products that are classified as "High Risk". He has trained and implemented Good Distribution Practice for Medical Device (GDPMD) and Good Manufacturing Practice (GMP) for Pharma for DKSH, XPO Logistics and DHL for their medical and pharma products. He was one of the first trainers to be certified to ISO 31000 risk management standard and certified trainer for SGS, BSI and BVQI certification bodies on risk management.

The Programme

8.30 am - Online Registration for Participants

9.00 am - Opening Remarks by MRC

9.10 am - Commencement of Webinar

Topic Outlines

* The Need for a Regulatory Authority for the Industry
* Device Classifications
* Risks to Humans by Devices
* Risk Based Classifications
* Regulations EU, US, Australia, Malaysia and Canada
* Quality Management Systems for Medical Devices
* Failure to Comply – Risks to the Manufacturer
* Best Practices & Approach Towards Compliance(s)

5.00 pm - End of Briefing

How to Register

Please log on to www.myrubbercouncil.com and register online **HERE**