Overview and Updates of
ISO 13485:2016
and
EU Medical Device Directives 2016

Aimed to provide an overview and updates of the revised ISO 13485:2016 and the impacts it will have on rubber product manufacturers, exporters and traders of rubber medical devices and highlight the updates, key aspects and impacts of EU Medical Device Directives 2016 .

PROGRAMME

8.30am	Registration of Participants
9.00am	Key Changes in ISO 13485:2016 covering Quality Management System, Management Responsibility, Resource Management, Product Realization, and Measurement, Analysis and Improvement
1.00pm	Lunch
2.00pm	Updates of EU Medical Device Directives 2016 including Market Availability, Obligations of Economic Operators, Reprocessing, CE Marking, Free Movement, Identification, Traceability and Registration of Devices and Economic Operators, European Database on Medical Devices, Classification and Conformity Assessment, Clinical Evaluation and Clinical Investigations, Post-Market Surveillance, Vigilance and Market Surveillance, Cooperation between Member States, Medical Device Coordination Group, Expert Laboratories, Expert Panels and Device Registers, Confidentiality, Data Protection, and Funding and Penalties.
4.30pm	Q & A Session
5.00pm	End of Session

SPEAKER

Ooi Soo Kang, is currently the Country Director for CI International Certification Sdn Bhd, the Certification Body for ISO 9001, ISO 14001, ISO 22000, OHSAS 18001, HACCP/GMP, ISO 13485/GDPMD, ISO27001, ISO20000, ISO50001, operates under CIUK Group, a Socotec Company which has offices in 26 countries. He is also the Head of Certification for 15 years and managed the operations of the certification services of CI Malaysia under the accreditation of Standards Malaysia and the United Kingdom Accreditation Services (UKAS).

Date
15 March 2018 (Thursday)

Time
9.00AM - 5.00PM

Venue
MREPC Seminar Hall, Unit 36-02,
West Wing, Level 36, Q Sentral, 2A,
Jalan Stesen Sentral 2, KL Sentral
50470 Kuala Lumpur

RM60
per participant
(Price is subject to 6% GST)

Register online now at www.mrepc.com for your seats!
For enquiries, please contact Ms. Madeline (madeline@mrepc.com) at 03-2782 2100