

Medical Device Single Audit Program (MDSAP): Implementations, Registrations and Regulatory Processes

10 July 2019

9am - 5pm

MREPC Seminar Hall

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



The Medical Device Single Audit Program (MDSAP) was developed to allow recognized auditing organizations to conduct a single audit of a medical device manufacturer that will be accepted by all five regulatory authorities participating in the program - Therapeutic Goods Administration (TGA) of Australia, Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil, Health Canada, United States Food and Drug Administration (US FDA) and Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA).

The briefing is aimed to provide knowledge and understanding on the objectives, requirements and structure of MDSAP and learn to recognize its relationship with other certifications. Information on MDSAP processes comprising of audit cycle, sequence, procedures, output and benefits will be presented to exporters of Malaysian rubber medical devices.

Programme

8.30am Registration of Participants

9.00am Introduction to MDSAP
The Audit Model of MDSAP

1.00pm Lunch

2.00pm How Does MDSAP Work? - Structure and Requirements
How Does MDSAP Fit With Other Certifications? - Relationships with Other Certifications

5.00pm End of Session

Speaker - Capt. A. Rajkumar



Capt. Raj holds a degree in Physics and Computer Science and advanced diploma in Applied Sciences. He is a certified Master Mariner with a career at sea spanning over 16 years and lead trainer and auditor in ISO 9001, 27001, 14001, 22301, 27001, 13485, 20000, 28000, 31000, 50000 Energy Management Standard and OSHAS. He has assisted medical device manufacturers on ISO 13485, conducted medical device risk management, trained trainers for FDA, trained and implemented Good Distribution Practice for Medical Device (GDPMD) and Good Manufacturing Practice (GMP). He is the appointed consultant and trainer for TUV STAR assessment project steered by MDeC and the founder and current chairman of Supply Chain Security Forum of Malaysia.

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For enquiries please contact Siti Najwa at najwa@mrepc.com or contact us at 03-27822100