BSI Training Academy

Healthcare Seminar on 24 January 2019

Essential information about the seminar

BSI Malaysia is proud to host our first healthcare seminar in 2019 for the medical device manufacturer regulatory affairs, quality assurance and related community. Our unique 1/2 day seminar event is exclusively focused on addressing European medical device regulatory and quality assurance requirements. We invite you to join our international experts on sharing of critical topics and valuable insights around the healthcare highlights in 2019 and beyond.

You will learn to:

- Explain and communicate any changes in the new aspects of the Regulation
- Unserstand Notified Body assessment of manufacturers of sterile products
- Identify common pitfalls and understanding additional MDR requirements
- Understand MDSAP programmes development, current state and future possibilities

Seminar highlights:

Topics

- Medical Devices Regulation (MDR) Highlight - Major Changes Moving From MDD to MDR
- Notified Body Assessment of Steriled Products
- Medical Device Single Audit Program (MDSAP)

Seminar Details

Date : 24 January 2019
Fees : RM250 per person
Venue : Kuala Lumpur

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Agenda

Time	Topics
12.00 noon	**Registration and light refreshments**
1.00pm	 **Medical Devices Regulation (MDR) Highlight - Major Changes Moving From MDD to MDR** Franceso Laterza, Regulatory Lead - Global Oversight, Global Regulatory Compliance On March 2017 a new Medical Device Regulation was approved in EU. This new regulation improves some aspects of the previous EU directives, extends the scope of application on other devices like devices with no medical purpose and introduces more stringent focus on pre-market approval of high risk devices. This session will provide a brief overview on the new aspects of the Regulation and provide feedback on the transition phase.
2.00pm	 **Notified Body Assessment of Steriled Products** Dr Yoann Buisson, Global Quality Management Systems Certification Lead - Medical Devices This session will be focusing on Notified Body assessment of manufacturers of sterile products, including common pitfalls and additional MDR requirements.
3.00pm	 **Medical Device Single Audit Program (MDSAP) Highlight - Current State vs Future Look** Patricia Murphy, Global MDSAP Manager, Global Healthcare Solution Reviewing the programmes development, current state and future possibilities. A look at the experiences of manufacturers who have undergone MDSAP audits for certification and the use of the MDSAP programme by the regulators.
4.00pm	**End of seminar**

Find out more.
Call: **+6 03 2242 4211**
Email: **info.malaysia@bsigroup.com**

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BSI Services Malaysia Sdn Bhd
Unit 10-03, Level 10, Tower A
The Vertical Business Suites
Bangsar South
No 8, Jalan Kerinchi,
59200 Kuala Lumpur.

T: +6 03 2242 4211
E: info.malaysia@bsigroup.com
bsigroup.com.my/training