# BSI Training Academy

# Healthcare Seminar on 25 January 2019

## Essential information about the seminar

BSI Singapore is proud to host our first healthcare seminar in 2019 for the medical device manufacturer regulatory affairs, quality assurance and related community. Our unique one 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 Device Single Audit Program (MDSAP) Highlight - Current State vs Future Look
- Medical Devices Regulation (MDR) Highlight - Major Changes Moving From MDD to MDR
- ISO 13485:2016 Transition Updates and Notified Body Assessment of Steriled Products

**Seminar Details**

**Date** : 25 January 2019
**Venue:** ParkRoyal on Kitchener Road
Sapphire 1 & 2 (Level 3)

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**Agenda**

**0930 – 1000hrs** **Registration and light refreshments**

**1000 – 1010hrs** **Welcoming Speech by BSI Singapore**

**1010 – 1100hrs** **ISO 13485:2016 Transition Updates**
Dr Yoann Buisson, Global Quality Management Systems Certification Lead –Medical Devices

**1100 – 1200hrs** **Medical Device Single Audit Program (MDSAP)**
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.

**1200 – 1300hrs** **Lunch**

**1300 – 1400hrs** **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 transitionn phase.

**1400 – 1500hrs** **Notified Body Assessment of Sterile 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.

**1500 – 1530hrs** **FAQ & Networking (Coffee & Light Refreshments will be served)**

**BSI Singapore Pte Ltd**
77 Robinson Road
#28-03, Robinson 77
Singapore 068896

Find out more
Call: **+65 6270 0777**
Email: **info.sg@bsigroup.com**
Website: **bsigroup.com.sg**