MEDICAL DEVICES REGULATORY TALK

19 JULY 2019

How ready are you for the Medical Devices Regulation?

The Medical Devices Regulation (MDR) (EU 2017/745) has replaced the Medical Devices Directive (MDD) (93/42/EEC) as the legislation detailing the requirements that medical device manufacturers have to meet to place medical devices on the EU market. The first part of the talk will share on the changes in MDR compared to MDD and how would these changes affect the medical device manufacturers placing their products in Europe.

This session will also cover the introduction of Unique Device Identification (UDI).

The second half of the talk will focus on compliance timeline. Getting ready to go through conformity assessment and to successfully transit from MDD compliance to MDR, including some common examples for the transition.

Programme Agenda:

0900 - 0930	Registration
0930 - 0945	Welcoming Speech by BSI Singapore
0945 - 1100	Medical Device Regulatory (MDR) • *What are the changes* • *How does it affect the Medical Device Manufacturers?*
1100 - 1115	Break
1115 - 1200	Medical Device Regulatory (MDR) compliance timeline and conformity assessment
1200 - 1230	Q & A Session
1230 - 1330	Lunch & Networking

Event Details:

Date: 19 July 2019

Time: 0930am - 1330pm

Venue: BSI Singpaore
77 Robinson Road
#28-03 Robinson 77
Singapore 068896

Keynote Speaker:

Francesco Laterza

Regulatory Lead - Global Oversight

Global Regulatory Compliance - EMEA

Francesco is a senior leader with extensive experience in Medical Device business and its European regulations. As an engineer with a major in biomedical field, he has great experience in Medical Device Conformity Assessment, new MDR/IVDR Regulation and regulatory changes.

He is also an expert in QMS design and development (ISO 9001, ISO 13485 including CMDCAS, 21 CFR part 820 FDA regulation) including Post-Market Vigilance, outsourced processes assessment and qualification (OEMs, dealers and distributors).

Find out more

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