MEDICAL DEVICES REGULATORY TALK

Dates & priorities, New Classification

28 April 2020 | 9:30am | Webinar

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

Event Details:

Date: 28 April 2019

Time: 0930am - 1330pm

Speaker:

David Huang

Client Manager, Trainer - BSI Singapore

With more than 30 years' of industry experience in system and functional processes, David offer clients from Design to Manufacturing services especially for medical devices to comply with the ISO 13485, GMP/GDP and for Quality and System implementation of the contractors and manufactures to ISO 9001 for livestock industry, for regulatory compliances (e.g. HSA, DEFRA).

David is a qualified Lead Assessor and trainer in Quality Management systems for ISO 13485, ISO 9001, OHSAS 18001/ISO 45001, GDPMDS/SS 620, ISO 14001 & Medical Device Single Audit Program (MDSAP)/MDD/MDR, FMEA and Process Validations etc.

Find out more

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