...making excellence a habit.™

# Seminar on MDSAP, MDR and IVDR Revision

## Get Prepared for the Change in Medical Device Industry

6 May 2019 (Monday)

The medical device industry is undergoing a period of tremendous change.

The new Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) has been published in the Official Journal of the European Union and came into force on 25 May 2017. The transition periods for MDR and IVDR are three years and five years respectively from the date of adoption.

Companies are required to have a thorough understanding of the new requirements. They have to plan and get prepared for the new rules as EU law does not allow grandfathering of devices. Therefore, every device must be certified under the new rules in the transitional time frames provided.

The seminar will highlight the key changes in regulations which help you consider what actions you have to start now in order to get prepared for the change in requirements.

***Seats are limited. First-come first-served.***

| | |
|---|---|
| **Date** | 6 May 2019 (Monday) |
| **Time** | 14:00 – 17:00 (Registration starts at 13:45) |
| **Venue** | 23rd Floor, Cambridge House, TaiKoo Place, 979 King's Road, Island East, Hong Kong |
| **Medium** | English |
| **Admission** | Free |
| **Rundown** | **14:00 – 14:15** **Welcoming address**<br>Ms Davis Leung, Senior Business Development Manager, BSI Hong Kong<br><br>**14:15 – 15:15** **The significant changes under MDR**<br>Mr Lane Ji, Healthcare Director, BSI China<br><br>**15:15 – 15:30** **Break**<br><br>**15:30 – 16:30** **Overview of IVD CE marking and key changes from IVD Directive to Regulation**<br>Ms Hailey Chu, Technical Specialist & Scheme Manager, BSI global IVD team<br><br>**16:30 – 16:55** **MDSAP Processes and frequent audit findings**<br>Mr Lane Ji, Healthcare Director, BSI China<br><br>**16:55 – 17:00** **Q&A** |
| **Enrolment** | TBC |

** Programme details are subject to change without prior notice*

**British Standards Institution**
23rd Floor, Cambridge House,
Taikoo Place, 979 King's Road,
Island East, Hong Kong

**Enquiry**
Ms Ming Tang
Assistant Marketing Manager
Tel : +852 3149 3324
Email : haming.tang@bsigroup.com