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BSI Medical Device Newsletter February 2015

Welcome to the February Medical Device Newsletter of 2015.

Our January Newsletter has been well received, and so we hope you enjoy the February update. We have successfully run our first Webinar of 2015, on the new MDSAP trial, if you missed it, don't worry, you can listen on playback via the webinar link below.

New Head of UK Notified Body, 0086

BSI would like to inform you that after many years' service as Head of Notified Body 0086, John Howlett, will be leaving BSI from January 2015. We wish John the very best for the future and thank him for helping to shape BSI into the world class Notified Body we see in 2015.

We are pleased to announce that Dr Suzanne (Suzie) Halliday has accepted the position as the UK Head of Notified Body 0086. Suzie has many years' experience working in medical devices for BSI, as a Technical Specialist, QMS Assessor, Team Leader and Head of Medical Device Operations and Training.

To find out more about Suzie, please visit our official announcement.

New BSI Webinars available

For 2015, to help you to keep up to date with a rapidly changing regulatory environment we are publishing a webinar schedule for the whole of 2015. The full list of webinars can be seen on our website, and the following webinars are open for registration:

- IVD regulatory framework
- 10 February 2015 - 16:00 to 17:00 GMT
- Japanese Pharmaceutical and Medical Device Act (PMD Act) regulation
- 13 February 2015 - 09:00 to 10:00 GMT
- Revision of the medical device regulatory framework, MDD and AIMD.
- 5 March 2015 - 16:00 to 17:00 GMT
- Medical device unannounced audits, lessons learnt.
- 17 March 2015 - 16:00 to 17:00 GMT

Come and Meet BSI

Topics will include:

- European Regulatory Update
- Clinical Data Evaluation
- Technical Files - Key Pitfalls
- Unannounced Audits Update

United Kingdom

Medical Devices Regulatory Update Seminar: Are you prepared?

Tuesday 24 February 2015, London and Thursday 26 February 2015, Nottingham

Register today

United States

The 2015 Medical Device Mini-Roadshow.

4 New Locations in March and April 2015

Register today

IVD Excellence

New IVD training courses.

On September 26, 2012 the EU Commission released its proposal for future regulation of In Vitro Diagnostic (IVD) devices. The IVD Directive will be replaced by a Regulation, and significant changes will occur around Technical Documentation and Performance evaluation and clinical evidence.

Technical Files and design dossiers for In Vitro Diagnostics (IVDs)
A required part of conformity assessment and CE-marking is the need for a Technical File (called a Design Dossier for high risk devices), which includes the collation of supporting information about your IVD device. Learn how to assemble this and other types of required information, so you can CE Mark your device in Europe. You'll also learn potential changes that may impact your Technical Documentation under the proposed future IVDR.

Performance evaluation and clinical evidence for In Vitro Diagnostics (IVDs)
When placing an IVD device on the European market, you must demonstrate that it complies with necessary regulatory requirements through appropriate conformity assessment procedures. Learn how to plan for appropriate performance studies for your IVD device and gather required information and data needed for a body of clinical evidence under the proposed future IVDR.

Full Details regarding these exciting new courses are on our website, where you can also request a quote for In-company training.

ISO 13485, Medical Devices Quality Management System

3rd Revision Update

January 2015
A finalized 2nd DIS (Draft International Standard) text, has been submitted to CEN/ CENELEC for translation, this is required for a parallel vote by ISO/CEN.

February 2015
A 2nd DIS will be issued for 2 month vote & parallel vote under the Vienna Agreement.

We will share a comprehensive update in late February.

BSI Global Medical Device.

This group is for professionals who design, develop, manufacture or distribute medical devices or related services, or are involved in developing medical device standards or regulations.

NEW BSI Whitepaper

[Negotiating the Innovation and Regulatory Conundrum]

Written by Mike Schmidt, Principal Consultant and owner of Strategic Device Compliance Services and Jon Sherman, Director, Sustaining Engineering, Atricure inc.

This paper raises important questions about the attitude to creative product development, illustrating the need for a closely documented approach throughout the process.

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