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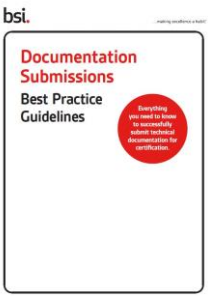
August Medical Device Newsletter, 2016

Are you confident in your technical documentation submissions?



One of the biggest challenges for manufacturers undergoing conformity assessment is the time it takes for technical documentation to be reviewed. There are two main reasons for slow review time; a lack of required information, or information being difficult to locate.

Well organized documentation can improve the efficiency of a review by making relevant files easy to locate, reducing the rounds of questions relating to document format and layout.

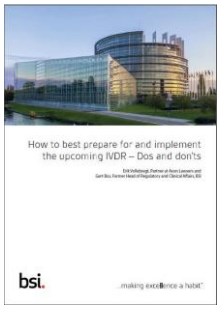
To help improve the efficiency of our reviews for your products, we have created the Documentation Submissions Best Practice Guidelines, which will allow you to create effective notified body submissions.

Download your copy

New IVD Regulation - Do you understand the implications?

BSI white paper - IVD Regulation

BSI's new white paper "How to prepare for and implement the upcoming IVDR – Dos and don'ts", is now available for download.



The magnitude of the changes affecting the IVD industry requires thorough understanding, robust plans and prompt action. Read this white paper to understand more about the changes you face.

Updated information for ISO 13485:2016

New Readiness Review

Following the revision of ISO 13485, it is important that you assess your Quality Management System against the new requirements of the standard before your transition audit.

The Readiness Review allows you to detail how you intend to meet the additional requirements of the new standard. A useful tool for analysing your progress, this document is designed to be used in conjunction with the standard.

Download your copy of the Readiness Review and make sure you're ready for transition.

ISO 13485:2016 revision webpage

Visit our revision webpage to access the latest guidance and updates on the new standard. Bookmark the page to make sure you stay up-to-date.

ISO 13485:2016 revision page

ISO 13485 Expert Commentary

The BSI Standards team have developed an expert commentary on the new version of ISO 13485, highlighting the key changes that you need to be aware of.

Download now

Learn more about the IVDR - listen back to our complimentary webinar

In Vitro Diagnostics Regulation – Changes to the IVD regulatory landscape

Stay informed on key updates

Make sure you remain updated with BSI's IVDR revision resources, including webinars, whitepapers and guidance on the new Regulation.

IVDR Transition page

NEW complimentary webinars

The role of the 'Person Responsible for Regulatory Compliance' in the future Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) - 28th September

One of the novelties introduced under the new European MDR and IVDR is the concept of the Person Responsible for Regulatory Compliance. Join our complimentary webinar to learn more about the requirements.

Download your copy

Updated ISO 13485 training

BSI has a range of courses on ISO 13485, from an introduction course for those new to the standard, to internal and lead auditor courses for those actively involved in the implementation of the standard in their organization.

We have recently updated our suite of ISO courses to reflect the requirements of the new standard, including:

Introduction to ISO 13485

ISO 13485 Clause-by-Clause

Implementing ISO 13485 Medical Devices

Internal Auditor ISO 13485 Medical Devices

Lead Auditor ISO 13485 Medical Devices

For those familiar with ISO 13485, our transition courses offer focused training on what's new and what's changed:

ISO 13485:2016 Transition

ISO 13485:2016 Auditor Refresher

ISO 13485:2016 Transition & Auditor Refresher

View the courses to find out more.

View all courses

How do you stay updated with

New version of MEDDEV 2.7.1 Revision 4: Key changes and clarification - 18th October

Revision 4 of the MEDDEV guidance document 2.7.1 - Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
under Directives 93/42/EEC and 90/385/EEC - was released by the European Commission on 1st July 2016. Join us to learn more about the key changes and clarifications.

Can't attend?
Sign up – we will make the recording and full slide deck available to you after the webinar.

BSI Medical Devices LinkedIn

Join the BSI LinkedIn Group to stay informed and updated with the latest news.

the latest news on the MDR?

Agreement has been reached on the new Medical Device Regulation, which will replace the current Medical Device Directive (93/42/EEC) and Active Implantable Medical Device Directive (90/385/EEC). This long awaited text brings with it more scrutiny of technical documentation.

The dedicated web page for the MDR revision can provide you with the latest updates - bookmark this page and stay informed.

MDR Transition page

Medical Device Regulation – Impact on manufacturer resources

Listen back to our recent webinar to understand more about the key requirements of the MDR, and what you need to consider for your transition and beyond.

Do you need the latest standard?

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Visit the BSI Shop to purchase the latest standards and related guidance relevant to your product, including the new ISO 13485:2016.

For all general enquiries call +44 345 080 9000 or visit the BSI Medical Devices website

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