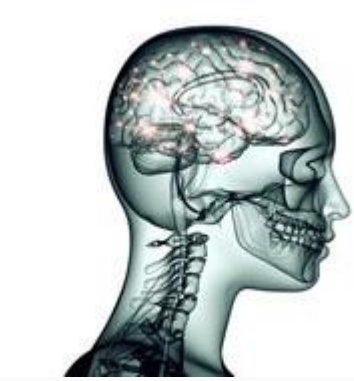
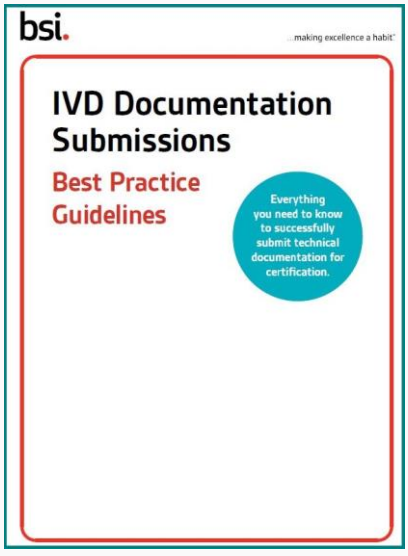
Contact us
+44 345 080 9000
bsigroup.com/medical



Regulatory review

Your monthly medical devices update

July 2017

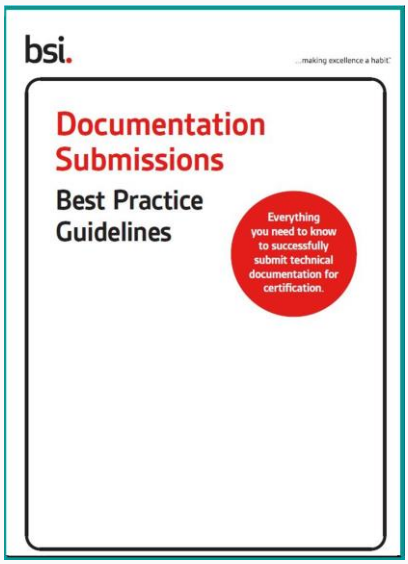


Ensure an efficient technical documentation review

Submitting compliant technical documentation can improve the efficiency of your BSI product review, with less time taken for locating the correct documentation, and fewer questions relating to document format and layout. Use our guidance document to understand what information you need to submit to the notified body and improve the process of technical documentation submissions.

Download our NEW guidance for IVD technical documentation submissions now.

Download your copy



For Medical Device technical documentation

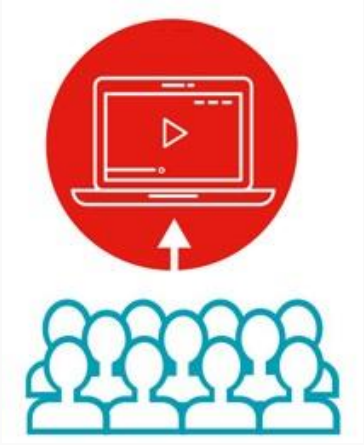
Download our Medical Device Documentation Submissions Best Practice Guidelines here.

Get more detail on the new regulatory requirements

Learn about the General Safety and Performance Requirements (SPR) under the IVDR including the implications of the new Regulation on manufacturers, by joining our live webinar on July 12.

Join us on July 25 to learn about the requirements for medical devices utilizing biological substances under the MDR, including implications of changes to classification rules and the Regulation's scope.

Sign up now



Have you missed any of our recent webinars?

BSI offers complimentary webinars on a range of topics. There are a number of recent webinars available, covering information on the roles and responsibilities under the MDR and IVDR, Post-Market Surveillance requirements, the Medical Device Single Audit Program (MDSAP).

You can see upcoming webinars and listen back to previous webinars on our website.

Listen back now

Don't miss the deadline for ISO 13485:2016

The ISO 13485:2016 transition period is well underway. You need to update your Quality Management System to meet the new requirements, and get assessed to the new Standard, to ensure you maintain your certification.

Download our Transition Toolkit and access all the resources you need to effectively transition, including explanatory webinars, expert commentary covering the key changes, training courses, your best practice journey guide and much more.

Find out more

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