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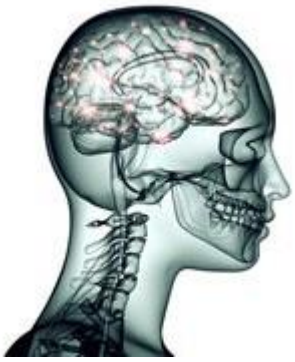


Regulatory review

Your monthly medical device update

September 2018

Two critical deadlines approaching: Act now to ensure you are prepared

Less than six months until ISO 13485 deadline, will you be ready in time?

ISO 13485:2016, the latest edition of the Medical Devices Quality Management System standard, is the only version of the standard that will be accepted from March 2019. Manufacturers that do not comply with the standard at this time will face losing their certificate. In some regulatory jurisdictions, this may mean having to stop placing product on the market.

With only six months of the transition period left, manufacturers need to be prepared to receive any final assessments against the new version of the standard to ensure that they are certified in time.

Be prepared by using our complimentary resources including FAQs, a Readiness Review and numerous webinars that discuss the changes to the standard and highlight areas of focus. Visit our transition web page and access these resources now.

Access our resources

Five months left - Don't lose access to the Canadian market

It is critical that you are prepared to meet the Medical Device Single Audit Program (MDSAP) deadline to maintain market access in Canada. MDSAP has been adopted by Health Canada in place of its current CMDCAS program for medical devices market access, and the transition period ends 31 December 2018. Manufacturers that are not prepared will have to remove their devices from the Canadian market.
Find out more about MDSAP by visiting our website.

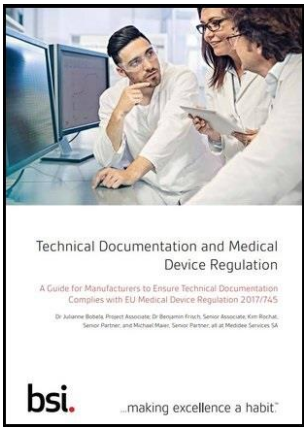
Find out more

New webinar: The latest update on the regulatory implications of Brexit

Three months on from our last update, join **Gary Slack, Senior Vice President Global Medical Devices**, for the latest on the regulatory implications of Brexit. The webinar will discuss how Brexit will impact the implementation of both the MDR and IVDR.

Join us on Tuesday 18 September 2018 at 4pm BST to learn more.

Register now



Have you got your copy of our latest white papers?

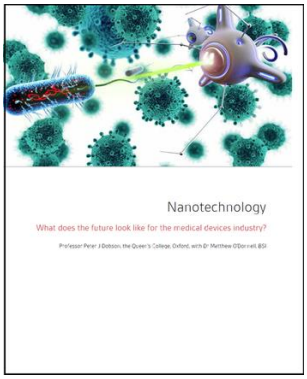
BSI has recently released two new white papers, "Technical Documentation and Medical Device Regulation", and "Nanotechnology".

The first explores the regulatory requirements for Technical Documentation and gives some insight into what will be expected under the new MDR. Download your copy now and use this as part of your comprehensive toolkit to plan for the new Regulation.

You can find out more about the MDR by visiting our dedicated MDR transition web page.

Download your copy

The use of nanomaterials in medical devices is of increasing interest as the industry continues to innovate. The "Nanotechnology" white paper provides a discussion of the uses of nanomterials in medical devices



and explores some of the regulatory requirements, standards and guidance around these materials.

You can find out more about nanomaterials by visiting our dedicated Nanomaterials web page.

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