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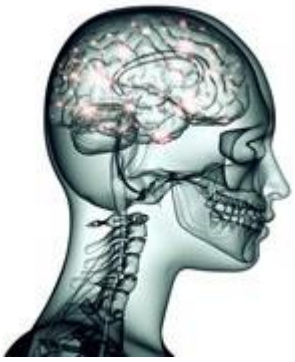
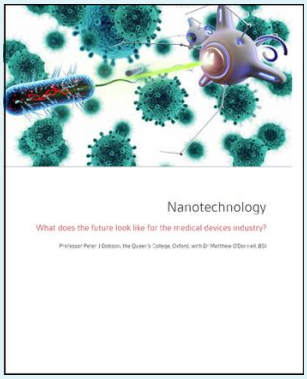


Regulatory review

Your monthly medical device update

August 2018



Nanotechnology: A new white paper

Nanotechnology is now a mature subject in terms of the basic science, and while there were many claims for what it could achieve 20 years ago, the application to medicine and healthcare has now become more well defined.

Co-authored by Professor Peter Dobson of Queen's College, Oxford, and BSI Nanomaterial expert, Dr Matthew O'Donnell, this review summarizes the application of nanotechnology in some specific medical device fields, including medical image enhancement, drug delivery vehicles and nanomaterials for

functional coatings. It identifies gaps in understanding and opportunities for the future.

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Find out more about nanomaterials by watching our webinar, or visit our **new** nanomaterials webpage.

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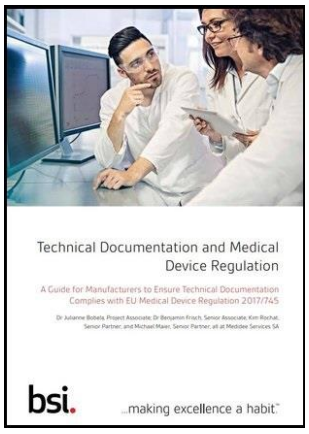
Make sure your Technical Documentation is compliant to the MDR



The Medical Devices Regulation (MDR), EU 2017/745, brings increased scrutiny on medical device manufacturers and all others in the supply chain through more prescriptive and numerous requirements. It is essential that you understand what you need to do to ensure your technical documentation is compliant and meets the new and clarified requirements of the MDR.

Our new white paper, **Technical Documentation and Medical Device Regulation**, reviews the technical documentation requirements of the Regulation, and explores specific themes including post-market surveillance and conformity assessment routes.

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You can find out more about the Regulation and access additional resources by visiting our transition web page.

Visit the webpage

Don't leave it too late to transition to the IVDR

The In Vitro Diagnostic Regulation (IVDR) was published in May 2017 with a five year transition period. The changes from the IVD Directive to the new Regulation are significant. Preparation is key to a successful transition; it's critical that you have understood the changes, implemented the Regulation and are ready to apply to your Notified Body when they are designated.

Use our tools and resources to ensure you understand what these changes are, so you can interpret how they impact your organization. Visit our transition web page to access our resources and find out more.

Visit the IVDR webpage

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