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

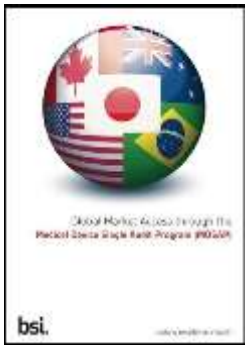
Regulatory review

Your monthly medical device update

February 2018

Understanding the Medical Device Single Audit Program (MDSAP)

An increasing number of manufacturers are adopting MDSAP, reducing the number and improving the efficiency of audits they receive. This is being driven by Health Canada confirming its plans to utilize only MDSAP for market entry from 2019.
Make sure you have submitted your application for MDSAP to ensure you are certified in time.



Download our new brochure to get more information on the Program, to learn how the Regulatory Authorities will utilize the Program locally and find out more about BSI's role as an Auditing Organization.

Download now

Listen back to BSI Global MDSAP Manager Patricia Murphy for a more detailed explanation of MDSAP and its audits.

Listen back

Our medical device vigilance reporting white paper outlines the MDSAP requirements in comparison with the requirements of the recently published European Medical Device Regulation (MDR). Download your copy now.

Download now

Do you want to continue receiving our updates?

The General Data Protection Regulation (GDPR) is coming on 25 May 2018. It requires organizations to only send emails to those who have requested to hear from them. Re-register with us today to continue receiving our updates.

Yes, please send me the medical devices updates

How will your QMS be affected by the MDR and IVDR?

Join Vicky Medley, BSI Global QMS Manager, Medical Devices, on 27 February to learn about the impact that the new Regulations will have on your QMS and how BSI will approach these assessments.

Register now

Did you miss last month's webinar on EU harmonization, standards and labelling? Listen back now.

Listen back

Compliance Navigator "has not only met our expectations, but in some cases it has exceeded them"

Read what Hologic had to say in full about BSI Compliance Navigator and the benefits that have allowed them to manage their regulatory information.

Read more

Stay up-to-date with the new Medical Devices and IVD Regulations and innovations in the medical device industry with Compliance Navigator Blog.

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