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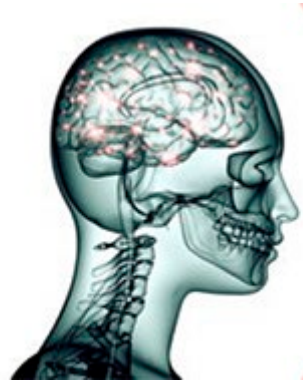

Regulatory review

Your monthly medical device update
June 2022

Featured in this Newsletter

- Introduction to Graeme Tunbridge, SVP Global Regulatory and Quality
- Hybrid audit webinar - listen back and video
- EU IVDR Transition Toolkit
- MDSAP audits
- Compliance Navigator Blog
- Events for your calendar

Watch the introductory video to Graeme Tunbridge, SVP Global Regulatory and Quality

We are delighted to welcome Graeme Tunbridge to the BSI Regulatory Services team.

Watch the video and listen to Graeme talk about:

- His first impressions of working within BSI.
- The team's main focus for the coming months and years.
- His past life at the MHRA and what the future for UK Approved Bodies could look like.
- How to expand the Regulatory Services Stream beyond Medical Devices and IVDs.
- His personal take on the future.

Graeme is already making his presence known in the industry by being named as one of the 30 Rising Leaders by In Vivo, the specialist resource for life sciences business strategy.

Watch video

Hybrid audit webinar - the new way of working post pandemic

On 25 May, we ran our webinar on hybrid audits – the new way of working post pandemic. This webinar looked at audit lessons learnt during the pandemic as well as how best to plan for future audits.
The webinar was presented by Linda Moon, Global Quality & Accreditation Manager, Regulatory Services. Linda was joined by subject matter expert Dr. Yoann Buisson, GQA Technical Manager, Regulatory Services.

On demand hybrid audit webinar and video

EU IVDR Transition Toolkit

The IVDR EU 2017/746 entered into force in May 2017 with a five-year transition. Take a look to the new IVDR Toolkit!

A useful guide to support our customers to access the resources they need for IVDR transition.
Here you can find brochures, guidances and documents about IVDR, as well as white papers, training, webinars and much more!

Access the toolkit

What is MDSAP audit?

A Medical Device Single Audit Program (MDSAP) audit allows a single audit of a medical device manufacturer's QMS, which satisfies the requirements of multiple regulatory jurisdictions.

Audits are conducted by Auditing Organizations (AO), such as BSI, which are authorized by the participating Regulatory Authorities (RA) to audit under MDSAP requirements.

Come and talk to us about your journey with MDSAP.

Find out more on our website.

Download MDSAP brochure

Have you read our medical devices blog?

The Compliance Navigator medical devices blog covers industry news on regulation, standards and technology. New posts are published bi-weekly and are written by industry experts. What's more, you can read the latest posts on the Compliance Navigator website today.

Visit website

Events for your calendar

BSI/AAMI International Standards & Regulations Conference

On the **29 and 30 June**, BSI is running the annual BSI and AAMI-sponsored International Standards & Regulations Conference. This year's event is online.

Targeted at healthcare and device manufacturers, we're covering what's new in the last year in regulation, standards, and patient safety that we think you should know about.
Whatever your area of interest, by participating you'll gain invaluable insights on the challenges faced by medical device manufacturers.

Book your free place

Find out more about our latest Events and Conferences.

bsi.

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Inspiring trust for a more resilient world.