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Regulatory review

Your monthly medical device update
February 2022

Featured in this Newsletter

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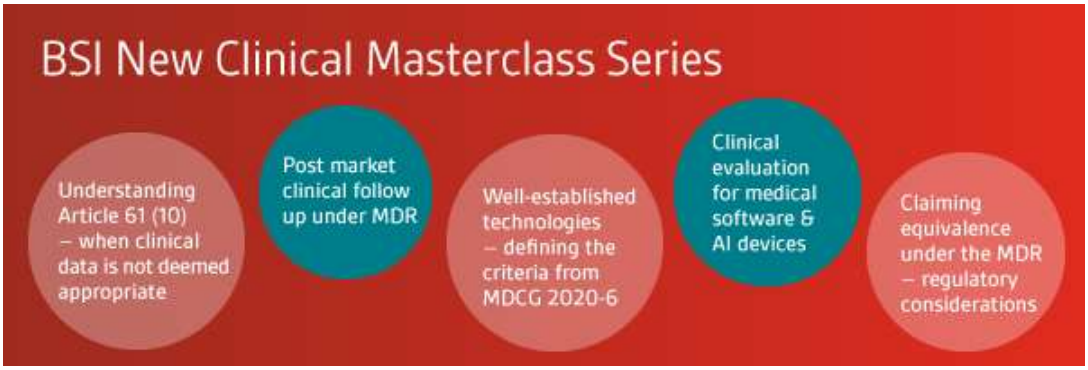
Register now for BSI's Clinical Masterclass Series



The timelines for ensuring your product maintains EU market access under the new, more stringent Medical Device Regulations (MDR) are challenging.

These five insightful webinars will help you focus on various aspects of the MDR, from looking at post-market clinical follow-up, to helping you with your medical device software and when a clinical evaluation is required.

Listen back to our first webinar of the series; **Well Established Technologies - Defining the criteria from MDCG 2020-6**

Our second webinar of the series; **Understanding Article 61 (10) – When Clinical Data is not deemed appropriate**, took place on 2 February and looked in detail at BSI's understanding of the occasions when it is appropriate that no clinical data is required for clinical evaluation.

To view more information about the upcoming series or to register ahead of time for the other webinars, please click below:

View the full Clinical Masterclass series

Feature enhancements to the Digital pre-applications Portal

As you will know, we launched the first phase of Digital Pre-Application (DPA) in August 2021, which marked the first significant milestone on our digital transformation journey. DPA is a dedicated client portal that enables certification applications to be submitted online.

We have had a great response from clients who have used DPA and are grateful to all those who have provided feedback.

As a result of that feedback, we have made some feature enhancements that will go live at the end of

February, including the ability to upload multiple applications with a single click, which will save time and ensure consistency across all applications submitted simultaneously.

Further enhancements to DPA are planned for the Spring, and these will include additional functionality designed to simplify and ease the pre-application process. We will let you know more about these features in the coming weeks.

Start your journey here

Hybrid audits and Sustainability

The COVID-19 pandemic has forced the medical device and IVD sector to consider new and innovative ways of meeting regulatory demands while keeping patient safety at the forefront of our role. As a sector, we have risen to the challenge of COVID-19 with professionalism and resilience, and we have found new ways of ensuring we meet our responsibilities. One benefit of hybrid audits is that it significantly reduces the carbon footprint by implementing less travel for our auditors.

BSI was established in 1901 with 'responsibility to society' as one of its main objectives, and this has never been more relevant than it is today. We are a signatory of the UN Global Compact, the world's largest sustainability network, and are proud to support its principles, as well as the UN Sustainable Development Goals. We are committed to advancing all the UN Sustainable Development Goals, making a positive impact both through our own actions and helping clients make sustainable choices.

The goals we believe will be impacted by our use of hybrid audits in the future:

- Goal 3: Good health and wellbeing
- Goal 7: Affordable and clean energy
- Goal 9: Industry innovation and infrastructure
- Goal 12: Responsible consumption and production.

Follow link to find out more about the new way of working post-pandemic.

UK regulations for medical devices

The UK Medicines and Healthcare products Regulatory Agency (MHRA) have started the process to update the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) and indicated that they will continue to recognize European CE marking until 30 June 2023. The UK Trade Association for healthcare industries have asked for a postponement of this date but there is currently no indication that there will be a delay.

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Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.

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