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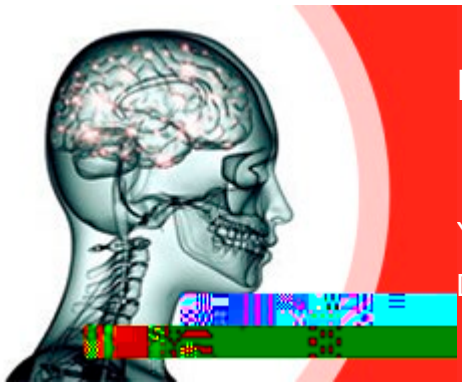


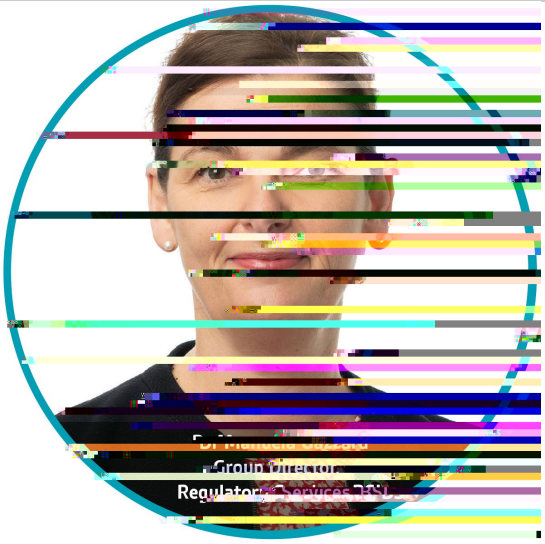
Regulatory review

Your monthly medical device update

December 2021

Featured in this Newsletter

Dr. Manuela Gazzard, Thank you



I am immensely proud of the dedication, hard work, and passion at BSI Regulatory Services and the difference the team has made throughout the year. 2021 has again been a challenging year for all of us with the continued impact of the global COVID-19 pandemic. However, our values and mission of ensuring patient safety and bringing innovation to market timely remained at the heart of what we do.

Our team keeps growing to ensure we have the capacity to support manufacturers with conformity assessments under the IVDR, MDR and UKCA whilst maintaining all our strict compliance responsibilities. We plan to have more than 900 colleagues by the end of the year as we welcome more diverse newcomers into our talent pool globally.

As you will know, the process for the Unit ed Kingdom Conformity Assessment mark is beginning to take shape, and we started accepting applications from January 2021. The date of application arrived in May, and I am proud of the whole team's efforts to ensure that all clients met this deadline, with no client being left behind. We end the year with a positive vote for the changes to the IVDR transition timelines addressing a concern the entire industry shared; we look forward to the formal announcement of the changes.

This year we launched the innovative digital pre-application portal, the first stage of our ongoing digital transformation. We are pleased about the positive feedback on the improvements you already realise in your applications to BSI.

As the year draws to a close, I would like to say a huge and heartfelt thank you to you for your flexibility and commitment during this challenging year.

Please continue to stay safe, and I wish you, your families and loved ones a restful festive season and a more stable year in 2022.

New for 2022 - 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 m edical device software and when a clinical evaluation is required.

Our first webinar of the series is Well Established Technologies - Defining the criteria from MDCG 2020 -6, on the 19 January .

Discussions will include the concept of well-established technologies under the medical device regulations and how to interpret the four criteria defined in MDCG 2020 -6. This session will also cover the levels of clinical evidence required for these devices to support your clinical evaluation.

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On 14 October 2021, The European Commission proposed to amend the transition period of devices covered by the IVDR. This urgently drafted proposal to change the implementa tion arrangements of the

As part of BSI’s continuing Prioritizing People campaign, this month we look at prioritizing the psychological and physical health, safety and well-

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