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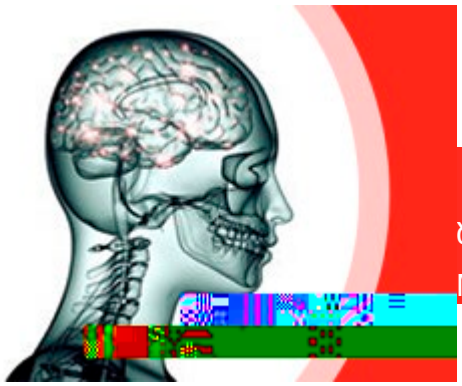


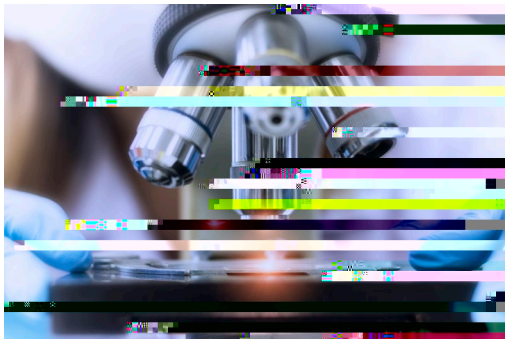
Your monthly medical device update

May 2022

- Clinical Series toolkit
- Hybrid audit - webinar and video
- IVDR Date of Application
- Medicinal Dossier
- Events for your calendar
- Using standards to demonstrate conformity

Our Clinical Masterclass series of webinars is now completed, and we hope you enjoyed the series.

Watch the Hybrid audit video



The IVDR EU 2017/746 entered into force in May 2017 with a five-year transition period.
Manufacturers have the duration of this period to update their Technical Documentation to meet the requirements and comply with the Regulation before the

To keep up to date with the timelines of the transition from IVDD to IVDR follow the weekly updates on the _____ and the _____

For devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR), the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC (the Medicinal Products Directive). Annex IX, 5.2(a) of the MDR states the notified body should seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device.

Download our guidance for devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR).

Find out more on our website.

Download our guidance

One important characteristic of standards is that they are voluntary – there is no obligation to apply them or comply with them, except in those few cases where their application is directly required by regulations. However, the application of standards in the medical devices sector has undoubtedly been accele(c)1 (10( )04t)2.6 (i9(i8(399 (t)0.7)0.7 (t)u(h)-2 (t)0.7)0.7 (t)u(h415.32 195)0.7 (w)2 (i)2.4 (80.7 (d835(r c)1 (o)3 (mpl)-

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