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Regulatory review

Your monthly medical device update

April 2023

Featured in this Newsletter

Extended Webinar - Pathways to IVDR Compliance
25 April 2023

Join this insightful extended webinar to hear subject matter experts, Alex Laan, BSI's Head of IVD Notified Body and Liz Harrison, Global Head of IVD, talk about the key IVDR changes and lessons learnt so far, as well as tips on preparing a comprehensive Technical Documentation and the Performance Evaluation requirements under the IVDR. You will also gain a better understanding of the status related to high-risk CDx & Class D devices.

The webinar will include:

- History Lesson: Key IVDR changes… why and when?
- Telling a Story: Creating effective technical documentation
- Clinical Evidence: Understanding the requirements
- High Risk update: Current status of CDx & Class D devices
- Q&A sessions with panel

Register for this extended webinar:

25 April 2023 | 14.30 – 17.00 BST

Webinar - A SMEs tailored overview of the MDR Conformity Assessment Routes in the AIMD space

Wednesday 24 May 2023

9.00 – 10.00 BST

16.00 – 17.00 BST

IVDR - Removal of the sell-off provisions

With the publication of the amending regulation (EU) 2023/607 in March 2023, the sell-off

Click here to visit our dedicated webpage.

On demand Webinar -

Events for your calendar