Medical Device Regulations: Strategies for Compliance

SMi Group reports: Medical Devices and IVD Conference 2021 which will convene on 15th and 16th November 2021 in London.

LONDON, UNITED KINGDOM, June 30, 2021 /EINPresswire.com/ -- Join Europe's leading Medical Device and IVD Conference which will address post-market surveillance and vigilance, clinical evaluations and investigations, medical device regulatory affairs in global markets, and much more.

Gain insights from pharma regulatory experts in compliance and companion diagnostics and hear key presentations from FDA, Amgen, Bristol Myers Squibb, UCB Biosciences, Federal Agency for Medicines and Health Products (FAMHP), Bayer Radiology, Merck Connected Health & Devices, Jazz Pharmaceuticals, GlaxoSmithkline, Austrian Medicines and Medical Devices Agency and many more!

More information on the programme and speaker line-up can be found here: www.medicaldevices-ivd.com/pr2ein

KEY TOPICS COVERED:
•IVDR implementation: State of play, the Notified Body view
•Combination Products: End-to-End Risk Management
•Practical implementation of IVDR - learnings on the path towards IVDR readiness
•Preparing for the IVDR
•Requirements and challenges under the new IVD regulation
•Regulatory Aspects of Codevelopment of an In Vitro Diagnostic Companion Diagnostic Test with a Therapeutic Product
•Notified body panel discussion: Reflecting on the EU MDR and IVDR: challenges and opportunities
•Post-Market Expectations/Surveillance and Vigilance

•Vigilance under the MDR/IVDR
•Transitioning from MDD to MDR – opportunities and challenges
•Practical considerations for implementing the MDR updates
•Impact of Article 117 on Non-Integral Drug Device Combinations
•Impact of Article 117 MDR on medicinal products with an integral medical device
•Regulation (EU) No. 2017/745 – Changes for clinical investigations
•Medical Device regulations: strategies for compliance
•Engaging the workforce in a successful MDR journey: Discover how Merck Connected Health & Devices engaged its entire workforce into the MDR journey and their successful path to CE mark

•Cybersecurity Updates from the FDA
•Development of Medical Devices: A Toxicologists Perspective

Register at: www.medicaldevices-ivd.com/pr2ein

#MedicalDevicesIVD

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About SMi Group:
Established since 1993, the SMi Group is a global event-production company that specializes in Business-to-Business Conferences, Workshops, Masterclasses and online Communities. We create and deliver events in the Defence, Security, Energy, Utilities, Finance and Pharmaceutical industries. We pride ourselves on having access to the world's most forward-thinking opinion leaders and visionaries, allowing us to bring our communities together to Learn, Engage, Share and Network. More information can be found at http://www.smi-online.co.uk

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