

## Key Presentations at the Medical Devices & IVD Conference Released

SAE Media Group reports: ahead of the conference in November, key presentations are released for the Medical Devices & IVD Conference

LONDON, NON UNITED STATES OR CANADA, UNITED KINGDOM, August 17, 2022 /EINPresswire.com/ -- Launching for the first time in London, UK on 14 and 15 November will be the Medical Devices & IVD Conference. The conference will consider the evolving regulatory landscape for digital health software.

Industry professionals will address post-market surveillance and vigilance, clinical evaluations and investigations, medical device regulatory affairs in global markets and much more.



Interested parties can register at <a href="http://www.medicaldevices">http://www.medicaldevices</a>-ivd.com/PR2EIN - register by 30 September to save £100.

Delegates will gain the chance to:

- •Engage with notified body and competent authority representatives addressing key MDR and IVDR requirements
- •Gain insights from pharma regulatory experts in compliance and companion diagnostics
- •Understand the latest guidance on IVD Regulations to overcome common challenges, in addition to considering evolving global regulations
- •Examine post-market expectations for surveillance and vigilance of your medical devices
- •Delve into advancements in the digitalisation of medical devices and the regulatory considerations surrounding this

SAE Media Group have released the key presentations that will be taking place at the Medical Devices & IVD Conference, see below for a snapshot:

Medical Device Development to Commercialisation: Collaborations & Regulations presented by Amanda Matthews, Senior Director, Pfizer which will cover:

- •What are the biggest challenges when collaborating between medical device and pharma companies?
- •What works well when collaborating across the whole lifecycle management?
- •Clarification of fundamental terms to improve communication (between manufacturers, regulatory bodies, and pharma companies)
- •Discussion of the impact of the EU MDR and IVDR and how collaboration can be improved to optimize processes

The IVDR: What Has Been Learnt So Far presented by Anne Whalen, Previously Director, Novartis, she will cover:

- •Discussion of the current experience in the industry with the IVDR rollout
- •Requirements for additional guidance in Europe and further IVDR interpretations
- •Exploring the role of notified bodies with the EMA- what is this consultation process?
- •Examining stakeholder challenges and relationships (NBs/manufacturers/ EMA)

EU MDR Clinical Aspects: Reviewing The Progress Of Implementation presented by Tom Melvin, Former Competent Authority Chair, Clinical Investigation & Evaluation Working Group, European Commission, this will focus on:

- •Assessing the clinical aspects of the EU MDR and best practices for compliance
- •Addressing the common challenges for new devices vs. legacy devices
- •Looking into the future: gaps in current guidance and how to address this

Complying to the Medical Device Regulations: Strategies presented by Jim Leamon, Director, Jazz Pharmaceuticals, he will focus on:

- •How can pharma companies work with notified bodies on endpoint expectations for MDR and IVDR compliance
- •Defining the medical device product: what do I have?
- •Medical device life cycle management
- •The impact of implementing the new IVDR and combination product regulations and discussion of their strategies for expanding the QMS to meet manufacturer requirements

EU Regulatory Update: Software as a Medical Device presented by Sandra Beltran Rodil, Associate Director, Teva Pharmaceutical, this will cover:

- •Exploring the regulatory landscape for software as a medical device under the MDR (classification)
- Engaging with a notified body
- ·Looking at the lifecycle management of software as medical device

To find out more about the expert speakers joining the Medical Devices & IVD Conference, please visit: <a href="http://www.medicaldevices-ivd.com/PR2EIN">http://www.medicaldevices-ivd.com/PR2EIN</a>

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