The new EU Medical Device & IVD Regulations: Implementation Insights Workshop

5 February 2019

Delivered by Psephos Biomedica
In Partnership with Medilink WM

Why attend?

The new EU Medical Device Regulation (MDR) is in its implementation phase and will be effective from May 2020. All medical devices will need to comply with this new legislation. Similarly, the IVD Regulation (IVDR) will be in force from May 2022. Many companies are not yet ready for the journey let alone have a roadmap of how to get to compliance.

This one-day event will:-

- Provide you with an overview of the key areas likely to need upgrading to comply with the MDR/IVDR
- Assist you in assessing your company's current preparedness for the transition
- Give you a clear, practical guide to the next steps that you and your company need to take to gain CE Marking under the MDR/IVDR

Outcomes:

- Gain an overview of the new EU Medical Device and IVD Regulations
- Understand the key areas of compliance required
- Understand the technical documentation that should be in place for each device
- Gain a plan of action for implementation and CE Marking under the new legislation

MEET THE TRAINERS

Mr Robin Stephens

Mr Robin Stephens is the CEO of Psephos Biomedica. He holds a degree in Applied Chemistry from Northumbria University and a Masters in Applied Theology from University of Wales, Bangor. He has 30 years of experience in regulatory and clinical affairs in the medical device and related fields. He holds membership of the Regulatory Affairs Professionals Society (RAPS) and The Organisation for Professionals in Regulatory Affairs (TOPRA), as well as the Royal Society of Chemistry (RSC) of Great Britain. He is a Board member of several medical device companies as well as a national director for the International Christian Chamber of Commerce.

Mr Jacques du Preez

Mr Jacques du Preez is the Managing Director for Mosaic Surgical. He holds an MBA from London Business School and is a Chartered Accountant. He has several years experience in medical device manufacturing and market access as well as a deep knowledge of medical device regulatory, clinical and quality management systems requirements.

Contact Vanessa Bailey, Events Co-ordinator
on 0121 452 5630 or email VanessaB@MedilinkWM.co.uk

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Agenda

Time	Programme
10.00 -10.15	**Registration & Refreshments**
10.15-10.25	Welcome and Introductions
10.25-11.05	MDR/IVDR Overview
11.05-11.50	Technical Documentation
11.50-12.05	BREXIT Update
12.05-12.20	Key Messages from the Morning
12.20-13.00	**Networking Lunch**
13.00-13.40	Post-Market Activities (inc PSUR)
13.40-14.10	Labelling, EUDAMED and UDI
14.10-14.30	**Refreshment Break**
14.30-15.10	Clinical Evidence
15.10-16.00	Roundtable Discussion on Implementation Strategies and BREXIT
16.00-16.15	**Final Q&A and event close**

Target Companies:

Medical Device & IVD companies as well as those Pharma companies with combination products

Target Market:

C-suite, executives, product owners, medical officers, regulatory and clinical specialists within a company that need to understand the overall requirements of the new Medical Device Regulation and IVD Regulation for their medical devices to enable them to place a device on the market and to maintain access after May 2020. All company sizes will find it useful, but particularly helpful for smaller, resource constrained organisations.

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