Concept Development & Quality Management Systems

7 March 2019

Delivered by Psephos Biomedica
In Partnership with Medilink WM

This one-day event will:-

- Provide you with an overview of the requirements for the concept design phase of a medical device
- Assist you in assessing your company's current readiness for implementing a Quality Management System
- Give you a clear, practical guide to the next steps that you and your company need to take the move through to the next design phase

Outcomes:

- Understand the key areas of concept development and what is required
- Gain an overview of the regulatory and quality management system requirements for a concept medical device
- Understand the technical documentation that should be in place for this stage of device development
- Explore early stage risk management and next steps planning

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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Time	Programme
10.00 -10.15	**Registration & Refreshments**
10.15-10.25	Welcome and Introductions
10.25-11.05	**Concept:** • Invention & Innovation • Review & Planning • Structuring the Project & Team • Developing to Design Concept
11.05-11.50	**Regulatory Strategy:** • EU & FDA Overview • Developing the Strategy • Implementing the Strategy
11.50-12.00	Key Messages from the Morning
12.00-12.40	**Networking Lunch**
12.40-13.20	**Developing & Implementing a Quality Management System (ISO13485) in a Growth Environment:** • Overview of the Quality Management System concept • Timing for Development of the Quality Management System • How to Operate a Quality Management System
13.20-13.50	**Risk Management:** • Basic Concepts and Introduction to ISO14971 • Hazard/Initial Risk Assessment • Design Inputs and Verification Testing
13.50-14.10	**Refreshment Break**
14.10-15.00	**Technical Documentation:** • Safety & Performance Requirements • Standards & Guidelines • Change Control
15.00-15.50	Roundtable Discussion on Implementation Strategies, including a Q&A session
15.50-16.00	**Final Questions & Event close**

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