MEDILINK

PROFESSIONAL DEVELOPMENT

MPD: RISK MANAGEMENT

Thursday 7 September 2017 **MEDILINKWM, Birmingham, B15 3BE**
9:00-17:00

COURSE OVERVIEW

In this one day training session we will start by exploring the ISO14971 standard, so we fully understand the basis of risk Management. From here we will examine different methods of risk assessment and application of the techniques in practical design and manufacturing situations.

Delegates will have the opportunity to review and discuss their own issues and explore solutions with other delegates.

Delegates will find that these methods are fundamental to systems designed to meet the new MDR and IVD R regulations and will also be the basis of successfully meeting the requirements for a "risk based approach" which satisfies the requirements of ISO13485:2016

LEARNING OUTCOMES

- The requirements of ISO14971:2012
- What documentation will be required
- The process required to identify hazards, for both medical and in vitro diagnostics medical devices
- How to estimate and evaluate risks
- The methodology in design and product management
- What considerations should be taken when running the process
- How this vital management information should be used, along with other critical elements

AcclaimBiomedical Consulting Ltd

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COURSE PROGRAMME

TIME	EVENT
09.30am	Registration & Refreshments
10.00am	Overview, Why Risk Management?
10.10am	What is Risk Management all about
10.40am	Why Manage Risks in Medical Devices
10.55am	How do we Process Information
11.10am	Refreshment Break
11.20am	Processing Information Continued
11.40am	Human Error and the Performance Continuum
12.10pm	Lunch & Networking
12.50pm	Risk Assessment and the Standards
13.50pm	ISO14971
14.30pm	The FDA and Risk Management
14.40pm	Risk Assessment Techniques
14.50pm	Risk Benefit Analysis
15.30pm	Refreshment Break
15.45pm	Workshop Session: Reviewing Risk Benefit and Risk Management Reports
16.40pm	An Overview of the Day - Q&A session
17.00pm	Event Close

MEET THE TRAINER

Richard Young, Managing Director, Acclaim Biomedical Consulting Ltd

Richards' core skills can be broadly divided into 4 main areas Regulatory Affairs, GMP (Quality Assurance), GLP (Laboratory Testing) and GCP (Clinical).

These core skill areas have been developed over 2 decades of experience with products ranging from class 3 devices such as Orthopaedic implants (IIb) neurological robots, through electromedical devices such as infusion systems and cardio vascular products.

Richard brings a blend of pragmatism and experience to these disciplines that facilitates insightful problem solving approaches as well as solid solutions.

Richard's skills and experience includes such areas as the development and implementation of effective quality management systems, auditing to ISO and FDA QSIT standards, and operating at national and international level through industry associations including Eucomed, ABHI and ABHI Technical Policy Group.

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