

Risk Management concepts and tools to meet the requirements within ISO 13485:2016

Date: 11th October 2017

Time: 08.30 registration tea coffee. Start 9am to 5pm. Lunch 12.30-13.15

Venue: Radisson Blu, Galway.

Cost: Irish Medtech Skillnet Members €180 pp. Non Member €240 pp

Introduction

The Irish Medtech Skillnet in collaboration with Meddev Solutions Limited is delighted to offer a one day in-depth overview of risk management concepts used throughout a Quality Management System (QMS). It focuses on the application of various risk management tools to meet the requirements within ISO 13485:2016.

The course is designed to enhance the level of understanding for those actively utilising and engaging with ISO1348:2016 and ISO14971:2012.

Background

ISO 13485:2016 has been revised to include a greater focus on risk management impacting both on the CE and QMS requirements. The course will examine each of these elements:

Overall view of ISO 14971:2012 requirements with special reference to the Z-Annexes

EN 62304: Software

EN 62366: Usability

60601: electrical safety

10993: Biocompatibility

Infrastructure and work environment

Product realisation

Design

Suppliers

Production

Virtual manufacturing

Product recall and traceability

ISO 13485:2016 introduces the imperative for medical device manufacturers to implement a QMS that has a greater emphasis on risk throughout product realisation and process. This course for medical device manufacturers has been developed to meet this more rigorous focus on risk management.

Overview of Course Structure

This course is interactive and will use accelerated learning techniques and uses exercises to consolidate understanding. Breakout exercises will be used throughout the day to reinforce the concepts and give attendees experience in applying risk management. Candidates will be actively engaged with emphasis on questions and group discussions to further assist their understanding.

Target Audience:

Quality assurance professionals, quality engineers, manufacturing engineers, Research and Design Engineers, regulatory professionals, and Internal Auditors. The content will have great value to individuals who are involved in any aspect of implementing or maintaining a QMS.

Program Objectives: Upon completion of the course, participants will further enhance their understanding of risk management, utilise the tools for effective risk management, and the risk requirements of ISO 13485:2016.

Richard Tully – Medical Device Consultant at Meddev Solutions Limited

Over 30 years as an Electrical Engineer, beginning in heavy electrical and electronics and moving to silicon design.

Working in the industry since 1986 covering metal, plastics, electrical, electronic, pneumatic systems, medical devices in a number of management and product specialist roles.

Specialist in QMS, including QA / RA, CAPA, Complaints, Vigilance, Medical Device directive, Risk Management

With an Engineering background, member of working group for anaesthesia with a MSc Micro-Electronic Systems Design, Brunel University. Went on to begin Doctorate specialising VLSI maths using the Chinese remainder theorem. Lives in United Kingdom. Now a member of Meddev Solutions, a medical device consultancy company.

The last 13 years having been spent in different areas of the medical device industry.

Previously spent six and a half years at a Notified Body as a technical expert in the active devices group, reviewing approving Technical Files, Essential Requirements, Product, Process Risk Management, further specialising as the ISO 13485 technical lead for EMEA, guiding numerous Clients through ISO13485 and CE Applications. Lead Auditor Qualified by Notified Body.

Software Expert in IEC62304, 62366

Tutor Qualified in the delivery for Medical Device related training, MDD, MDR, Risk 14971, Clinical. ISO13485

Ivan Whelan – Quality & Regulatory Consultant Meddev Solutions Limited

Working in the industry since 1997 covering plastics, pharmaceutical, biotechnology, clinical microbiology and medical devices in a number of Quality management and product specialist roles. With a Microbiologist background BSc(Hons) Applied Biosciences from University of Ulster, member of Institute of Biology Ireland with a Post Graduate from Queen's University Belfast in Management and Communications.

Previous Head of 13485 Assessment Delivery for a Notified Body responsible for the Client Manager Assessor Team in EMEA. Lead Auditor Qualified

Now as part of his remit with Meddev Solutions Limited provides expert opinion on remediation activities, implementation and training to ISO standards for Medical Devices including Lead Auditor, Risk, MDD, MDR, Clause by Clause.