

Medical Device Single Audit Programme (MDSAP)

Date: 14th Nov to 16th Nov 2017

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

Venue: The Connacht Hotel, Dublin Road, Renmore, Galway City.

Cost: Irish Medtech Skillnet Members €430 pp. Non Member €570 pp

Introduction

The Irish Medtech Skillnet in collaboration with Meddev Solutions Limited is delighted to offer a 3 day in-depth interactive training course on Medical Device Single Audit Programme for Medical Device Clients selling into multiple jurisdictions and specifically into Canada where deadline is fast approaching.

The course is designed to enhance the level of requirements and understanding for those actively both developing and engaging in a MDSAP 13485 Programme.

Description:



The MDSAP is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the program.

Format:

This course will be highly interactive and will use accelerated learning techniques and therefore use exercises to consolidate learning

Course Overview:

What is MDSAP

How MDSAP Works

How Does MDSAP fit with other Certifications

How an MDSAP Audit Differs

Interactive Session on completing and participating in a Mock MDSAP Audit

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: Aim to aid Develop, manage, and oversee a single audit program that will allow a single **regulatory audit** to satisfy the needs of multiple regulatory jurisdictions to promote greater alignment of regulatory approaches and technical requirements To promote consistency, predictability, and transparency of regulatory programs, it does NOT stop the regulators from still auditing the QMS

Phil Parten – Medical Device Consultant at Meddev Solutions Limited

Background: Over 40 Years Engineering background in Aerospace and Medical Device, Industry Knowledge Management systems Experience in Medical Devices.

Moved to medical devices as quality engineer. Here involved in setting and meeting the validation requirements to meet MDD Annex II requirements for Class IIb active device. This included the preparation for submission to the FDA for Class III approval.

Designed packaging testing and validation process to ensure product remained fit for purpose during transportation as part of CFR Pt 4 requirements

Authorised to inspect and conclude if product could be sold under concession post full detailed report involving risk management reviews.

Wrote procedures and work instructions to meet the requirements of the ISO standards and Regulations that applied to our products which included MDD, CFR, CMDR and Australian regulations.

As part of role in Notified Body assessed many primary sterile packaging companies and reviewed the validation and verification methods used and protocols.

As a MDSAP Auditor completed regulatory audits on behalf of the FDA and other jurisdictions including Canada, Brazil, Australia, Japan.

Lead Auditor Qualified by Notified Body.

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