Quality System Regulations for Medical Devices

Learn how to meet the FDA's requirements for selling medical devices in the USA on this Quality System Regulations for Medical Devices training course.

This practical 1-day course examines the demands of the FDA's Quality System Regulations (QSR) and related product safety requirements with a view to the design and delivery of compliant products.

Interactive workshops and discussions will allow your team to consider together how they may successfully implement methods and ideas learned on this course.

COURSE DURATION
1 day

CPD
Equivalent to 7 hours

COURSE PRICE
TBC

IN-COMPANY TRAINING
Check availability

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

This course will be helpful to anyone involved in the development and sales of medical devices to markets where the FDA's Quality Systems Regulations are applied. This includes:

- executives and senior management
- R&D managers/engineers and members of design review teams
- RA/QA managers and management representatives
- members of multi-discipline design teams
- sales and marketing, production, shipping, MIS, purchasing

Key topics

Topics covered on the course include:

- FDA requirements and how they might affect an organisation
- implementing the requirements effectively so as not to affect other regulatory requirements
- locating key pieces of information within the appropriate documents (DHF, DMR and DHR)
- review of related standards such as risk analysis and the applicable guidance documents
- the relationship between QSR and the Medical Devices Regulation/In Vitro Diagnostic Medical Regulation (MDR/IVDR) and ISO13485/ISO9001 standards requirements
- regulatory requirements for reporting incident/near incidents (MDR)
- addressing 21 CFR Part 11 Electronic Signature and Records
- adding value to an organisation's management system
- preparing for an FDA Quality System Inspection Technique (QSIT) type audit
- sources of information and further development

Skills gained

By the end of this training course, delegates will be able to:

- interpret the requirements of QSR and its relationship with MDR/IVDR and ISO 13485/ ISO 9001 requirements
- identify the methods for successful implementation of the regulations
- prepare for an FDA QSIT-type audit and add value to an organisation's management system


Bywater

CERTIFICATE
of Completion

Jennifer Smith

has attended the Bywater

QUALITY SYSTEM REGULATIONS FOR MEDICAL DEVICES TRAINING COURSE

and has completed all elements of the course

Completion Date
01/01/2020

CPD Hours
7

David Cole | Director

SAMPLE

Delegates will also be awarded with a certificate of completion in recognition of their new knowledge and skills in QSR for medical devices.

Course agenda >

Course agenda

Our training courses are designed to optimise the learning experience for delegates both in face-to-face settings and in our Virtual Classroom.

Under the guidance of our expert tutors, attendees will follow an agenda which is briefly outlined below:

- Welcome and Introductions
- Module 1 Overview of Medical Device Regulation in the EU
- Module 2 The USA's FDA Approach
- Module 3 Workshop 1: The Company Design Processes
- Module 4 Comparisons – FDA/ISO/MDD
- Module 5 The Requirements of QSR
- Module 6 FDA Inspections and QSIT Audits
- Module 7 QSR Design Controls
- Module 8 Workshop 2: Using QSIT
- Module 9 Device Classification
- Module 10 Pre-Market: PMA and PMN 510 (k)

In-company training

Receive this course exclusively for your organisation, either in-person at your chosen venue or online in our user-friendly Virtual Classroom.

Enjoy cost-effective flexibility and personalised learning with tailored messaging designed to address your unique business challenges.
Contact us for a quote.

Thorough explanation of all modules involved whilst keeping it engaging through the use of discussion and workshops.

Endomagnetics Ltd

The tutor made the content of the course interesting and engaging - the breakout room exercises were relevant and supported the information which had been presented.

UK Health Security Agency (UKHSA)

Very good course, information was communicated very clearly and was very time effective. The tutor was very knowledgeable.

Natrox Wound Care

Read our Medical Devices course reviews

Why train with Bywater?

Bywater is the leading independent provider of professional management systems training in the UK.

Our expert training offers practical understanding of how to realise the benefits and assess the success of implementing and operating successful management systems.

Bywater delegates know they can rely on proven training delivered by experts at times and locations to suit their needs.

40 years established

100+ course titles

15 UK locations

1000+ courses annually

Global Virtual Classroom

CQI & IRCA, ISEP, RSS and IOSH approved training provider.

CHECK AVAILABILITY

Booking is easy

Simply select a course date and venue and fill in the online form. View our full range of courses at **www.bywater.co.uk**

If you have any questions please call us on 0333 123 9001, use our online chat or email **contact@bywater.co.uk**

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