Qserve®

.....the practical approach

Training Program for **European Market Access**

Europe - Amsterdam (HQ) | **USA -** Boston - San Francisco | **China -** Nanjing

Contents

Introduction

Qserve offers medical device manufacturers training on all regulatory levels. As a leading medical device consultancy group with offices in Europe, the United States and China, we offer years of international experience, with both broad and specific expertise for a wide range of medical devices.

Our practical approach makes our training a perfect fit for all companies that are looking for in-house training to changing worldwide regulations or to improve RA/QA/CA knowledge.

1 Introduction to ISO 13485

Learn about the scope and use of ISO 13485 as a basis of Medical Device Regulations worldwide. After just 1 day you will be able to interpret the clauses of ISO 13485 and recognize the role and responsibilities of management.

Duration: 1 day
Interesting for: Senior Management, Quality Managers, RA/QA Managers and staff, Internal and External Auditors

2 Introduction to the NEW ISO 13485

Just released and still fresh and shiny, are you ready for the NEW ISO 13485:2016? Learn about the scope and use of the NEW ISO 13485:2016 and after just 1 day you are able to interpret the clauses of the NEW ISO 13485 and recognize the role and responsibilities of management.

Duration: 1 day
Interesting for: Senior Management, Quality Managers, RA/QA Managers & staff, Internal and External Auditors

3 ISO 13485 Conversion

What is the difference between the existing ISO 13485 and the just released 2016 version? During one full day you will learn about the differences and how this will impact your existing processes and requirements. A first step towards transition.

Duration: 1 day
Interesting for: Senior Management, RA/QA Managers and staff, Internal and External Auditors

4 Risk Management for Medical Devices ISO 14971

Learn about the basic concepts of Risk Management and how to explain the Risk Management Process in relation to the Product Lifecycle. Practice with the stages in the Risk Management Process, practice with Risk Management tools on a Medical Device.

Duration: 1 day
Interesting for: Senior Management, RA/QA Managers & staff, Product Managers & Developers, Risk Managers.

5 Internal Auditor ISO 13485

From an internal auditor perspective, you will learn about the scope, use and clauses of ISO 13485. Get to know the basics of auditing, the different types of auditing, the techniques for interviewing and assessing processes and how to prepare and perform an internal audit including the communication of the results in a report.

Duration: 2 days
Interesting for: Internal and External Auditors, Quality Managers and Regulatory Affairs Managers

6 Introduction to the European Medical Device Directives (MDD)

Get to know the basics about the MDD in the current legal framework in Europe. You will learn about the structure and purpose of the Medical Device Directives and practice the use of the Essential Requirements and standards. Identify the different conformity assessment routes and know more about the role of Risk Management and Clinical Evaluation.

Duration: 1 day
Interesting for: Senior Management, Regulatory and Quality Managers, Design, Development, Manufacturing and Marketing Managers, Internal and External Auditors

7 Introduction to the NEW European Medical Device Regulation (MDR)

Be sure to know the basics of the upcoming Regulations if you want to (continue to) market products on the European market. You will learn about the structure and purpose of the NEW MDR including scope and classification changes, the new Essential Principals, identify the revised conformity assessment routes and hear about the increased importance of Risk Management, Clinical Data & Evaluation and Post Market Surveillance.

Duration: 1 day
Interesting for: Senior Management, Regulatory Affairs Managers, Quality Managers, Design, Development, Manufacturing and Marketing Managers, Internal and External Auditors

8 Fundaments of the European Medical Device Directives (MDD)

You need to know more than the basics? Take the 2-day course and build some fundaments when it comes to the Medical Device Directives. Listen first and then apply your knowledge using some practical cases. Essential Requirements, standards, conformity assessment routes, Technical Documentation requirements, Risk Management and Clinical Evaluation.

Duration: 2 days
Interesting for: Senior Management, RA/QA Managers, Design, Development, Manufacturing and Marketing Managers, Internal and External Auditors

9 Fundaments of the NEW European Medical Device Regulation (MDR)

You need to know more than the basics of the NEW MDR? Take the 2-day course as there are a lot of changes! Build a solid foundation to ensure compliance. Your fresh knowledge can be used directly during practical cases, based on your company's situation. Essential Principles, Technical Documentation requirements, Risk Management, Clinical Evaluation and Post Market Surveillance.

Duration: 2 days
Interesting for: Senior Management, Regulatory and Quality Managers, Design, Development, Manufacturing and Marketing Managers, Internal and External Auditors

Practical Regulatory, Quality and Clinical training in small groups

10 MDD to MDR Conversion

The impact will be huge and you need to be ready to ensure continued compliance, especially if you are involved in manufacturing high risk medical devices. Qserve's knowledge about European regulation is top level, together with our practical approach this will give you the basis for a transition plan towards continued compliance. Do not miss this training!

Duration: 1-2 days
Interesting: Senior Management, Regulatory Affairs Managers, Quality Managers, Design, Development, Manufacturing and Marketing Managers, Internal and External Auditors

11 How to construct a Technical File for worldwide use (STED model)

Learn in only 1 day how to define the Regulatory requirements for Technical Documentation, structure the documentary evidence according to the STED Guidance, define key subjects as part of Technical Documentation and prevent serious shortcomings in parts of the Technical Documentation of a Medical Device. May be adjusted to the new IMDRF ToC format if so desired.

Duration: 1 day
Interesting for: QA/RA Managers, Design and Development Specialists, anyone involved with Product Development, Sales and Marketing

12 Clinical Evaluation based on ISO 14155 & MEDDEV 2.7.1

Learn the basics of Clinical Evaluation, such as how to explain the requirements, outline a Clinical Strategy, plan and document the results of a Literature Investigation, understand the requirements for a Clinical Trail, define procedures and understand the rules and approach for Post Market Clinical Follow Up.

Duration: 1 day
Interesting for: Clinical Specialists, Product Development & Product Managers, QA/RA Managers, anyone involved in Clinical Evaluation

Qserve's Training Format

All our training is based on the in-company concept with small groups to keep it interactive and practical. Training material will be provided on a USB. Interested in receiving an official Certificate of Attendance? No problem, this is available for a small fee.

This is only a part of our training selection, more training subjects like software, IEC standards, QSR or FDA training can be found on our website. Please have a look for yourself.

If you are interested in more information, please send your request to: sales@qservegroup.com

Invest in knowledge, train your staff!

Global Medical Device Regulatory Compliance Consultants

Clinical Evaluation

Regulatory Compliance

Global Registration

Training

Quality Assurance

Auditing

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