TRAINING & SOLUTIONS GUIDE

2020 - 2021

MEDDEV SOLUTIONS

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Welcome to the Meddev Solutions Training Guide for 2020 - 2021.

Meddev Solutions are a team of experienced QA/RA professionals, working in the medical device industry for both manufacturers and notified bodies.

Each team member has at least 20 years' experience in the industry and have worked on a wide range of products from all classes, including implantable, active, software and combination devices.

We routinely train and provide consultancy services to the top medical device manufacturers around the globe and have authored the highly rated 'Guidebook Series' to assist manufacturers in complying with the EU MDR and IVDR.

Our team has been widely recognised and voted the 'Best-In-Class' Medical Device Regulatory Consultancy company of 2020 by MedTech Outlook magazine.

Due to our experience training both notified bodies and competent authorities, we can ensure our solutions work first time, every time.

2017
Founded In

65+
Years Of Experience

100+
Clients

5,000+
Attendees Trained

Contents

What we offer

In-House Training Courses
If you have a number of staff who require training, in-house training may be the best solution for you. In-house training eliminates travel expenses and time spent away from the office whilst keeping your content and discussions completely confidential.

Public Training Courses
We offer our most popular training courses as public courses across the UK and Ireland. Each course takes place in a relaxed and collaborative environment away from office distractions and allows for networking with people from other organisations. Locate your nearest course on our website.

Bespoke Training Courses
We find a lot of our clients prefer a bespoke combination of our courses because it delivers the most value for them. Bespoke courses are customised to meet your exact needs and can be delivered in-house or virtually using our online classroom software at a time convenient for you.

Virtual Training Courses
Virtual courses are an excellent alternative to traditional classroom training. Theses courses bring you, our expert tutors and fellow delegates together on a web based classroom where you can fully engage in group activities, ask questions and share materials as if you were in a real classroom. Virtual courses can also be run privately just for your company.

eLearning Courses
We have partnered with leading online training provider, Comply Guru, to offer certified EU MDR training courses that can be completed at your own pace on desktop, mobile or tablet from anywhere in the world. Enrol on your next course today on our website.

Medical Device Regulation (EU MDR) 2017/745

If you already sell medical devices into Europe, you probably already know that CE marking is changing. But do you fully understand what the impact is for your business, products and your supply chain?

If you are not 100% sure or would like to refresh your knowledge, this 2 day course is most definitely for you.

Created by industry leading experts, this course has been designed to help medical device manufacturers understand the additional requirements of the standard, so you know what you need to do for your business and products to meet the new MDR.

Our expert trainers will take you through the MDR, not just from an industry perspective, but also from a Notified Body perspective, so you understand what both sides are looking for.

"Fantastic to have an instructor with subject knowledge that was able to relate to the experience of participants. Presented and delivered at a good pace to allow understanding and ample opportunity for specific questions."

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

Find out more:
info@meddevsolutions.co.uk
www.meddevsolutions.co.uk/training

Course Content

- Introduction to the EU MDR
- Medical Devices covered by the EU MDR
- Placing a device on the market
- Device Classification
- Unique Device Identifiers (UDI)
- Routes to Conformity
- Clinical Data Evaluation
- Technical File documentation
- GSPR & Risk Management
- Post Market Surveillance & Vigilance

Who should attend?

This EU MDR training course has great value for anyone involved in implementing or maintaining a QMS.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Available as
In-House • Public • Virtual • eLearning

Bespoke
Our experts can customise this course purely for your business needs.

In Vitro Diagnostic Regulation (EU) 2017/746

The IVDR will replace the current EU Directive on in vitro diagnostic medical devices (98/79/EC) and will be effective in all EU member and EFTA states.

This 2 day training course focuses on the application of the key principles and practices required for the new In Vitro Diagnostic Medical Devices Regulation.

You will gain an appreciation for the changes and new requirements of the IVDR and take away practical skills and guidance on how to transition to the new regulation that you can implement into your organisation immediately.

"I have been attending Medical Device trainings for 20 years and I can truly say this was the best course I have ever taken.

The trainers are subject matter experts who were able to effectively communicate and explain core and technical concepts while keeping the audience engaged. The course materials are well designed with an abundance of examples and color coding for navigation ease. I highly recommend this course."

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

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www.meddevsolutions.co.uk/training

Course Content

- EUDAMED
- Routes to conformity
- Performance evaluation
- Risk analysis and trending
- Unique Device Identifier (UDI)
- Safety and performance requirements
- Classification and recognition of devices
- Post-market surveillance
- Requirements for manufacturers and economic operators

Who should attend?

This course will enhance the level of understanding for those actively engaged with IVDs and placing them on the market.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Available as
In-House • Public • Virtual

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Clinical Evaluation for Medical Devices

If you are actively involved with the creation and maintenance of clinical evaluation files, this 2 day course will enhance your level of understanding on the application of key methods to ensure that the requirements of the new MDR are met.

Our expert tutors will give you the necessary skills to ensure all the requirements of the law are met and provide an insight into how the clinical evaluation is integrated with risk management, post-market surveillance, the periodic safety update report, the summary of safety and clinical performance, trending and the CAPA system.

We perform clinical data evaluation reviews for notified bodies and can offer you insights into the common pitfalls. Plus you will get an understanding of what the requirements are really asking for.

"The CER course was great in confirming my current knowledge of Clinical Evaluation and expanding on this with the requirements for MDR. Rod was a great tutor full of knowledge, advice and enthusiasm for a subject which can be pretty dry!"

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

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www.meddevsolutions.co.uk/training

Course Content

- PMCF
- Planning
- Data analysis
- Data appraisal
- Data identification
- Regulation intentions
- Clinical investigations
- Post-Market Surveillance
- Practical use of MEDDEV 2.7.1 rev4
- Methods of real-world literature review

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining clinical evaluation files.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

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Medical Device Single Audit Program (MDSAP)

MDSAP is intended to allow MDSAP recognised Auditing Organisations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulator authorities participating in the program.

This 1.5-day in-depth training course on the Medical Device Single Audit Program (MDSAP) has been created for Medical Device Clients selling into multiple jurisdictions and specifically into Canada.

This is not just a simple read and understand course, this is a practical 'how to' guide course which you can actually use immediately to get you through the MDSAP audit process.

"A very well organised course and trainer was very knowledgeable."

" An exceptionally well presented course - very useful and perfectly paced."

Course Content

- What is the Medical Device Single Audit Program (MDSAP)
- How the MDSAP works
- Preparation
- How the MDSAP fits with other certifications
- The process
- How an MDSAP audit differs
- Interactive session on completing and participating in a mock MDSAP audit

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining a QMS.

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Risk Management (ISO 14971:2019)

This 2 day ISO 14971:2019 Risk Management course focuses on the application of various risk management tools to meet the requirements of the harmonised standard ISO 14971:2019.

ISO 13485:2016 requires medical device manufactures to implement a Quality Management System (QMS) that has a greater emphasis on risk.

This course for medical device manufactures has been developed to meet this more rigorous focus on risk management.

Our expert tutors will provide you with an in-depth understanding of ISO 14971:2019 and compare ISO 14971:2019 with the requirements of the EU Medical Device Regulation (MDR) 2017/745.

"Highly recommend this course to those in the medical device industry! Rod was competent in all aspects of the course, I now have a clear understanding of risk management application!"

Course Content

- Introduction to ISO 14971:2019
- Regulation and the Z-Annexes
- The procedure and plan
- FMEAs and fault trees
- Application to ISO 13485

The relationship with other standards:

- The 60601/61010 series
- Usability (EN 62366)
- Biocompatibility (ISO 10993)

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining a QMS.

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- Internal Auditors
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- Manufacturing Engineers
- Regulatory professionals

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Internal Auditor (ISO 13485:2016)

Would you like to know what a Notified Body Auditor is looking for when they audit you against the 2016 versions of ISO 13485?

Well look no further. Our trainers trained the Notified Bodies.

Our two day internal auditor training course focuses on the application of key principles and practices in accordance with ISO 13485:2016 and 19011:2018 “Guidelines for auditing management systems”.

Our expert tutors will give you the necessary skills to perform internal audits on an organisation’s Quality Management System (QMS) to the requirements of ISO 13485:2016.

You will gain the necessary auditing skills through a balance of tutorials and group workshops.

"It's excellent to have a trainer who also consults in the field, it really shows through with all the real life examples."

"Excellent training, I really enjoyed the course!"

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

Find out more:
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www.meddevsolutions.co.uk/training

Course Content

- Practical use of ISO 13485:2016
- Auditing, the cycle and objectives
- Auditing skills and techniques
- Planning
- Selection of audit teams and training
- Evaluation of information and findings
- Opportunities for Improvements
- The significance of nonconformities
- Communicating and presenting reports
- Corrective actions
- Improvements

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining a QMS.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Available as
In-House • Public • Virtual

Bespoke
Our experts can customise this course purely for your business needs.

Overview of EU Medical Device Regulation (MDR 2017/745)

eLearning

This fully online and self-paced eLearning course is ideal for anyone working in the Medical Device Industry looking for a general overview of the EU Medical Device Regulation (MDR).

The certification that you will earn through the course assessments can be used to demonstrate your knowledge to your employers and Notified Bodies.

We have partnered with leading online training provider, Comply Guru, to give you the best training experience possible.

- ☑ Self-Paced
- ☑ 100% Online
- ☑ Tutor Support
- ☑ Accessible from any device 24/7
- ☑ Formal Assessment And Certification

"I thoroughly enjoyed the General Overview course. It is a well-structured course, the information is streamlined to provide a coherent overview. It was a great idea to include videos whereby some provisions of the MDR are explained via recording. I would highly recommend this course to those who are at the starting point of the MDR learning."

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

Enrol now:
info@meddevsolutions.co.uk
www.meddevsolutions.co.uk/elearning

Course Content

- History of MD Scandals
- Purpose of the EU MDR
- Structure of the EU MDR
- Definitions
- Key Changes
- Timelines for Transition
- Medical Devices coveredby the EU MDR
- Overview of Articles 10, 11, 13-15
- Overview of Articles 5, 19 & 20
- Roles
- Brief overview of Classification, Conformity assessment, EU declaration of conformity and CE Marking

Who should attend?

This course is not just for Regulatory Professionals and a suitable course for anyone wishing to gain a general overview of the EU MDR.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Quality Managers

Available as
2 hour eLearning course

Discounts
Discounts are available for 10+ persons

EU Medical Device Regulation In-Depth Foundation Course

eLearning

Our revolutionary Exemplar Global Certified EU MDR 2017/745 In-Depth Foundation Course will take you through the regulation, not just from an industry perspective, but also from a Notified Body perspective, which means you get the benefit of understanding what both sides are looking for.

This course focuses on the overview & application of the MDR– it isn't just a simple 'read and understand,' it is a practical 'how to' guide, which you can actually use immediately.

- ☑ Self-Paced
- ☑ 100% Online
- ☑ Tutor Support
- ☑ Accessible from any device 24/7
- ☑ Exemplar Global Certified
- ☑ Formal Assessment And Certification

"A very positive experience, the design of each program is on the money! The content is of a high standard and has the right match of clarity and detail. The delivery of the content is very smooth and professional. As a quality/regulatory professional with over 20 years experience and a MSc in Medical Technology Regulatory Affairs, I fully endorse Comply Guru/Meddev as a preferred supplier of Quality/Regulatory training."

Course Content

In this course, you will cover 9 units:

- Introduction to the EU MDR
- Medical devices covered by EU-MDR
- Placing a Device on the Market
- Device Classification
- Routes To Conformity
- GSPR & Risk Management
- Clinical Evaluation
- Technical Documentation
- Post Market Surveillance & Vigilance

For a full list of topics covered in each unit, please visit our website.

Who should attend?

This EU MDR training course has great value for anyone involved in implementing or maintaining a QMS.

- Quality Assurance professionals
- Quality Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Upon successful completion of the course you will receive an Exemplar Global certified certificate.

Enrol now:
info@meddevsolutions.co.uk
www.meddevsolutions.co.uk/elearning

Available as
20 hour eLearning course

Discounts
Discounts are available for 5+ persons

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