qtec
academy

Dear Ladies and Gentlemen

Thank you for your interest in the qtec Academy.

Training courses should be interesting and instructive, but they should also be fun and user-oriented. We would like to give you an insight into our training topics and have prepared a catalog with all important information for you.

Please contact me if you have any questions
Yours, Juliane Celik

Juliane Celik,
Contact person

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About qtec

80+ Experts for your needs

qtec Academy

Your partner for successful resource qualification

The medical technology industry is turning faster and faster, but the entire working world is also constantly adapting to new requirements.

The right further education and training is an important step to build up additional expertise and secure it in the long term.

But not every type of learner is the same. That's why the qtec Academy offers a wide variety of continuing education options to find the right format for you.

Details

Take advantage of our

- Presence seminars
- Online seminars
- In-house trainings
- Workshops
- E-Learnings
- Coachings

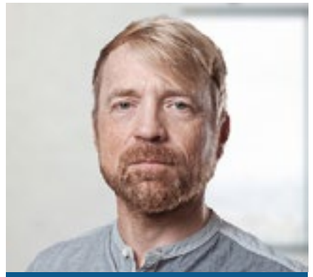
and learn how to safely develop, market, and distribute your medical devices.

qtec Academy speakers

Timo Bohnhoff
Senior QA / RA Manager

Juliane Celik
Manager of Excellence

Hyun-Woo Cho
QA / RA Manager

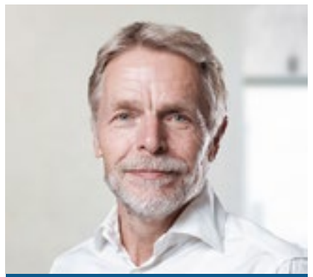


Dr. Lars Dahms
Senior QA / RA Manager

Dr. Normann Decker
Software Quality Manager

Dr. Alexandra Deters
Biologist

Sebastian Dittmar
QA / RA Manager



Dr. Hans-Achim Graf
CEO

Andreas Genßler
Senior QA / RA Manager

Delvyn Heinsch
Senior QA/RA Manager

Torsten Hertz
Senior Software QA Manager

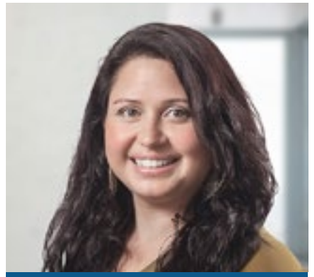
Diana Hohage
Senior QA / RA Manager

qtec Academy speakers

Prof. Dr. Michael Imhoff
Clinical director

Birte Kappertz
Senior RA / QA Manager

Dr. Kristin Mertins
Clinical Affairs Manager



Andreina Pietzka
RA / QA Manager

Dr. Klaus Pollmeier
Senior QA / RA Manager

Dr. Claudia Rampp
QA / RA Manager

Dr. Anja Rämisch
Toxicologist

Dr. Anna Schade
RA / QA Manager

Dr.-Ing. Tim Suthau
Agile Transition Coach

Dr. Franka Teuscher
Senior CA / RA Manager

Christian Wolf
Senior QA / RA Manager & Auditor

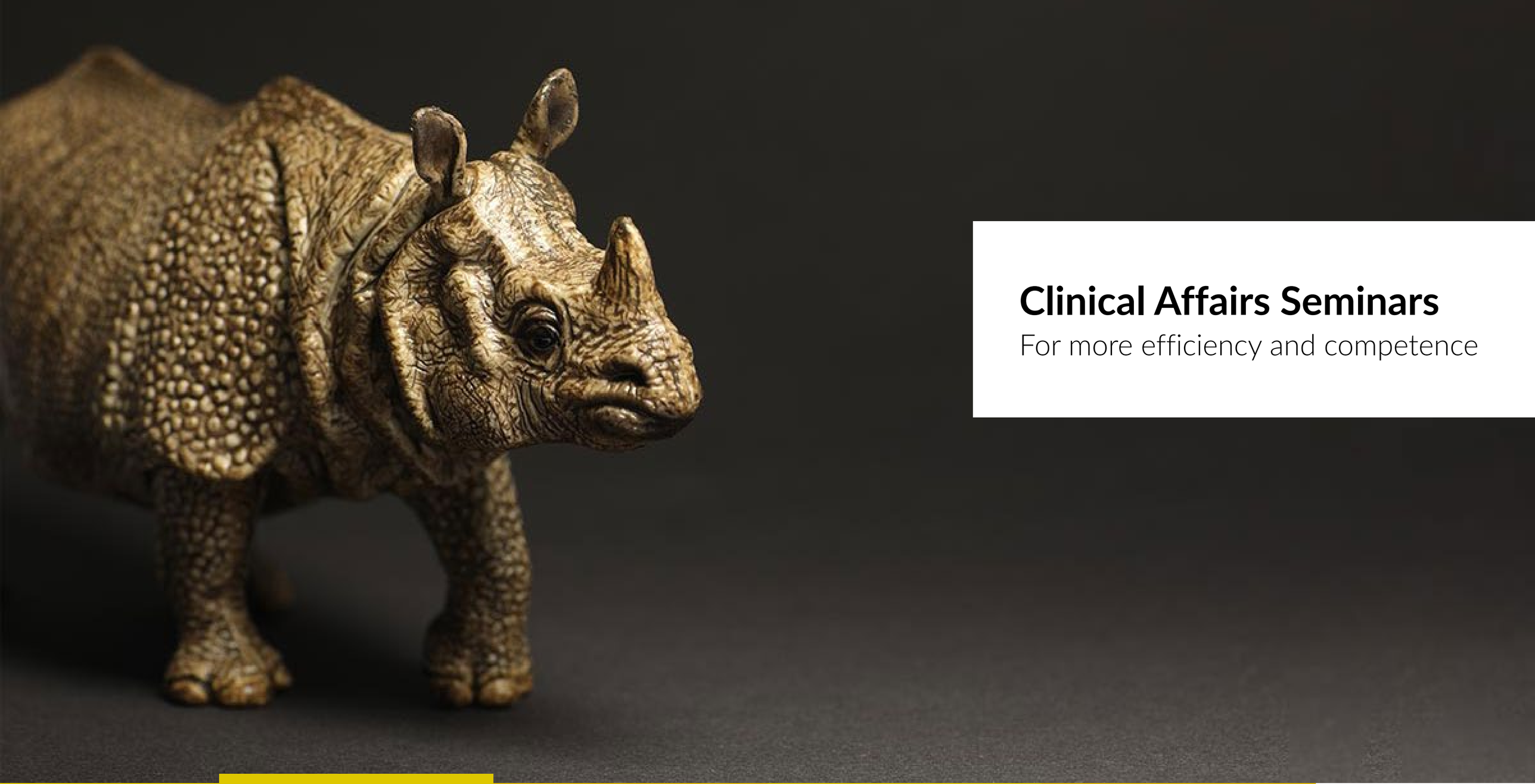
Our training catalog

Online seminar or in-house training

Do you know the following situation? A quality manager is looking for training for the QM department that covers several standards. She wants the team to be familiar with the different regulatory requirements in other areas in the future. She also wants the departments to develop a better understanding of what other departments are doing.

According to this brief, we develop a training package for you that is individually tailored to your needs. In doing so, we filter out the necessary content and put together a seminar that exactly matches your company's objectives. Finally, with this training we ensure that the team can further optimize the cooperation with the other departments.

Topics



Clinical Affairs Seminars

For more efficiency and competence

Clinical data for PMCF

Seminar | Clinical Affairs

One day basic course

August 23rd 2024 | 11:00 a.m. – 3:00 p.m., online

Avoid the typical stumbling blocks in the PMCF area!

A key component of post-market surveillance activities is proactive post-market clinical follow-up (PMCF) by the manufacturer. As a manufacturer, you need to ensure the safety and performance of your product throughout its lifetime. Both safety and performance are outlined in the Clinical Evaluation and continuously assessed through ongoing market surveillance.

In our online seminar, we will give you an insight into the various requirements for the PMCF.

You will get answers to important questions like:

- What is clinical data?
- What data do you always need (literature, PMS, studies, ...)?
- When are clinical trials required for PMCF?
- How are such PMCF studies organized and what are the advantages of each form of study?
- Does it make sense to be a study sponsor?
- Which typical mistakes should you urgently avoid?

Contents

- General requirements for the PMCF
- Clinical Data – Sources of Clinical Data
- Data from the literature for PMCF
- PMCF Studies
- PMCF Surveys
- Dos and Don'ts

Benefits

Two-day application course
June 19 – 20 2024 | 10:00 a.m. – 3:00 p.m. each, online
November 25 – 26 2024 | 10:00 a.m. – 3:00 p.m. each, online

Clinical Evaluation

Seminar | Clinical Affairs

How to meet all clinical evaluation requirements in the future

Is your clinical evaluation still up to date? Can you continue to use your equivalent devices? Clinical evaluations today must meet more requirements than ever before. MEDDEV 2.7/1 Rev 4 provides helpful guidance on the content and conduct of a clinical evaluation report, but the Medical Device Regulation in particular places many more stringent requirements on the use of clinical data.

Learn about the entire clinical evaluation process. Workshops on literature searches and a wealth of practical tips will help you to put the know-how you have learned to good use in your own company.

Benefits

Contents

- Regulatory requirements according to MDR, MDCG guidelines and the MEDDEV 2.7/1 Rev. 4
- Implementation of the requirements throughout the product life cycle
- Structure and organization of the clinical evaluation
- Interfaces to technical documentation
- Clinical and preclinical data
- Clinical evaluation report
- Literature search protocol
- Workshop: literature search
- Audit: how to avoid problems with the Notified Body

One day basic course

Contact us for an offer

Clinical Investigations

Seminar | Clinical Affairs

Clinical investigation of medical devices according to Regulation (EU) 2017/745

Clinical data are required as evidence of safety and performance of a medical device and represent a decisive factor throughout the life cycle of a product. With the entry into force of Regulation (EU) 2017/745 (Medical Device Regulation – MDR), these requirements have increased dramatically. Clinical investigations as the most important source of clinical data with high evidence will be increasingly necessary in the future for the CE marking of medical devices of class III as well as for implantable devices and new devices based on innovative technologies.

This training will give you an overview of the current regulatory status in Europe for the planning, application, conduct and completion of a clinical trial. The contents of the updated international standard ISO 14155:2020, which represents Good Clinical Practice regarding the clinical testing of medical devices on humans, are also discussed.

Contents

- Overview on clinical data for clinical evaluation and post-market clinical follow-up
- Types of clinical studies
- General requirements for clinical investigations
- Informed consent including special cases
- Application for authorization to the authority and the ethics committee
- Conduct of a clinical trial
- Substantial modification of a clinical trial
- Coordinated assessment procedure
- Recording and reporting of adverse events

Benefits

Introductory course
July 7th 2024 | 10:00 a.m. – 12:30 p.m., online
September 9th 2024 | 10:00 a.m. – 12:30 p.m., online

Benefits

Clinical Studies for Medical Devices

Seminar | Clinical Affairs

From surgical instrument to active implant

Clinical studies with medical devices can be conducted for a variety of reasons: To develop new applications, to demonstrate performance, safety and benefit in the approval process, for post-market surveillance or to gain scientific knowledge.

This interactive seminar introduces the most important study types and regulations. Practical examples will be used to explain how to choose the most appropriate study type, how to prepare study protocols as efficiently as possible while still being comprehensive, and which legal requirements need to be taken into account.

Contents

- Clinical studies and why they are so important
- Regulatory and legal requirements for studies
- Choosing the right type of study
- Preparation of study protocols
- Sample sizes
- Recommendations for the practical conduct of clinical studies

One day basic course

Contact us for an offer

Benefits

Literature Search - Workshop

Seminar | Clinical Affairs

How to succeed in literature research using Embase as an example

The requirements for clinical evaluations of medical devices have increased. Furthermore, the literature search for the CER (Clinical Evaluation Report) is an essential and important part.

If possible, two different sources (databases) should be used for these literature searches. Since MEDDEV 2.7/1 Revision 4, the inclusion of a literature database that better reflects the European area is explicitly required in addition to the most frequently used database MEDLINE. Embase is the recommended database here

In this workshop you will learn how to set up a literature search and receive practical tips and implementation strategies to optimize your literature search.

Contents

Post-Market Surveillance

Seminar | Clinical Affairs

Two-day application course

Contact us for an offer

How to implement a successful post-market surveillance process

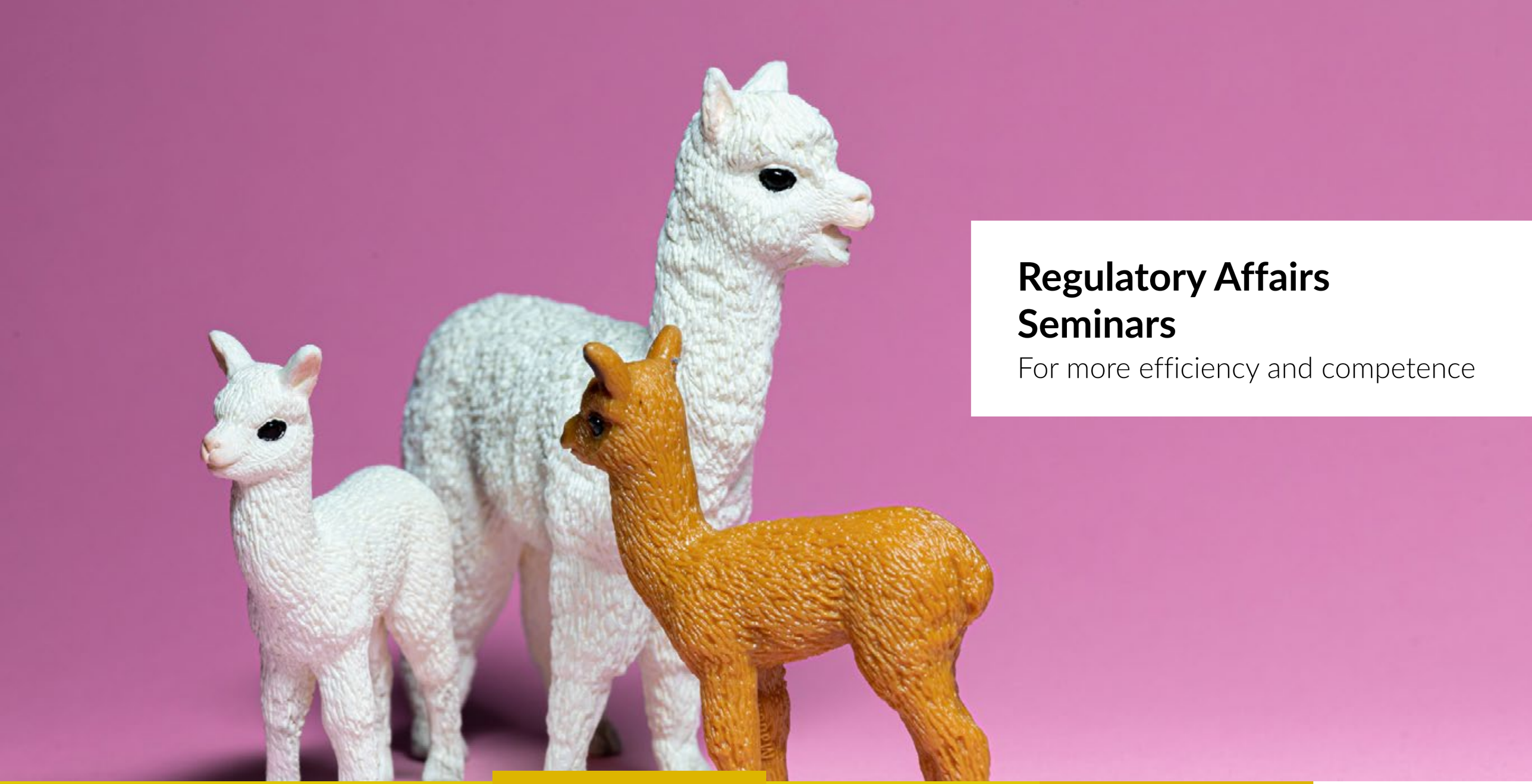
Regulation (EU) 2017/745 (MDR) requires a post-market surveillance (PMS) system. As a manufacturer, you must therefore systematically and actively collect information about the experience regarding your devices.

In this interactive seminar, you will learn how to demonstrate the safety and clinical effectiveness of your entire product life cycle.

Contents

- Regulatory basics
- Terms and definitions
- Successful implementation of a post-market surveillance system
  - Requirements of Regulation (EU) 2017/745 for the PMS
  - PMS plan
  - PMS report and PSUR
  - Vigilance
- Post-Market Clinical Follow-up
  - Post-market
  - Clinical follow-up
  - PMCF Study
  - Context PMS and PMCF
- Integration into technical documentation
- Interfaces with summary report on safety and clinical performance (SSCP)
- Involvement of Notified Bodies and Authorities

Benefits



Regulatory Affairs Seminars

For more efficiency and competence

"Drug-Device" Combinations

Seminar | Regulatory Affairs

One day basic course

Contact us for an offer

Requirements for medical device & medicinal product combinations

Medical device & medicinal product requirements
The term combination product does not officially exist in the EU. Products that are a combination of a medical device and a medicinal product are regulated as either a medical device or a medicinal product. With the implementation of the MDR, the requirements for these devices have become significantly more complex.

The authorisation process for devices containing an integral medicinal product, which fall within the scope of the MDR, has been revised. Process changes and documentation requirements now also affect manufacturers whose products contain a medical device component, such as packaging. The involvement of a Notified Body may suddenly become necessary. In this interactive training course you will learn how to best implement the increased requirements in your company. Best practice methods and workshops ensure optimal knowledge transfer.

Contents

- Legal basics
- Requirements for production and documentation during the development phase of drug-device combinations
- The consultation procedure
- Examples of the problem of demarkation
- Rules and requirements for products falling within the scope of the scope of Article 117 of the MDR and so-called "co-packed" combinations
- Notified bodies and regulatory surveillance

Benefits

Economic operator Manufacturer

Seminar | Regulatory Affairs

Two-day application course

Contact us for an offer

Tasks and obligations of medical device manufacturers under the MDR

Are you considering becoming a medical device manufacturer, but not sure what your responsibilities will be? Both before and after placing medical devices on the market, there are explicit requirements for the manufacturer, regulated by the Medical Device Regulation (EU) 2017/745 (MDR). This new regulation also introduces a number of new tasks and obligations for medical device manufacturers and other economic operators.

Therefore, a medical device manufacturer must first obtain sufficient clarity about the constellation in which they find themselves with other economic operators and the resulting responsibilities. In addition, a manufacturer must quickly address the regulatory requirements assigned to him before implementing them in his quality management system and in his medical devices.

In this course you will learn what you need to be aware of as a medical device manufacturer, what requirements you need to meet and what you need to consider with other economic operators such as "importers", "distributors" and "authorised representatives".

Contents

- What is a manufacturer?
- Difference between producer and legal manufacturer
- Tasks and duties of manufacturers
- Requirements for manufacturers before placing on the market a medical device
- Requirements for manufacturers after placing a medical device on the market
- Outsourcing of processes and related requirements for suppliers and subcontractors
- EUDAMED
- Requirements for a quality management system according to MDR and EN ISO 13485
- Person Responsible for Regulatory Compliance according to Article 15, MDR
- Other economic operators and their tasks
- Sanctions and liability

Benefits

Two-day application course

May 15 – 16 2024 | 09:00 a.m. – 3:00 p.m. each, online

Introduction into the requirements of the medical device industry

Seminar | Regulatory Affairs

Benefits

Better understanding of responsibilities and interfaces

Are you fresh out of university or are you entering the world of medical devices as a career changer, but don't yet know what tasks and duties await you?

You work in a specialist department (e.g. PMS) and perform your tasks conscientiously, but you don't know how other specialist departments are influenced by your work or what they do with the documents you create? Maybe there are conflicts between the departments from time to time?

Anyone working in the medical device industry should know and understand the big picture. Day-to-day work is based on the requirements of the Medical Device Regulation (EU) 2017/745 (MDR). This new regulation brings with it a whole range of tasks and obligations for medical device manufacturers and other economic actors. It is not only helpful to know the responsibilities and interfaces between the economic actors, but also between the specialist departments within an organization.

In this interactive seminar, you will learn about the various requirements and interfaces in medical technology and learn how to effectively implement the various requirements using hands-on examples.

Contents

- Legal framework
- Medical device submission
- General obligations of manufacturers
- MDR Article 10
- MDR Article 15
- Vigilance
- Other economic operators and registration obligations

One day basic course

Contact us for an offer

Benefits

In-vitro-diagnostica (IVDR)

Seminar | Regulatory Affairs

Its impact on market access for ivd manufacturers

Regulation (EU) 2017/746 (IVDR) imposes a number of new requirements on manufacturers: the scope has been extended, new classification rules have been introduced and higher demands have been placed on technical documentation.

We will show you how to put the IVDR requirements into practice and help you prepare for implementation. Learn how to reclassify your products and select the appropriate conformity assessment procedure.

Content:

- Introduction to the regulatory and normative requirements
- Entry into force, effective date, and transitional provisions
- Information, Harmonized standards, Common Specifications
- Obligations of economic operators
- Person responsible for regulatory compliance
- Requirements for suppliers and subcontractors
- European Database for Medical Devices (EUDAMED)
- Requirements for a quality management system according to IVDR and ISO 13485
- Technical documentation (Annex II, III)
- Quality assurance agreements and contract audits
- Sanctions and liability

Two-day application course

Contact us for an offer

Medical Device Regulation (MDR)

Seminar | Regulatory Affairs

Benefits

How to successfully access the European market

Any manufacturer of Class I to III medical devices must comply with the requirements of the Medical Device Regulation (EU) 2017/745 (MDR). For the first time, products that are not technically medical devices are now regulated by the Medical Device Regulation.

The European regulation brings significant changes depending on the organizational objectives. Profound changes occur in the areas of technical documentation, post-market surveillance (PMS) and through the introduction of the European database EUDAMED.

Contents

- Principles and content of the Medical Device Regulation (MDR)
- Validity of conformity assessment and certificates, transition periods
- Classification/reclassification of devices procedures
- Common specifications
- Non-medical devices under the scope of the MDR
- Requirements for the different economic operators
- Person responsible for compliance (PRRC)
- General Safety and Performance Requirements (GSPR)
- Technical documentation requirements
- Clinical evidence and post market surveillance
- Eudamed database
- UDI

Two-day application course

October 16 – 17 2024 | 09:00 a.m. – 3:00 p.m. each, online

Medical Device Single Audit Programm (MDSAP)

Seminars | Regulatory Affairs

How to successfully prepare for your MDSAP audit

MDSAP describes a uniform approach to quality management audits. Australia, Brazil, Canada, Japan, and the USA are involved in the program. Started by a global initiative, the aim was to streamline the auditing process of quality management system audits for medical device manufacturers by conducting a single audit able to check the relevant quality management requirements of several countries at the same time.

But the preparations for such an audit are very time-consuming and cost intensive. For many companies, the audit program therefore represents a major challenge.

This interactive seminar not only shows you an insight into the planning and process of MDSAP audits, but also provides you with useful tips on how to efficiently implement the requirements in your company.

Contents

- Basic knowledge about MDSAP in Australia, Brazil, Japan, Canada and USA
- IMDRF & MDSAP
- MDSAP Organization: RAC & SME
- Audit Related Documents, IMDRF Documents
- MDSAP Audit Cycle & Model
- MDSAP NC Rating System
- Audit time estimation
  - Time calculation models
  - Time calculation example
- ISO 13485 vs. MDSAP: Similarities and differences
- Regulatory requirements MDSAP

Benefits

Two-day application course

December 02 – 03 2024 | 10:00 a.m. – 3:00 p.m. each, online

Benefits

Person responsible for Regulatory Compliance (PRRC)

Seminar | Regulatory Affairs

PRRC and related responsibilities

The Medical Devices Regulation (EU) 2017/745 (MDR) Article 15 requires that each medical device manufacturer and EU authorized representative has at least one person responsible for regulatory compliance.

In doing so, the responsible person replaces the medical device safety officer, but has significantly more duties and responsibilities than the safety officer previously had. As the person responsible for the conformity of delivered medical devices, you should be fully aware of the requirements and obligations and implement them accordingly.

Contents

- EU regulations for medical devices
- European legal framework
- MDR vs. ISO 13485:2016
- Terms and definitions
- Requirements for manufacturers after placing on the market
- Article 15 MDR
- Registration of the PRRC
- Safety Officer according to § 30, MPG vs. PRRC Vigilance
- Liability issues

One day basic course

Contact us for an offer

Registration of medical devices in the USA

Seminar | Regulatory Affairs

Successful product registration in the USA

There are many requirements you must meet before you can successfully obtain product approval in the USA. For example, your quality management system must be in compliance with 21 CFR Part 820 and other regulatory requirements.

In addition to registering with the FDA and appointing a US representative, you will also need to select the correct product classification and market access strategy for your product.

What makes our training different?

In this interactive training you will not only learn about the different requirements, we will also show you how to implement market access based on your products.

Many illustrative examples and concrete tips will help you to successfully enter the US market with your products.

Content

- Normative and legal requirements
  - Organization of the FDA
  - Overview of legislation
  - U.S. Agent
- Access to the US market
  - Product classification
  - PMA - Premarket Approval Application (overview)
  - 510(k) - Premarket Notification
  - De-Novo (overview)
  - Labelling / UDI
  - Identification of a suitable market access strategy
  - Determination of a Product Code / Regulation Number
  - Submission types according to product code
  - Registration and Listing
- Quality Management Requirements USA 21 CFR 820

Benefits

Two-day application course

July 08 – 09 2024 | 09:00 a.m. – 3:00 p.m. each, online

Technical Documentation of medical devices

Seminar | Regulatory Affairs

Successful implementation of the requirements of the MDR

The creation of a technical documentation poses challenges for many manufacturers. If you do not work carefully and do not meet requirements, you risk not only time-consuming but also cost-intensive inquiries and additional demands from notified bodies.

Medical device manufacturers must provide a technical documentation for each medical device, as it is a prerequisite for its approval. Depending on the intended purpose and risk classification, specific requirements for the technical documentation must be implemented. These result from the applicable general safety and performance requirements and the associated applicable standards and guidelines.

In this seminar, in addition to the new and changed requirements, you will learn how to create a compliant technical documentation. You will learn which typical hurdles you can overcome with practical tips and how you can successfully transfer an already existing technical documentation.

Benefits

Contents

- Introduction to technical documentation
- Legal requirements
- Relevant laws, directives, standards etc.
- Basics of device registration in the EU
- Requirements of the MDR according to Annexes II and III
- Designing documentation narrowly and pragmatically
- Composition, possible structures and layout, of technical documentation
- Consequences of incorrect documentation preparation
- Practical tips for meeting the general safety and performance requirements

One day basic course

Contact us for an offer

UKCA - Labelling

Seminar | Regulatory Affairs

Product Compliance in the UK

As the UK leaves the European Union, it is saying goodbye to CE marking. The new UKCA (UK Conformity Assessed) mark is the new mark for devices in the UK and makes it clear that a device placed on the UK market meets national requirements. Again, the basic idea is product safety for medical devices. The new UKCA mark will be mandatory from 1 January 2023.

Find out who is responsible for UKCA marking and how to successfully implement the requirements in your company.

Contents

- Differences between the UKCA mark and the CE mark
- Presentation of the conformity assessment process
- Marking options (CE, UKCA, UKNI)
- Situation of the responsible person in Great Britain
- Special case Northern Ireland

Benefits

Quality Management Seminars

For more efficiency and competence

One day basic course

Contact us for an offer

Cleanroom validation

Seminar | Quality Management

Validation of cleanrooms for the manufacture of Medical Devices

ISO 13485 requires the validation of manufacturing processes that are not verifiable. Learn how to implement this based on ISO 14644 and the GMP guideline for cleanrooms. Although ISO 13485 is based on the fundamentals of ISO 9001 and the PDCA cycle (Plan-Do-Check-Act), but differs significantly in its focus from ISO 9001.

The validation of cleanrooms is an important milestone in demonstrating control over the quality-relevant influences of the production conditions. Together with other validation measures, it forms the basis for a safe production environment.

Gain an understanding of the planning documentation and the implementation of validation under the special conditions of cleanroom requirements. Learn which regulatory requirements you need to consider and how to implement them successfully. Learn about a possible sequence of validation measures.

This also includes the preparatory activities, such as the risk analysis, the preparation of a purity and hygiene concept and the concept and the specification of technical requirements. You will also gain an insight into the documentation that required in the event of an audit.

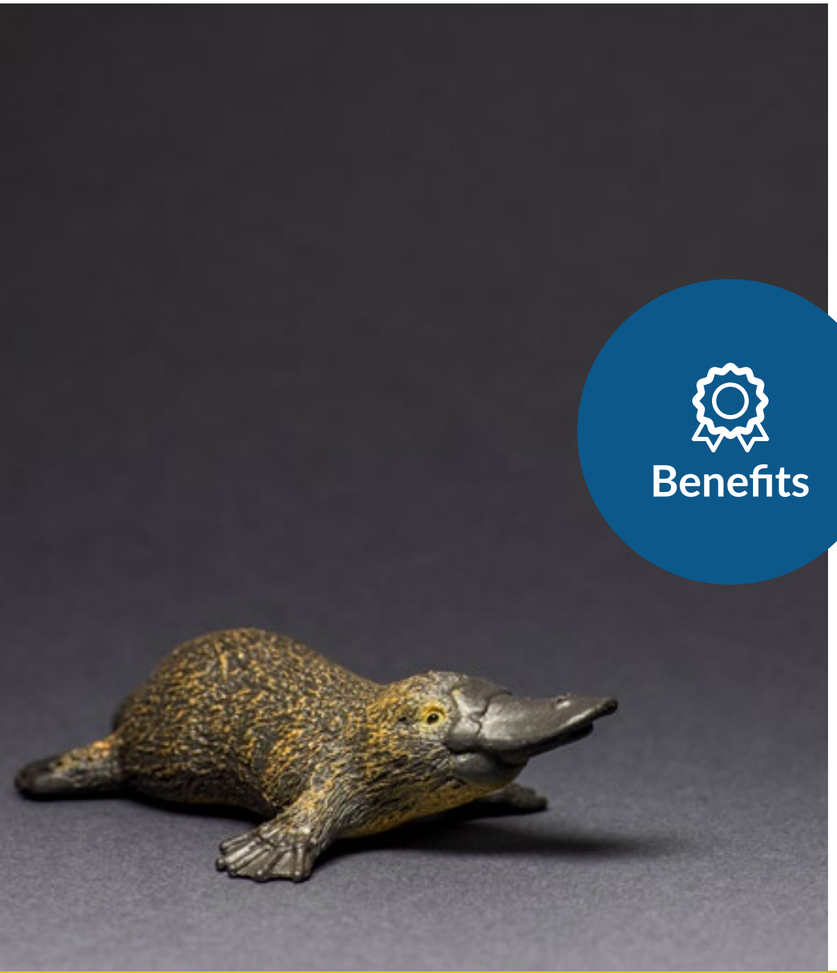
Content:

- Basics of cleanroom technology
- Overview of relevant standards for cleanroom cleanroom operation
- Sequence of validation measures
  - Preparations and input documents
  - Planning the validation
  - Implementation according to DQ, IQ, OQ and PQ
  - Documentation of the validation
  - Documentation of regular operation
- Revalidation
- Operation and monitoring

Benefits

Two-day application course

June 10 – 11 2024 |
Day 1: 10:00 a.m. – 05:00 p.m., online
Day 2: 09:00 a.m. – 04:00 p.m., online



Benefits

Internal Quality Audits

Seminar | Quality Management

Perform internal audits successfully

Audits are performed to verify the effectiveness of your systems and processes, as well as the reasonableness, cost-effectiveness and the efficiency of existing operations. The ISO 19011 standard is a general guide to auditing quality management systems that can be applied to all organizations that perform internal and external audits of their management system or are responsible for managing an audit program.

In this interactive seminar, we prepare you for planning and performing internal audits. Learn how to integrate your audit process into your quality management system and get practical tips for a successful implementation in your company.

Contents

- Legal and normative framework
- Audit principles and types
- Requirements for internal audits
- Application of the ISO 19011 standard – Guide to internal audits
  - Management of an audit program
  - Audit activities according to ISO 19011
  - Qualification of auditors and lead auditors
- Process internal audits
  - Description of the process and its requirements
  - Standard Operating Procedures (SOP)
  - Preparation of (quality) records as evidence
  - Practical examples
- Competent behaviour in the audit
- Communication in the audit team
- Follow-up and evaluation of audit results
- Identify potential for improvement
- Creation of audit checklists
- Complete process of an audit from the introductory meeting to the final meeting

One day basic course

Contact us for an offer

Benefits

ISO 9001:2015

Seminar | Quality Management

Similarities and differences to ISO 13485

ISO 9001 is often referred to as the 'mother' of quality management standards. Common standards in the field are based on this standard. For this reason, many organisations use it for their quality management. ISO 13485 is relevant to the medical device industry, and not just to medical device manufacturers. Although ISO 13485 is based on the principles of ISO 9001 and the PDCA (Plan-Do-Check-Act) cycle, it differs significantly from ISO 9001 in its focus.

Organisations seeking certification of their QMS to both standards must therefore familiarise themselves with the similarities and differences between them.

Learn about the structure and content of ISO 9001 and the relevant similarities and differences to ISO 13485. Learn how to set up, maintain and optimise your QMS standards with many practical examples.

Contents

Two-day application course

Contact us for an offer

Process Validation

Seminar | Design Control

Benefits

Validation of cleanrooms for the manufacture of Medical Devices

Process validation enables you to demonstrate that manufacturing processes have been designed safely and will operate reliably throughout the product lifecycle.
In this interactive seminar, you will increase your knowledge and be able to successfully perform and design a process validation. You will learn about the requirements of ISO 13485, 21 CFR 820 (FDA) and the Medical Device Single Audits Program (MDSAP) and will be provided with proven methods and techniques to validate processes successfully and audit proof in the future.
Many clear examples and concrete tips will help you to apply the requirements to your company and products.

Contents

- Introduction to process validation
- Current status of regulations
- Definitions
- Validation planning
- Risk-based sampling
- Sample determination, statistical principles
- Documentation practices
- Change Management
- How to create a concrete validation plan
- Sample IQ and/or OQ protocols and important conditions during implementation
- Summary and validation reports

Two-day application course

March 18 – 19 2024 | 10:00 a.m. – 3:00 p.m. each, online

Quality Management according to EN ISO 13485

Seminar | Quality Management

How to successfully set up and maintain a process-oriented quality management system.

EN ISO 13485 is based on the principles of EN ISO 9001 and the PDCA cycle (Plan-Do-Check-Act). Nevertheless, EN ISO 13485 places far more requirements on a complete quality management system, which also increases the documentation effort.

Learn about the structure and contents of EN ISO 13485 and find out how to set up, maintain and optimize your quality management system using many practical examples.

Content:

- Introduction to quality management
- Regulatory requirements for medical devices
- Application areas
- Documentation requirements
- Management responsibility and commitment
- Quality policy
- Quality objectives
- Internal communication
- Management assessment, human resources, infrastructure
- Development requirements
- Procurement
- Measurement, analysis and improvement
- Differences to the U.S., ISO 9001 and MDR

Benefits

Two-day application course

June 03 – 04 2024 | 10:00 a.m. – 3:00 p.m. each, online

Sterilization of medical devices

Seminar | Quality Management

Basics and common procedures and pitfalls in practice

Sterilization of medical devices for a safe application on patients is a key element in the manufacture, use and reprocessing of medical devices. Validation of the sterilization process is the key to reliably achieving a reproducible result.

The course provides an overview of the current regulatory and normative requirements for sterilization and the differnt sterilization processes used for medical devices, as well as an in-depth explanation of the validation activities.

Gain an understanding of the process of validating sterilization processes and learn about the normative principles according to DIN EN ISO 11135, DIN EN ISO 11137 and DIN EN ISO 17665.

Learn how to select representative devices, process parameters and service providers, what your tasks and responsibilities are as a manufacturer, service provider or testing laboratory, and how to maintain sterility in the long term..

Content:

- Regulatory and legal requirements for the sterilization of medical devices
- Basics of sterilization of medical devices
- Sterilization methods
  - Sterilization with ethylene oxide
  - Sterilization with radiation (gamma and e-beam)
  - Steam sterilization
- Proof of sterility
- Requirements for packaging materials for sterilization
- Labelling of sterile products

Benefits

One day basic course

Contact us for an offer

Sterilization using ethylene oxide

Seminar | Quality Management

EO Sterilization of medical devices, appliances, and instruments

Ethylene Oxide (EO or EtO) treatment is one of the most commonly used methods for sterilizing medical equipment/ devices and instruments. EO sterilization involves exposing products to ethylene oxide in a sealed vacuum chamber. EO sterilization is a safe method of ensuring that devices on the market always maintain the required level of sterility.

Ethylene oxide is particularly suitable for sterilizing a wide range of materials that are otherwise incompatible with other sterilization methods because it penetrates many layers of an air-permeable package.

Learn how the ethylene oxide sterilization process works and how to successfully implement the various requirements in your company. Understand the necessary steps for pre-treatment, sterilization and ventilation during the process.

Content:

- Regulatory and legal requirements for the EO sterilization of medical devices
- Basics of EO sterilization of medical devices
- EN ISO 11135
- Phases of sterilization
- Preconditioning
- Sterilization
- Aeration
- Characterization
- Product definition
- Process definition
- ISO 10993-7 - Limits for sterilization residues

Benefits

Design Control Seminars

For more efficiency and competence

Two-day application course

February 28 - 29 2024 | 10:00 a.m. – 3:00 p.m. each, online

Assessment of the zoonosis risk of medical devices

Seminar | Design Control

Benefits

Successful implementation of risk identification and risk control for medical devices manufactured using materials of animal origin

Zoonoses are infectious diseases that can be transmitted naturally from animals to humans. Zoonotic agents include bacteria, yeasts, fungi, parasites, viruses, and prions. Zoonoses occur in both humans and animals and are transmissible from animal to human and/or from human to animal.

When using medical devices manufactured using materials of animal origin, the natural routes of transmission are often bypassed. In addition, the activity of a patient's immune system cannot be compared to that of a healthy person. Therefore, for medical devices using materials of animal origin, the risk of pathogen transmission must be assessed in advance.

Learn how to avoid, minimize, and control the risk of pathogen transmission at the animal source material selection, supply chain, and medical device manufacturing stages.

Gain knowledge of methods to demonstrate minimization of infection risk. Using examples, practice assessing the risk of infection for your products and define acceptable risk.

Content

- Basics and definitions
- Requirements by laws, standards and guidelines
- Bacterial and viral zoonoses and mycoses and parasitoses
- Transmissible spongiform encephalopathy (prions)
- Data collection and analysis
- Risk control and measures
- Inactivation of pathogens and methods for testing effectiveness
- Evaluation of the residual risk

Two-day application course

April 24 - 25. 2024 | 10:00 a.m. – 3:00 p.m. each, online

Biocompatibility for Medical Devices

Seminar | Design Control

Benefits

Successfully implement biocompatibility testing according to ISO 10993.

The goal of all medical device manufacturers is to provide maximum benefit to patients with minimal biological risks.

The importance of biocompatibility has increased enormously in recent years. Regulations such as (EU) 2017/745 (MDR) require proof of biocompatibility for all materials that come into direct or indirect contact with patients. Biocompatibility testing is an integral part of the biological risk assessment process.

Learn how to optimize the testing strategy for biological safety testing of your medical device(s), which current standards you need to consider, and how to successfully perform biological risk assessment.

It also takes into account the current approach to toxicological risk assessment according to ISO 10993-17:2023 (published in September 2023).

Content

- Basics and definitions
- Overview of relevant standards for biological evaluation
- Biological evaluation according to ISO 10993-1
- Material characterization and chemical characterization
  - Analysis of the materials used and the manufacturing process
  - The chemical analysis of leachable substances
- The toxicological evaluation
- Biological testing
- Consideration of the life cycle of a medical device
- Special case: particle toxicity
- Documentation

One day basic course

Contact us for an offer

Configuration Management in RQM/ETM and DOORS Next

Seminar | Design Control

Safe development of manufacturing processes for your medical devices

What is Configuration Management? How does it work and what are the benefits of Configuration Management for the development of your project?

This course will enhance your knowledge of local and global configuration management.

Using an example, you will learn how to set up new projects, what is important when working with local configurations and how to work correctly with branching strategies and components.

Learn how global configuration management works in conjunction with DOORS Next.

Many clear examples and concrete tips will help you to apply the requirements to your company and your products.

Content

- What is Configuration Management and how does it benefit the development of your project?
- Local Configuration Management based on RQM/ETM
- Setting up a new project
- Working with local configurations
- Branching strategies
- Components
- Global Configuration Management in combination with DOORS Next
- Functionality in DOORS Next
- Branching strategies
- Enabled workflows
- Component strategies

One day basic course

Contact us for an offer

How to plan the Biological Safety Assessment - Workshop

Seminar | Design Control

Benefits

Optimization of the biological assessment plan

The requirements for assessing the biological safety of your devices have increased significantly in recent years. The update of ISO 10993-1 in 2018 plays a particularly important role here.

In this interactive workshop, you will work together on a fictitious product example to:

- determine which parameters should be considered in the biological assessment plan
- the requirements for a test sample or reference devices which data are relevant for the safety assessment
- how material selection can influence the test strategy
- and how to create a product-specific test strategy.

Optimize your test plan creation and learn how to build your test strategy in a meaningful way.

This workshop is aimed at professionals who already have practical experience in the field of biocompatibility.

Content

- Workshop:
- Planning the biological safety assessment
- Necessary contents for the test plan
- Relevant data for the preparation of the test plan

Two-day application course

Contact us for an offer

Benefits

Design Control for Medical Devices

Online and In-House seminars | Design Control

Trust is good but control is better? – Trust in the creativity of your developers and use design control to steer development

You want to develop safe and efficient medical devices that not only meet regulatory requirements, but also to optimally serve the needs of the market?

To do this, you need an excellent development team, but also a process that does not creativity and innovation, but rather and steers it in an orderly direction. The control of design and development, in short development control, is not only sensible, but is also regulatory requirement of ISO 13485 as part of quality management. It is also a basic prerequisite for CE marking according to the EU regulations (MDR 2017/745, IVDR 2017/746) or product approval in the USA.

In this interactive seminar you will gain an understanding of the development of medical devices. You will learn about both European and US requirements, as well as useful tools for efficient design control.

Content

- Development and its significance for product approval
- Regulatory and normative requirements for development control
- The development process as part of the overall project
- Introduction to the design control concept
- The Design Controls in detail
- Important interfaces: Risk management and usability
- The Design History File (DHF): What all belongs in the DHF

Two-day application course

Contact us for an offer

Benefits

Requirements Engineering

Seminar | Design Control

Modern requirements analysis for medical technology

To ensure that applications do not drive the process, but follow a defined process, it is important to create, manage and successfully implement technically correct requirements. ach requirement should be specified against a clearly defined system architecture.

Finally, the requirements should be verified by a set of test cases to provide the evidence for the device under consideration to enable a successful approval on the international markets.

In this interactive training course, you will learn which linguistic tools will improve your requirements analysis, how to adapt the process to the given project environment, and how to lay an important foundation for the success of your products.

Content

- Basic knowledge of requirements engineering
- Requirements engineering and system elements in interaction
- Verification and validation of requirements
- Tool-supported requirements engineering using the example of a medical device

Two-day application course

April 29 – 30 2024 | 09:00 a.m. – 3:00 p.m. each, online

Risk Management for Medical Devices

Seminar | Design Control

EN ISO 14971 and MDR - Regulatory requirements for risk management

In this interactive seminar, you will learn how to implement and document a professional risk management process according to EN ISO 14971, consider the influences on interfaces such as Technical Documentation including Clinical Evaluation and Usability for Use, and derive necessary measures for risk governance.

Many illustrative examples and concrete tips will help you to apply the requirements to your company and your products.

Content

- Risk management – Why?
- Risk management according to ISO 14971:2019
- Risk management fast forward
  - Risk management planning
  - Risk analysis – Hazard identification
  - Risk management tools
  - Interfaces
  - Risk analysis – Risk assessment
  - Risk evaluation – Acceptance criteria
  - Risk control – Manage the risk
  - Risk management review
  - Interfaces
- Risk management documentation

Benefits

Two-day application course

Contact us for an offer

Safety of medical electrical equipment according to IEC 60601-1

Online and In-House seminars | Design Control

How to meet the requirements of the IEC 60601-1

Medical electrical equipment is subject to the requirements of the IEC 60601 family of standards. IEC 60601-1 (Edition 3.2) is of particular interest as it defines the basic safety and essential performance characteristics of electrical medical devices.

The many different requirements of the standard need to be considered in your medical device development process. Want to develop safe and compliant products? Then our interactive basic course is for you.

Contents

- Introduction to the standard requirements
- Regulatory requirements for medical devices
- Safety philosophy of IEC 60601-1
- General requirements
- Integration into risk management
- Testing in IEC 60601-1
- Classification, applied parts and protection classes
- Electrical and mechanical hazards of ME equipment and ME systems
- Integration of Usability according to IEC 62366-1
- Protection against excessive temperatures and other hazards
- Controls, PEMS and design requirements
- Accompanying documents

Benefits

Toxicological characterization for medical device manufacturers

Seminar | Design Control

Two-day application course

September 02 – 03 2024 | 10:00 a.m. – 3:00 p.m. each, online

Successful performance of toxicological characterization

Toxicological characterization of material components or extractables is an important tool for identifying potential health risks. It can be used as a basis for argumentation to avoid certain biological tests on animals or to justify why animal testing cannot be avoided. In particular, the current ISO 10993-17:2023 standard sets new standards for toxicological risk assessment.

In this interactive seminar, you will learn which toxicological endpoints play a role for medical devices and how particularly hazardous substances can be identified. You will learn which components belong to a toxicological characterization, how to derive limit values and which biological endpoints can be covered by the toxicological characterization.

Hazard identification will be deepened in group work based on substance examples.

Content

- Introduction to toxicology and relevant toxicological endpoints
- Identification of particularly hazardous substances
- Sequence of toxicological characterization
  - Determination of the hazard potential
  - Investigation of the dose-response relationship
  - Limit value derivation
  - Exposure assessment
  - Calculation of Margin of Safety
- Substance examples for hazard identification

Benefits

Two-day application course

Contact us for an offer

Usability

Online and In-House seminars | Design Control

Benefits

EN 62366-1 - how to succeed in usability-oriented development

In this interactive course, you will learn how to meet the usability requirements of EN 62366-1 and the Medical Device Regulation (EU) 2017/745 (MDR) in your organisation. We will provide you with human-centred content that is important from a regulatory point of view in the course of the development and approval of medical devices.

Contents

- Introduction to Usability
- Regulatory requirements for usability engineering
- General requirements for usability engineering
- Product life cycle
- Usability Engineering Team
- Usability Engineering File
- Usability Engineering Process
- Creation of the Use Specification
- Determine features of the user interface in terms of safety and possible use errors
- Identify known or foreseeable hazards and hazardous situations
- Create the User Interface Specification
- Create a plan for the user interface evaluation
- Formative and summative evaluation

Event calendar

February 2024

28th - 29th	Assessment of the zoonosis risk of medical devices »

March 2024

18th - 19th	Quality Management according to ISO 13485 »

April 2024

29th - 30th	Risk Management for Medical Devices »
24th - 25th	Biocompatibility for Medical Devices »

May 2024

15th - 16th	Introduction into the requirements of the medical device industry »

June 2024

3rd – 4th	Sterilization of medical devices »
10th – 11 th	Internal Quality Audits »
19th – 20 th	Clinical Evaluation »

July 2024

3th	Clinical Studies for Medical Devices »
8th - 9th	Technical Documentation of medical devices »

August 2024

23rd	Clinical data for PMCF »

September 2024

2nd – 3rd	Toxicological Characterization for medical device manufacturers »
9th	Clinical Studies for Medical Devices »

October 2024

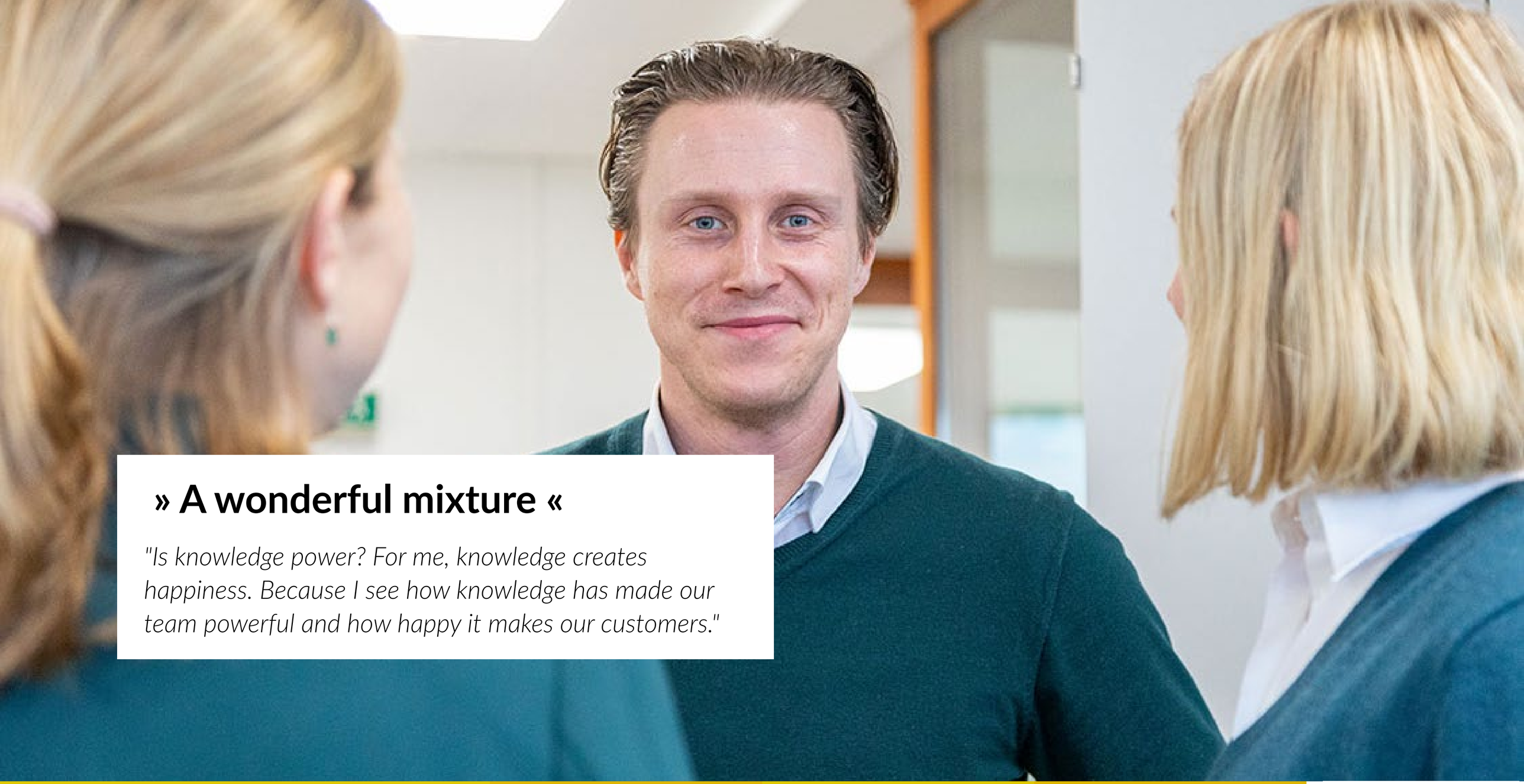
16th - 17th	Medical Device Single Audit Programm (MDSAP) »

November 2024

25th - 26th	Clinical Evaluation »

December 2024

2nd - 3rd	Person responsible for Regulatory Compliance (PRRC) »



» A wonderful mixture «

"Is knowledge power? For me, knowledge creates happiness. Because I see how knowledge has made our team powerful and how happy it makes our customers."

Our expert knowledge for your success

With our network of specialists, we provide a team that is up to the tasks of your company. Maybe we can even do a little bit more.

Find out how we can ensure your success and contact me.

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