MEDICAL & IN VITRO DIAGNOSTIC DEVICES TRAINING GUIDE

For all economic operators and related companies

EASY. PERSONAL. SCHWUNG.

GET MORE SCHWUNG OUT OF YOUR ORGANIZATION AND YOUR TEAM

ECONOMIC OPERATORS

“Organizations involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and develop- ment, or provision of associated activities (e.g. technical support).”

MANUFACTURER
IMPORTER
DISTRIBUTOR
AUTHORISED REPRESENTATIVE
SUPPLIERS AND SUBCONTRACTORS

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version 01/2024

ABOUT US

13 Traction makers , 8 coaches and numerous professional partners, that’s Allanta. We are your personal coach, guide and support in the regulatory maze you are immersed in. Great to meet you!

Allanta makes learning easy.
Our personal approach will create schwung to quality and regulatory compliance.

Easy. Personal. Schwung. These are the values we aspire throughout every- thing we do. Our team will support you from the first contact, during the search for the suitable training or support, to the follow-up.
Choose from our wide selection of planned training courses, solutions tailored to your company, or something different such as a gap analysis, internal audits, or even an occasional Q&A. Not sure what your organization needs? Don’t worry, we’ll figure it out together.

TRAINING VENUES

Our scheduled training courses usually take place alternating between Hasselt, Geel and Ghent. In addition, we collaborate with around ten training venues spread across Flanders and the Netherlands. Arrive by public transport or use your own (electric) car, there are plenty of parking facilities. Do you prefer a location of your own choosing? With pleasure, our hospitality is felt everywhere.

WHAT WE DO

No dull training courses at Allanta. Instead, our enthusiastic coaches make your learning experience as easy as possible. Impersonal presentations steps aside for interactive (live online) coaching moments full of inspiring working methods with added value. No one-way exchange, but learning from and by each other.

In addition to training, we also offer various solutions to further professionalize the internal operations of your organization:

- Coaching
- Audits: system, process, product or supplier audits
- Implementation of management systems or the application of quality methods

FINANCIAL BENEFITS

Qualified service provider
Allanta is a recognized service provider for the SME portfolio, the subsidy measure of VLAIO.
Our approval number under which applications must be made is DV.O105117.

Small enterprise
For a small enterprise a support percentage of 30% is applied up to a maximum of € 7,500 support on an annual basis.

Medium-sized enterprise
For a medium-sized enterprise, a support percentage of 20% is applied up to a maximum of € 7,500 on an annual basis.

Membership
As a member of the Allanta collective, our members enjoy a number of benefits:

- A preferential rate for you and all your colleagues when participating in training courses, workshops and study days organized by Allanta.
- Free participation in a selection of information sessions organized by Allanta
- A loyalty premium: 25% discount on Allanta membership from the second year

COURSE MATERIAL

Please note that our medical training courses are, by default, given in Dutch (English or French only on request). This English guide will provide you more insight into possible training courses and learning journeys. For more information, please contact our training coordinator. She will help you on your way.

YOUR CONTACT

Training coordinator
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- Open calendar trainings
- In-company trainings
- Live Online Trainings

CLASS ROOM TRAINING

LIVE ONLINE TRAINING

SUPPORT

AUDITS

Open Calendar
In-company training

Open Calendar
In-company training

Gap analysis & Implementation

Internal • Suppliers • Process • Product

WE PERSONALLY ENSURE THAT YOUR PEOPLE, PROCESSES AND SYSTEMS GET SCHWUNG.

Choose your own learning journey with our extensive range of solutions.

No company works the same. That is why you will find, at Allanta, a range ocustomizable solutions, designed to the strategy and (personal) growth objectives. Here you will find tailor-made solutions for SMEs to multinationals.

Our expertise focuses on Quality Management Systems and regulatory requirements for medical devices and in vitro diagnostic medical devices.

Easy. Personal. Schwung.

CONTENT

*Our interactive (online) classroom trainings and workshops in open calendar are also possible as in-company training and are even more beneficial starting from five participants. More information is available through info@allanta.be. Please note that our medical training courses are, by default, given in Dutch. English or French only on request.

LEARNING JOURNEYS

A learning journey consists of a multi-day combination of different sessions in open calendar and/or in-company trainings which are tailored to the individual employee. A participant takes part in two or more training courses to ultimately achieve his/her learning goal.
Thus, our learning journeys are an ideal solution to guide you towards additional or new responsibilities. Our enthusiastic coaches will make your learning experience as effective as possible with the combination of planned trainings, practical workshops, and/or in-company sessions.

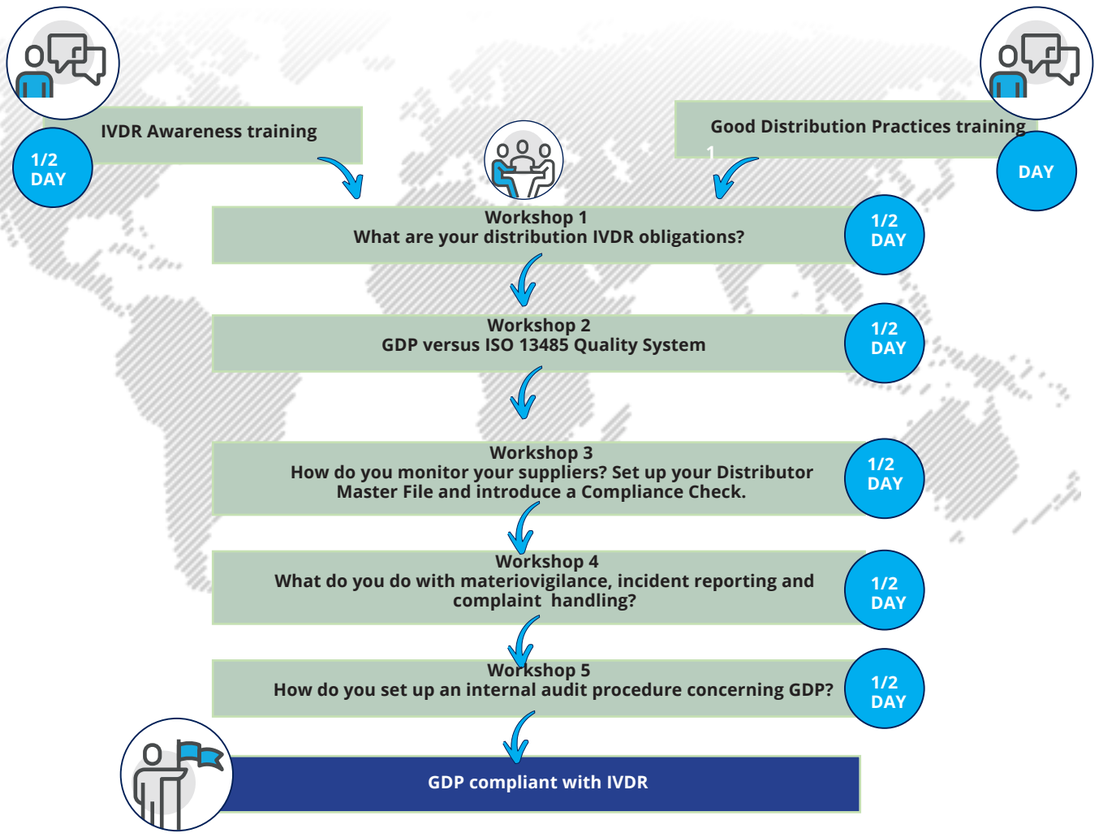
The Allanta approach?

Each learning journey starts with an introduction between one of our coaches or our training coordinator. As soon as the knowledge level, learning objectives and expectations are clear to everyone, the coach proposes a program. You will get in-depth knowledge of the subject matter and techniques, a realistic picture of your tasks, but above all the enthusiasm to apply your learnings in your own work place.
In short, Schwung!

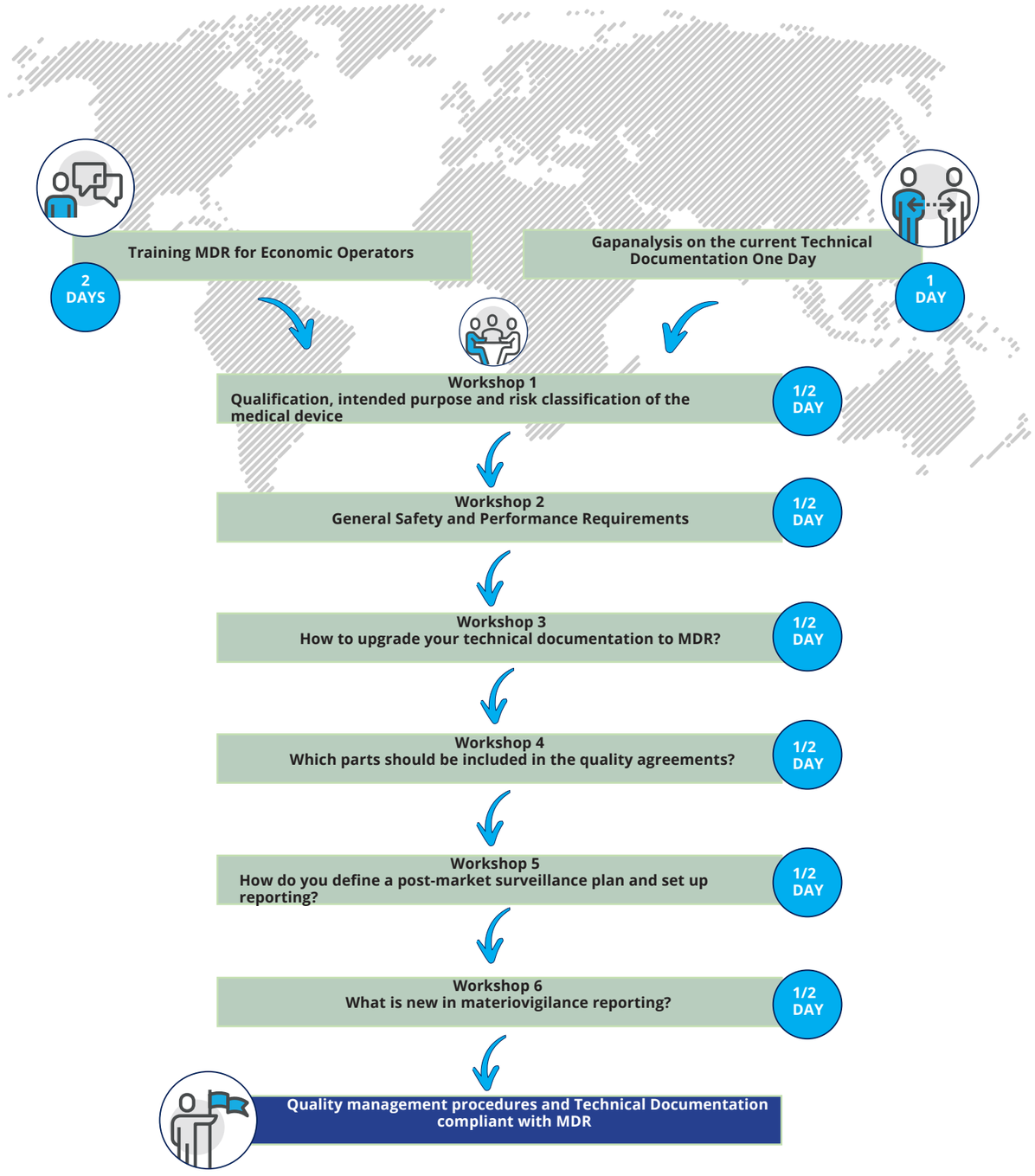
What does such a learning journey look like?

To give you an idea of the possibilities, on the following pages we have outlined two examples for you.

IVDR A PRACTICAL GUIDE FOR DISTRIBUTORS



TRANSITION MDD TO MDR, A PRACTICAL GUIDE FOR MANUFACTURERS



OUR LEARNING JOURNEYS

Transition MDD to MDR, a practical guide for MANUFACTURERS
In 6 workshops, the coach guides you through the obligations of the MDR for manufacturers. In each training session, you get a short presentation of the regulatory requirements and practical know-how on how to update quality management procedures and technical documentation.
Read more

Transition IVDD to IVDR, a practical guide for MANUFACTURERS
This six-part workshop will ease your transition from IVD to IVDR. Step by step, the coach helps you in bringing your organization, processes and medical devices in line with the IVDR.
Read more

Transition MDD to MDR, a practical guide for DISTRIBUTORS
This learning journey the coach guides you from MDD to MDR. In 5 workshops, bring step-by-step your procedures, Good Distribution Practice and MDR requirements up to date.
Read more

Transition IVDD to IVDR, a practical guide for DISTRIBUTORS
This learning journey guides distributors to the IVDR transition. Bring your procedures, GDP and other IVDR obligations up to date in five short workshops.
Read more

Do you have your own idea of a learning journey?
Let us know and we will set it up together!
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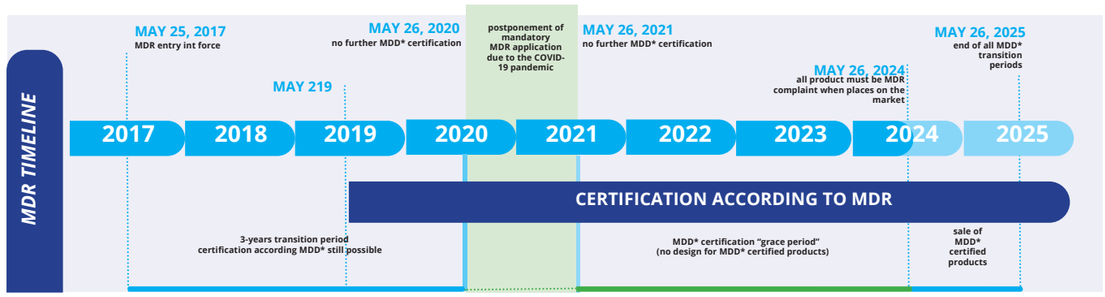
REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Today, anyone who develops a medical device and puts it on the European market is facing strict regulations and quality standards. Since May 26, 2021, the Medical Device Regulation (MDR - 2017/745) is applicable to all medical devices placed on the European market.



What's changing in the Medical Industry?
Manufacturers shall conduct clinical evaluations and studies. Notified Bodies and Competent Authorities (e.g. FAMHP) are involved. Moreover, the risk classification is higher, including reusable surgical instruments. On top of that, each medical device is given a unique device identification (UDI) registered in EUDAMED.

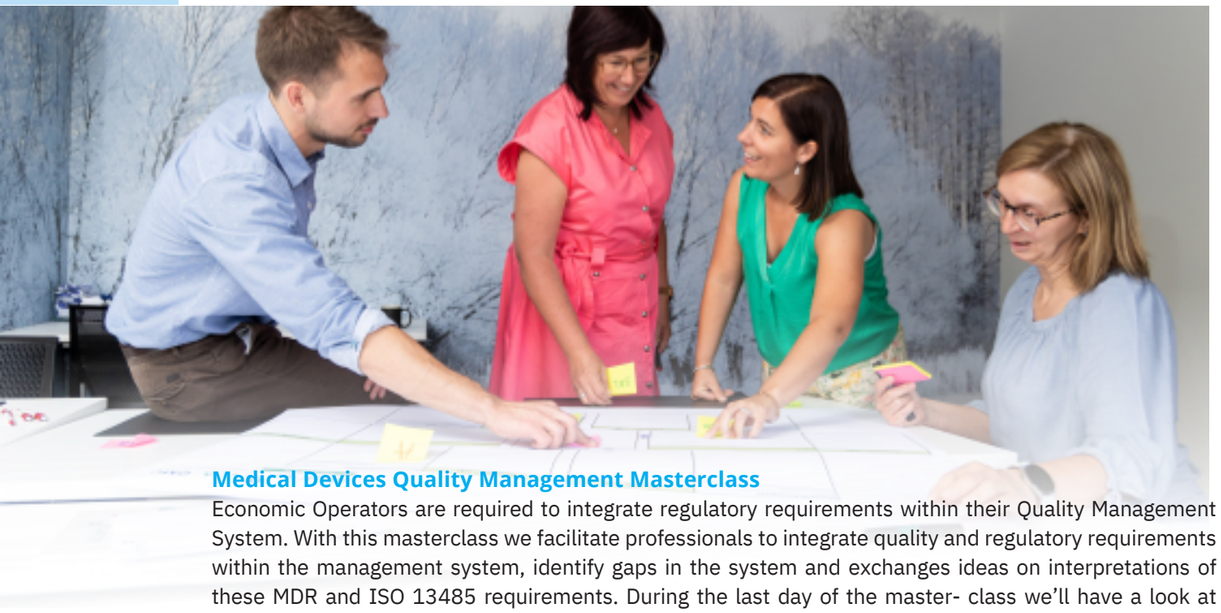
1 MDR involves all economic operators
The Medical Device Regulation has involved manufacturers, authorised representatives and distributors, to even hospital departments.

2 Stricter requirements on clinical data
There is a greater emphasis on clinical data for registration of medical applications. Requirements on post-marketing product safety are more stringent. Manufacturers must prepare a clinical evaluation report and maintain extensive documentation.

3 More transparency throughout the medical supply chain
Each medical device receives a Unique Device Identifier (UDI). An electronic database (EUDAMED) keeps track of these registrations.

4 Wider scope of medical products
The MDR extends the scope of its own standards to products, which strictly speaking do not serve a medical purpose, but pose a similar risk. Consider, for example, cosmetic contact lenses and equipment for liposuction. A new class of medical device has also been created. Namely, one for reusable surgical instruments. This type of product is now also subject to evaluation by a Notified Body.

OUR TRAINING COURSES*



Medical Devices Quality Management Masterclass

Economic Operators are required to integrate regulatory requirements within their Quality Management System. With this masterclass we facilitate professionals to integrate quality and regulatory requirements within the management system, identify gaps in the system and exchanges ideas on interpretations of these MDR and ISO 13485 requirements. During the last day of the master- class we'll have a look at real-cases that participants present and try to understand how integration can be accomplished during the final day.

Read more

MDR | For all economic operators

Manufacturer, Authorised Representative, Importer, Distributor and Procedure/System Pack Producers should operate accordingly their specific obligations.

This interactive training helps you to understand and apply quality and regulatory requirements, to understand what is mandatory or 'nice-to-have' from regulatory point of view and helps you challenge customer's requirements related to the medical devices.

Read more

MDR | Awareness for SMEs

This course is ideal for small and medium-sized enterprises updating their knowledge on medi- cal devices and EU legislation. The management and employees will understand the need-to-knows on Medical Device Regulation and what quality and regulatory requirements are mandatory or nice-to-have.

Read more

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MDR & GDP | Import and Distribution of medical devices including Good Distribution Practice

The publication of the medical device regulation has a major impact on the obligations of the distributor and Importer. The distributor (registration in Fagg Webportal, IGJ) and Importer (actor registration in EUDAMED) have similar registration obligations.

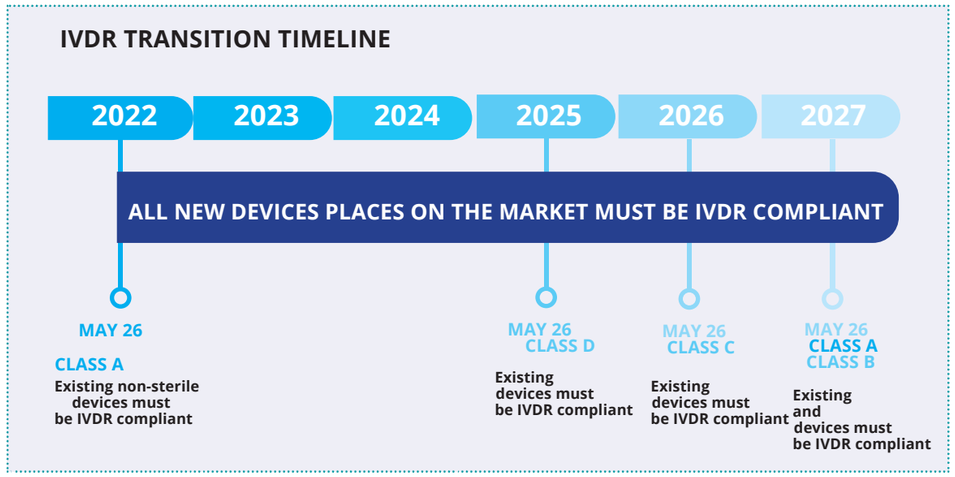
During this training we identify MDR and GDP requirements and implement them for your organization. This interactive training helps Distributors and Importers to set up the required quality system procedures, upgrade your quality system documentation so you can deliver the required evidence by your next customer audit of inspection by the competent authorities.

Read more

IN VITRO DIAGNOSTIC MEDICAL DEVICES IVDR N° 2017/746

The new IVDR legislation completely changes the entire classification system and tightens the requirements for almost all In Vitro Diagnostics. This means, among other things, that only the Happy Few (<15%) will not need to call upon a Notified Body from now on. So it does not need to be said that the impact of the IVDR on the sector is unprecedentedly large.

The final transition deadline from the IVDD to the IVDR is May 2022, but due to a huge bottle neck in the certification process this deadline was postponed. For class A devices the due date has already passed.



Not meeting this deadline is undoubtedly not an option for you: if you are not in compliance with the IVDR, you will no longer be able to place IVDs on the European market from that moment on.

Are you preparing the audit and technical documentation yourself and are you looking for a second opinion from one of our Allanta experts? Allanta takes care of your needs.

On request

Guidance on your IVDR challenges is something we like to do personally and fully customized for your organization.

Please contact our Training coordinator
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- Open calendar trainings
- In-company trainings
- Live Online Trainings

TECHNICAL DOCUMENTATION

Technical documentation is mandatory for CE-compliancy of any class of medical device. Manufacturers must disclose information about the design, manufacturing, intended use and potential risks, among other. This demonstrates that the medical device is safe for use and meets quality and regulatory requirements.

An incomplete technical document is likely to lead to significant delays in the approval process. Moreover, as a manufacturer, you will be charged additional costs for the assessment by the NB.

What's the status of your conformity assessment?

These courses teaches you how to get your (current) technical file and structure in compliance with the Medical Device Regulation (MDR) or In Vitro Diagnostic Medical Device Regulation (IVDR).

- Technical documentation & CE marking process for MDR
- Technical documentation & CE marking process for IVDR
- IEC 60601 - Standards | Safety and essential performance effectiveness of medical electrical equipment
- PMS - Post Market Surveillance (ISO/TR 20416: 2020) complaint handling and Materiovigilance for MD and IVD
- BASIC-UDI-DI, UDI and LABELLING of MD and IVD

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OUR TRAINING COURSES*

Technical documentation & CE marking process for MDR
The coach helps to prepare and draft the Technical Documentation of your medical device with the goal of CE-certification by the Notified Body.
Read more

Technical documentation & CE marking process for IVDR
The coach helps prepare and draft the Technical Documentation for the purpose of CE certification for your In Vitro Diagnostics (IVDR).
Read more

IEC 60601 - Standards | Safety and essential performance effectiveness of medical electrical equipment
The IEC 60601 standard contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. After attending this one-day introduction course, participants will understand the importance of the standards, be able to apply the standards in development projects, understand the key principles of the standards and be able to participate with test labs in preparing compliance testing.
Read more

PMS - Post Market Surveillance (ISO/TR 20416: 2020) complaint handling and Materiovigilance for MD and IVD
In this training, employees gain insights on complaint handling processes. The coach will take everyone through the post-market surveillance system and the vigilance process you need to implement as a manufacturer of MD or IVD. Come discover how these processes are connected to each other and to the risk management process.
Read more

BASIC-UDI-DI, UDI and LABELLING of MD and IVD
Learn all about label design and UDI. Coach shows how to identify your medical device individually or classify it in a group.
Read more

QUALITY STANDARDS AND GUIDELINES

The MDR and IVDR requires organizations to ensure performance, safe use and compliance with these regulations, safety and sustainability. A quality management system shall be documented and implemented embedding regulatory requirements.

- Medical Devices Quality Management Masterclass
- ISO 13485:2016 | Quality Management System - Requirements for regulatory purposes
- ISO 9001:2015 | Quality Management System
- ISO 27001, ISO 27002 and ISO 27701 - Implementation and Auditor | Cybersecurity
- IEC 60601 | Medical Electrical Equipment – general safety and essential performance
- IEC 62304 | Medical Device Software – Software life cycle processes
- IEC 62366 | Application of Usability Engineering to medical devices
- ISO/IEC 17025:2017 | General requirements for the competence of testing and calibration laboratories
- EN ISO 15189:2022 | Laboratories Medical laboratories - Requirements for quality and competence

OUR TRAINING COURSES*

Medical Devices Quality Management Masterclass
Economic Operators are required to integrate regulatory requirements within their Quality Management System. With this masterclass we facilitate professionals to integrate quality and regulatory requirements within the management system, identify gaps in the system and exchanges ideas on interpretations of these MDR and ISO 13485 requirements. During the last day of the masterclass we'll have a look at real-cases that participants present and try to understand how integration can be accomplished during the final day of this Masterclass.
Read more

ISO 13485:2016 - Standard | Quality Management System - Requirements for regulatory purposes
Now that the medical world is getting ready for the Medical Device Regulation, it is a good time to upgrade your Quality Management System as well. After completing this course, you will have a clear understanding of the requirements imposed by ISO 13485:2016. You will also have a better understanding of what inspections, notified bodies and customers consider important.
The requirements of the ISO 13485:2016 standard will be translated into a practical application so that you can apply them effectively in your organization.
Read more

ISO 9001:2015 - Standard | Quality Management System
This international standard specifies the requirements for a Quality Management System (QMS). SMEs and large corporations that want to demonstrate that they consistently deliver products and services that meet customer requirements and regulations, align their processes and quality policies with this popular standard. During the two-day ISO 9001:2015 training course, you will gain knowledge of the standard requirements and apply a quality system in your organization.
Read more

ISO 27001, ISO 27002 and ISO 27701 - Implementation and Auditor | Cybersecurity
Medical devices which contain software that allows them to interact with other devices, programmes and apps are becoming more and more common. Applications are growing rapidly, creating new threats in cyberattacks. Thorough security is crucial. This two-day training course shows in practice how to implement and audit an Information Security Management System (ISMS).
Read more

IEC 60601 - Standards | Medical Electrical Equipment – general safety and essential performance
The IEC 60601-1 standard deals with the basic safety and essential performance requirements of medical electrical equipment, and serves to ensure that no single electrical, mechanical or functional failure shall pose an unacceptable risk to patients and/or operators. After attending this one day introduction course, participants will understand the importance of the standards and will be able to select and apply the applicable IEC 60601 standards in product development projects.
Read more

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IEC 62304 - Standard | Medical Device Software – Software life cycle processes
Software is often an integral part of medical device technology. Establishing the safety and effectiveness of a medical device containing software requires knowledge of what the software is intended to do and demonstration that the use of the software does not lead to any unacceptable risks. In this training you will understand the framework of life cycle processes necessary for the safe design and maintenance of medical device software.
Read more

IEC 62366 - Standard | Application of Usability Engineering to medical devices
Both European and American Competent Authorities require medical device manufacturers to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. After attending this training course, you will understand all the clauses of the IEC 62366 and be able to assess risks by using the standard in the development of Medical Devices.
Read more

ISO/IEC 17025:2017 - Standard | Quality management system for test and calibration laboratories
ISO/IEC 17025:2017 specifies the general requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results.
This training gives you insights in these ISO 17025 requirements. It gives you the necessary support for converting the requirements into your own laboratory environment to develop and maintain an effective QMS. An accreditation will increase confidence of your clients in the operation of your laboratory and this training will help you to reach this goal.
Read more

ISO 15189:2022 - Medical laboratories - Requirements for quality and competence
ISO 15189 specifies requirements for quality and competence of medical laboratories.
This training gives you insights in the new ISO 15189 requirements and gives you the necessary support for converting the requirements into your own medical laboratory environment to develop or maintain an effective QMS. Be one of the first to be instructed in the new version of the standard and to be better and earlier prepared for this significant change.
Read more

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INTERNAL AND SUPPLIER AUDITS

New and experienced auditors who want to sharpen their knowledge and auditing skills to various standards, have the choice today of our renewal training programmes.

- ISO 19011:2018 | Guidelines for auditing management systems
- ISO 17025:2017 - Internal auditor
- ISO 13485:2016 - Internal auditor
- GDP Medical Devices - Internal auditor
- EN ISO 15189:2022 - Internal auditor

ISO 19011:2018 | Guidelines for auditing management systems
ISO 19011:2018 is the required guideline for internal audits of management system standards, such as ISO 13485:2016 for medical devices. This training is the basic training for each two-day internal auditor training. During the second day the internal audit principles are applied on each specific standard or guideline.
Read more

ISO/IEC 17025:2017 - Internal auditor
In this two day course you will become a qualified internal auditor for ISO 17025. The first day is a common day together with other internal auditor course participants where you are trained in ISO 19011 principles. This heterogenic mix of ISO-participants enriches the mutual experiences. The second day is only focused on ISO 17025. You will learn to put the knowledge gained during the first session into practice and several ISO 17025 criteria will be audited during the day. Additional the trainer will share a lot of practical experience with you so that you can start as a qualified and confident internal auditor in your company.
Read more

ISO 13485:2016 - Internal auditor
During this two-days course, you will learn how to develop an audit plan and apply a process- or risk-based approach during the internal audit of the ISO 13485:2015 quality system. Learn to set up audit trails and report your audit findings and conclusions.
Read more

OUR TRAINING COURSES*

GDP Medical Devices - Internal auditor
In this half-day course, as a GDP-auditor you will know how to audit and report on a GDP quality system using a pragmatic approach with the use of a GDP-checklist.
Read more

EN ISO 15189:2022 - Internal auditor
In this two day course you will become a qualified internal auditor for ISO 15189. The first day is a common day together with other internal auditor course participants where you are trained in ISO 19011 auditing principles. This heterogenic mix of ISO-participants enriches the mutual experiences. The second day is only focused on ISO 15189. You will learn to put the knowledge gained during the first session into practice and several ISO 15189 criteria will be audited during the day. Additional the trainer will share a lot of practical experience with you so that you can start as a qualified and confident internal auditor in your company.
Read more

RISK MANAGEMENT

Medical devices are designed, manufactured and placed on the market with a specific medical purpose. It is important that devices are safe for use, meet the performance standards they claim and comply with regulatory requirements. Manufacturers are required to assess, evaluate and mitigate medical device risks during the whole life-cycle of a medical device.

ISO 14971:2019 defines the requirements for the risk management process, ISO/TR 24971 sets out the guidelines how to implement the process.

OUR TRAINING COURSES*

EN ISO 14971:2019 | Application of risk management to medical devices &
ISO/TR 24971:2020 | Guidance on the application of ISO 14971:2019
ISO 14971 and ISO/TR 24971 are two guidances that define the risk management process for medical devices. This course explains the ISO 14971:2019 in detail and introduces you to risk management techniques. This will enable you to fully understand the principles of risk management and apply them in practice.
Read more

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GOOD DISTRIBUTION PRACTICE (GDP)

Good Distribution Practice (GDP) are European guidelines for distributors of pharmaceuticals and medical devices aimed at ensuring product quality and safety throughout the distribution chain. An important nuance, for medical devices the distribution chain runs from manufacturer to patient and within medicinal the responsibility is limited to the pharmacy.

FIND A TRAINING APPLICABLE TO YOUR ROLE AS A DISTRIBUTOR OR TRANSPORTER

	GDP+ MDR	GDP MEDICINAL	GDP MEDICINAL REFRESHER	GDP TRANSPORT	GDP INTERNAL AUDITOR	MDD/IVD TO MDR/IVDR FOR DISTRIBUTORS	ISO
	1 DAY NO PRIOR KNOWLEDGE REQUIRED	1 DAY NO PRIOR KNOWLEDGE REQUIRED	1 DAY PRIOR KNOWLEDGE REQUIRED	1/2 DAY NO PRIOR KNOWLEDGE REQUIRED	1/2 DAY NO PRIOR KNOWLEDGE REQUIRED	LEARNING JOURNEY NO PRIOR KNOWLEDGE REQUIRED	1-2 DAY NO PRIOR KNOWLEDGE REQUIRED
DISTRIBUTOR							
PHARMA + MEDICAL	✓	✓	✓		✓	✓	ISO 9001 ISO 13485 (MD)
PHARMA		✓	✓		✓		ISO 9001
MEDICAL	✓				✓	✓	ISO 9001 ISO 13485 (MD)
TRANSPORTER							
PHARMA AND/OR MEDICAL				✓	✓		ISO 9001 ISO 13485 (MD)

OUR TRAINING COURSES*

GDP & MDR | Import and Distribution of medical devices including Good Distribution Practice
The publication of the medical device regulation has a major impact on the obligations of the distributor and Importer. The distributor (FAGG, IGJ) and Importer (EUDAMED) have similar registration obligations.
During this training we identify MDR and GDP requirements and implement them for your organization. This interactive training helps distributors and importers to set up the required quality system procedures, upgrade your quality system documentation so you can deliver the required evidence by your next customer audit of inspection by the competent authorities.
Read more

GDP | Medicinal products
In one day, medicinal product distributors learn to apply the European GDP directives to the organization. This training proves the necessary competence.
Read more

GDP | Medicinal products - refresher course
Are you a responsible person already trained in GDP some time ago or do you just want to have a short refresher training on GDP principles for medicinal products, this session will take you through all GDP requirements by challenging your actual knowledge in an interactive session based on everyday situations.
Read more

GDP | For transporters of Medical Devices or Medicinal products
What happens when distributors outsource their transport? Then they are responsible for ensuring that their transporters also comply with relevant GDP requirements.
In this 4-hour training you will get the essence of GDP for transporters, both for the transport of non-refrigerated goods and time- and temperature-sensitive products.
Read more

GDP Medical Devices - Internal auditor
In this half-day course, as a GDP-auditor you will know how to audit and report on a GDP quality system using a pragmatic approach with the use of a GDP-checklist.
Read more

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NON EU MARKET

Ready for the overseas market?
These courses will familiarise you with special regulations and guidelines for medical devices outside the European Union.

OUR TRAINING COURSES*

MDSAP – Medical Device Single Audit Program – Awareness
MDSAP allows an MDSAP recognized auditing organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the US, Japan, Brazil, Australia and Canada.
This training gives you an overview of the structure of the standard, its significance in each regulation as well as the auditing process. After the training you will understand why MDSAP is developed and structured, how it is audited and what the impact is on your organization.
Read more

MDSAP - Medical Device Single Audit Program
This MDSAP training will accelerate your MD or IVD certification for the overseas market. Get your company ready for Canada, Brazil, Australia, Japan or the US with this training.
This training is recommended if you are a manufacturer who intends to put medical devices on these markets or if you want to train your (new) personnel involved in the implementation and maintenance of this standard. After the training the participant will have a clear understanding of what MDSAP means for the organization and gained an in depth knowledge of the 90 tasks that are listed in the standard.
Read more

FDA 21 - CFR part 820 and 803 | Quality System Regulation and Medical Device Reporting
Before you can register your company to the US market, you have to make sure that your Quality System complies with the statutory USA requirements. During this training you will be introduced to FDA 21 - CFR part 820 & 803 and learn how to adapt your organization and QMS to these requirements.
Read more

PNP - Premarket Notification Process - 510k for US market | FDA
This course gives an overview of the regulations and policies set by the FDA for the pre-market approval, manufacture and post-marketing compliance of medical devices. The course will provide an understanding of the paths to obtaining agency approval, the type of controls, systems and documentation they expect to see in place, how the FDA performs inspections, and the variety of outcomes from each inspection.
Read more

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AUDIT AND COACHING

Guidance and learning paths are structured in such a way that they will launch your organization from it’s starting point to the most optimal objectives.

- MDR - Compliance audit
- IVDR - Compliance audit
- MDR | Technical Documentation compliance audit
- IVDR | Technical Documentation compliance audit
- ISO 13485:2016 gap analysis
- Internal audit of a MD or IVD related regulation, standard or guideline
- Supplier and subcontractor audits (2nd party audit with audit criterium
- ISO 13485:2016 and/or ISO 9001:2015 including quality agreement)
- MDSAP - Medical Device Single Audit Program, gap analysis and internal audit

GET IN TOUCH

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