BSI Training Academy

By Royal Charter

Your complete guide to

ISO 13485:2016

Training

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...making excellence a habit.™

Quality Management System (QMS) ISO **13485** Certification

What is an ISO 13485 Quality Management System?

ISO 13485 is a stand-alone QMS standard, derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical device manufacturing environment. While ISO 13485 is based on the ISO 9001 process model concepts of Plan, Do, Check, Act, it is designed for regulatory compliance. It is more prescriptive in nature and requires a more thoroughly documented quality management system.

ISO 13485 was written to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

What are the benefits of being certified to ISO 13485?

Whether you are looking to operate internationally or expand locally, ISO 13485 Certification can help you improve overall performance, eliminate uncertainty, and widen market opportunities. Companies with this certification communicate a commitment to quality to both customers and regulators.

- Increase access to more markets worldwide with certification
- Outline how to review and improve processes across your organization
- Increase efficiency, cut costs and monitor supply chain performance
- Demonstrate that you produce safer and more effective medical devices
- Meet regulatory requirements and customer expectations

Why make BSI your first choice for **ISO 13485:2016** training

Our tutors

When it comes to teaching how to make standards work, our tutors are the best in the business. As experienced assessors with years of hands-on business and industry experience, they understand the challenges you're most likely to face. They are passionate about standards and have a proven ability to facilitate great learning.

Our approach - Accelerated Learning

We really understand how training works and that everyone learns and retains knowledge differently. Based on the latest research, our accelerated learning approach is proven to fast-track learning, improve knowledge retention and ensures you can apply your knowledge straight away. We constantly evaluate our results based on your satisfaction and success rate, to provide the best training experience in the industry.

Our expertise

As the world's first National Standards Body and founding member of ISO, no one knows standards like BSI. And when you train with us you benefit from this experience. You can trust us to say we know what we're talking about and you'll benefit from a premium learning experience. When it comes to standards even our competitors choose us.

Our solution

We provide a proven pathway to success, wherever you are in your training journey. So whether you want to build your knowledge, learn how to implement or how to audit and improve your management system, we have the right solution for you. You'll also learn right beside your peers; we'll discuss real-world challenges and share best practice based on over 100 years' experience.

Why invest in training from BSI?

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples that means you can focus on learning.

Public Training Courses are available

Network and learn best practices from a variety of sectors with our diversified schedule of courses and locations.**Talk to one of our experts to find out more.**

Training delivered at your site

This could be a convenient and cost effective option, especially if you have multiple delegates. **Talk to one of our experts to find out more.**

Our BSI Training Academy ISO 13485:2016 courses

ISO 13485:2016 SAMDL – 1 day

Level 1

Who is this for	You'll discover	How this will help you
• Manufacturers, importers, distributors and wholesalers of medical devices, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, and Quality Assurance personnel.	• Explain the requirements in the structure and administration of the legislation • Recognize new economic operators affected by the legislation	• Understand the requirements to the new MDL • Communicate the impact to your organization of the key requirements introduced by the MDL, and the transition arrangements defined within the MDL

ISO 13485:2016 Requirements – 1 day

Level 1

Who is this for	You'll discover	How this will help you
• Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.	• Use of ISO 13485:2016 as the basis for a QMS for medical device manufacturers • Relationship between ISO 13485:2016 and European Medical Device Directives	• Take the first steps towards ISO 13485:2016 certification • Understand how you can better meet regulatory requirements

ISO 13485:2016 Clause by Clause – 2 days

Level 1

Who is this for	You'll discover	How this will help you
• Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.	• ISO 13485:2016 Requirements • ISO 13485:2016 Scope and structure • How requirements are established and maintained within an organization.	• Be able to describe the requirements and structure of ISO 13485:2016 • Interpret and apply requirements relevant to your organization.

ISO 13485:2016 Implementation – 2 days

Level 1 2

Who is this for	You'll discover	How this will help you
• Anyone involved in defining, planning, or implementing an ISO 13485:2016 QMS, as well as management representatives and implementation team members.	• Define a ISO 13485:2016 QMS Identify the steps for defining, planning, organizing and scheduling necessary activities.	• Understand how to implement a QMS as required by medical device directives • Plan the implementation of ISO 13485:2016 within your organization.

ISO 13485:2016 Internal Auditor – 2 days

Level 1 2 3

Who is this for	You'll discover	How this will help you
• Medical device professionals with knowledge of ISO 13485:2016 and individuals interested in conducting first-party or second party audits, management representatives, internal auditors and consultants	• Structure and scope of ISO 13485:2016 and how it applies to your organization • Identify the key principles of auditing/auditor responsibilities	• Maintain compliance with ISO 13485:2016 • Improve a global benchmark in quality standards • Be confident that your organization can rely on competent auditors

ISO 13485:2016 Lead Auditor IRCA Certified (A17955) – 5 days

Level 1 2 3 4

Who is this for	You'll discover	How this will help you
• Anyone with the need to audit an organization's ISO 13485:2016 QMS.	• Gain the skills to plan, conduct, report and follow up an audit in accordance with ISO 19011 • Identify the purpose and benefits of an ISO 13485:2016 QMS	• Identify the aims and benefits of an ISO 13485:2016 audit • Interpret ISO 13485:2016 requirements for audit application

Our BSI Training Academy ISO 13485:2016 courses

MDR Requirements – 1 day

Who is this for	You'll discover	How this will help you
• New starters in Regulatory Affairs (RA) and those increasing their responsibility in this area, and RA professionals who are not familiar with the European MDR • Anyone working with Regulatory Affairs departments, e.g. top management, manager or project member in QM/QA, R&D, design, manufacturing, supply chain, customer service and sales	• Communicate the key requirements and concepts within the Regulation • Reference aspects and evaluate if and how your company is affected by the MDR and to what extent • Explain the structure and administration of the Regulation	• Understand the key requirements and concepts of the MDR • Communicate the impact of the key requirements introduced by the MDR to your organization

MDR Implementation – 3 days

Who is this for	You'll discover	How this will help you
• RA, QM, and QA professionals who need to implement the MDR • Anyone concerned with certification or active in projects for CE marking	• Evolve a strategy for regulatory compliance as stipulated by MDR • Implement requirements concerning conformity assessment • Fulfil technical documentation requirements	• Implement the requirements of the European Medical Devices Regulation • Guide and support other people and partner organizations affected by MDR • Set up and update required documentation

ISO 13485:2016 SAMDL - 1 day

Level 1

This course will introduce you to the long awaited MDL, the publication of which in December 2016 marked the start of a transition period for the medical device industry in South Africa: You will be guided through the changes that will affect all medical device manufacturers (including some classes of devices without a medical purpose), importers, distributors and wholesalers. The course aims to enable your organization to place medical devices on the market by providing an in depth analysis of the new requirements for local technical documentation, assessment of product safety and performance, clinical evaluation and post-market clinical follow-up, and requiring labelling and traceability of devices through the supply chain.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Relationship between ISO 13485, ISO 9000 series & ISO 14971
- ISO 13485 compliance with worldwide regulatory requirements
- Introduction to auditing
- Process approach & process auditing
- Managing an audit programme
- Audit activities
- Auditor competence & responsibilities
- Plan an internal audit
- Creating work documents
- Conducting an opening meeting
- Collecting & verifying audit information
- Audit techniques
- Gathering & verifying information
- Audit findings & nonconformities
- Conducting the audit

Make sure this is the right course for you.

What will I learn?

By the end of the course delegates will be able to:

- Explain the requirements in the structure and administration of the legislation
- Recognize new economic operators affected by the legislation
- Identify key requirements concerning steps for conformity assessment, including:
- Check device is within the scope of the MDL
- Determine risk class of device
- Select conformity assessment procedure
- Identify applicable safety and performance requirements
- Assemble technical documentation
- Apply conformity assessment procedure
- Assign unique device identification (UDI)
- Complete legislation documentation and Declaration of Conformity (DoC)
- Post-market surveillance and updates
- Explain the main impacts on the QMS relating to conformity assessment, including:
- Frequency, extent and conduct of audits
- Electronic data management and public access to data
- Clinical investigations, clinical evaluation and post-market surveillance
- Roles of commercial partners
- Communicate the transition arrangements as stipulated within the legislation

Who Should attend

Manufacturers, importers, distributors and wholesalers of medical devices, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, and Quality Assurance personnel.

Please note: This course does not focus on mapping the AIMD to the MDL, however, the course will provide value to AIMD clients by looking at the new legislation and how to transition to the MDL. It will reference In Vitro Diagnostic Devices.

How will I benefit

This course will help you:

- Understand the requirements to the new MDL
- Communicate the impact to your organization of the key requirements introduced by the MDL, and the transition arrangements defined within the MDL
- Identify the next steps for your organization to meet the MDL requirement

Book today at
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ISO 13485:2016 Requirements - 1 day

Level 1

Gain a better insight into the use of ISO 13485:2016 as the basis for a Quality Management System (QMS) implemented by medical device manufacturers. This course explores the requirements of ISO 13485:2016, discussing key principles and how the standard interacts with ISO 9001:2015, the European Medical Device Directives and US FDA's Quality System Regulation. The relationship with ISO 14971 'Application of Risk Management to Medical Devices' is also explored during the course.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Quality definitions & process approach
- Medical devices within the industry
- Introduction to ISO 13485:2016
- ISO 13485:2016 in detail
- Clauses 1, 2, & 3
- Clause 4 & 5
- Clause 6: Resource management
- Clause 7: Product realization
- Risk management
- Clause 8: Monitoring & measurement
- ISO 13485:2016 FDA, QSR, MDSAP & other regulations
- Reflection & feedback• Identifying risks & opportunities

Make sure this is the right course for you.

What will I learn?

- Use of ISO 13485:2016 as the basis for a QMS for medical device manufacturers
- Relationship between ISO 13485:2016 and European Medical Device Directives
- Use of ISO 13485:2016 as the basis of regulatory requirements worldwide.

Who Should attend

Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyoneinvolved with the implementation of the standard.

How will I benefit

- Take the first steps towards ISO 13485:2016 certification
- Understand how you can better meet regulatory requirements leading to increased patient safety
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement
- Develop safe and effective medical devices
- Motivate employees through CPD.

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ISO 13485:2016 Clause by Clause - 2 days

Level 1

Demonstrate your ability to provide medical devices and related services that meet quality and regulatory demands in line with ISO 13485:2016 Medical Device requirements for a Quality Management System (QMS). This course enables a clause by clause understanding of ISO 13485:2016, providing an effective solution to meet the comprehensive requirements of an effective QMS.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Conflict of interest & expertise
- Overview of ISO 13485:2016
- Activity 1: PDCA & ISO 13485:2016
- Discussion of Clause 1, 2 & 3
- Activity 2: Clauses 1, 2 & 3
- Overview of Clause 4
- Activity 3: Clause 4 Quality management system
- Clause 5
- Activity 4: Management responsibility
- Activity 5: Clause 6 resources

Day 2

- Review of Day 1
- Conducting the audit (Part 2)
- Generate audit findings
- Identify & define nonconformities
- Prepare audit conclusions
- Write an audit report
- Closing meeting
- Conduct audit follow-up
- Course review & questions
- Reflection & feedback

Make sure this is the right course for you.

What will I learn?

- ISO 13485:2016 Requirements
- ISO 13485:2016 Scope and structure
- How requirements are established and maintained within an organization
- What systems are required for implementation
- How to gain or maintain certification to ISO 13485:2016.

Who Should attend

Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.

How will I benefit

- Be able to describe the requirements and structure of ISO 13485:2016
- Interpret and apply requirements relevant to your organization
- Appreciate how a QMS can be applied as a framework to produce safer medical devices
- Evaluate how requirements can be effectively implemented to meet and maintain regulatory compliance.

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ISO 13485:2016 Implementation - 2 days

Level 1

Develop your knowledge and skills in the process of implementing ISO 13485:2016 within your organization.You'll be introduced to the concepts needed to understand, develop and implement a Quality Management System (QMS). This course provides the knowledge and process steps to enable the effective implementation of a QMS that is in line with the requirements for ISO 13485:2016 certification.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Boundaries: Conflict of interest & expertise
- Management systems fundamentals
- ISO 13485:2016 QMS
- ISO 13485:2016 purpose, structure & requirements
- Implementation process
- Implementation outline
- Top management commitment
- Promoting awareness
- Performing gap analysis
- Reviewing current system
- Identifying risks & opportunities

Day 2

- Review of Day 1
- Develop implementation plan
- Approve implementation plan
- Operate & assess the system
- Continual improvement
- Certification & registration
- Course review & questions
- Reflection & feedback

Make sure this is the right course for you.

What will I learn?

- Define a ISO 13485:2016 QMS
- Identify the steps for defining, planning, organizing and scheduling necessary activities
- Implement an effective quality management system
- Conduct a base line review of an organization's current position with regard to ISO 13485:2016.

Who Should attend

Anyone involved in defining, planning, or implementing an ISO 13485:2016 QMS, as well as management representatives and implementation team members.

How will I benefit

- Understand how to implement a QMS as required by medical device directives
- Plan the implementation of ISO 13485:2016 within your organization
- Take the first steps towards ISO 13485:2016 certification
- Identify how you can better meet regulatory requirements
- Find ways to increase efficiency and add value through quality management
- Monitor supply chains to achieve continuous improvement.

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ISO 13485:2016 Internal Auditor - 2 days

Level 1 C 2 C 3

An ineffective audit can mean severe consequences resulting in process failure, patient dissatisfaction and regulatory noncompliance. Optimize your auditing skills with the internationally recognized ISO 13485:2016 and boost your internal audit capabilities. Gain confidence in planning and performing an effective audit, as well as reporting and taking corrective action where necessary.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Relationship between ISO 13485, ISO 9000 series & ISO 14971
- ISO 13485 compliance with worldwide regulatory requirements
- Introduction to auditing
- Process approach & process auditing
- Managing an audit programme
- Audit activities
- Auditor competence & responsibilities
- Plan an internal audit
- Creating work documents
- Conducting an opening meeting
- Collecting & verifying audit information
- Audit techniques
- Gathering & verifying information
- Audit findings & nonconformities
- Conducting the audit• Identifying risks & opportunities

Day 2

- Review of Day 1
- Conducting the audit (Part 2)
- Generate audit findings
- Identify & define nonconformities
- Prepare audit conclusions
- Write an audit report
- Closing meeting
- Conduct audit follow-up
- Course review & questions
- Reflection & feedback

Make sure this is the right course for you.

What will I learn?

- Structure and scope of ISO 13485:2016 and how it applies to your organization
- Identify the key principles of auditing auditor responsibilities
- Plan an internal audit
- Conduct an effective audit based on process identification, sampling and questioning
- Determine if corrective action has been effectively implemented.

Who Should attend

Medical device professionals with knowledge of ISO 13485:2016 and individuals interested in conducting first-party or second party audits, management representatives, internal auditors and consultants

How will I benefit

- Maintain compliance with ISO 13485:2016
- Improve a global benchmark in quality standards
- Be confident that your organization can rely on competent auditors
- Motivate colleagues through CPD and ensure rigorous regulatory internal processes
- Write factual audit reports and suggest corrective actions.

Book today at
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ISO 13485:2016 Lead Auditor - 5 days

IRCA Certified (A18190)

Level 1 2 3 4

Gain the confidence to effectively audit a QMS in accordance with internationally recognized best practice techniques. Demonstrate your commitment to the quality of medical devices by transforming existing auditor skills to ISO 13485:2016. Consolidate your expertise with the latest developments and contribute to the continuous improvement of the business.

Our Course Agenda

Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- First, second & third party audits
- Typical audit activities
- Audit objectives, scopes & criteria's
- Audit resources
- Roles, responsibilities & confidentiality
- Audit methods
- Stage 1 audit
- Stage 2 audit
- Audit plan
- Work documents
- Opening meeting
- Audit evidence
- Effective communication
- Audit findings
- Audit meetings
- Closing meeting
- Audit reports
- Audit follow-up

Day 2

- Purpose & business benefits of a QMS
- Terminology
- Plan-Do-Check-Act
- Processes & context
- Role of the auditor
- QMS documentation
- Initiating the audit
- Document review
- Audit plan
- Work documents
- Opening meeting
- Observations
- Auditing top management

Day 3

- Specimen exam: Sections 1 & review
- Auditing: Planning to meet requirements
- Auditing: Design & development
- Tutorial on body language
- Audit Trails
- Auditing: Purchasing
- Auditing: Monitoring & measurement

Day 4

- Specimen Exam: Section 3 review
- Auditing: Improvement
- Nonconformities
- Closing Meeting
- Audit report
- Audit follow-up
- Specimen exam: Section 4

Day 5

- Hand in homework: Audit report
- Final questions/revision
- BSI Registered Auditor Qualification
- Evaluation
- Introduction to the exam
- Exam
- Reflection & feedback

Make sure this is the right course for you.

What will I learn?

- Structure and scope of ISO 13485:2016 and how it applies to your organization
- Identify the key principles of auditing auditor responsibilities
- Plan an internal audit
- Conduct an effective audit based on process identification, sampling and questioning
- Determine if corrective action has been effectively implemented.

Who Should attend

Medical device professionals with knowledge of ISO 13485:2016 and individuals interested in conducting first-party or second party audits, management representatives, internal auditors and consultants

How will I benefit

- Maintain compliance with ISO 13485:2016
- Improve a global benchmark in quality standards
- Be confident that your organization can rely on competent auditors
- Motivate colleagues through CPD and ensure rigorous regulatory internal processes
- Write factual audit reports and suggest corrective actions.

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Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Requirements of the Medical Device Regulation (MDR) training course - 1 day

This course will give you an understanding of the key requirements, which will provide essential knowledge to understand Regulatory Affairs of medical devices in the EU. It's relevant to top management, managers or project members in quality management, quality assurance, research and development, design, manufacturing, supply chain, customer services and sales.

It will give you the ability to understand the demands of the subcontractor, supplier, original equipment manufacturer, authorized representative, importer and distributor, allowing better relationships between them and the legal manufacturer. It also forms a basis on which to learn later about the implementation of CE marking projects.

Make sure this is the right course for you.

This course is for:

- New starters in Regulatory Affairs (RA) and those increasing their responsibility in this area, and RA professionals who are not familiar with the European MDR
- Anyone working with Regulatory Affairs departments, e.g. top management, manager or project member in QM/QA, R&D, design, manufacturing, supply chain, customer service and sales
- Staff working for organizations that partner with medical device manufacturers, e.g. as subcontractor, supplier, OEM, authorized representative, importer, distributor, auditee etc.

What you'll learn:

You'll be able to:

- Communicate the key requirements and concepts within the Regulation
- Reference aspects and evaluate if and how your company is affected by the MDR and to what extent
- Explain the structure and administration of the Regulation
- Recognize partners of manufacturers affected by the Regulation
- Describe the key steps of a conformity assessment
- Explain the main impacts on the QMS relating to the MDR
- Recognize the requirements for PMS and updates

Benefits:

This course will help you:

- Understand the key requirements and concepts of the MDR
- Communicate the impact of the key requirements introduced by the MDR to your organization

Implementation of the Medical Device Regulation (MDR) training course - 3 days

This three-day training course will help you to implement the requirements of European Medical Device Regulation (MDR) to obtain and maintain CE marks for your product, giving you access to a market with 500+ million people.

Make sure this is the right course for you.

This course is for:

- RA, QM, and QA professionals who need to implement the MDR
- Anyone concerned with certification or active in projects for CE marking
- Employees working for organizations that partner with Medical Device manufacturers e.g. as subcontractor, crucial supplier, OEM, authorized representative, importer, distributor, auditee

What you'll learn:

You'll be able to:

- Evolve a strategy for regulatory compliance as stipulated by MDR
- Implement requirements concerning conformity assessment
- Fulfil technical documentation requirements
- Plan post-market activities required by MDR
- Put into effect your knowledge of implementation of MDR requirements into your organization, e.g. in projects for CE marking

Benefits:

This course will enable you to:

- Implement the requirements of the European Medical Devices Regulation
- Guide and support other people and partner organizations affected by MDR
- Set up and update required documentation
- Take the necessary steps for your organization to meet the MDR requirement
- Maintain compliance to MDR and other/future documents related to Medical Device legislation
- Systematically explore and implement more detailed and updated provisions (e.g. common specifications (CS), delegating and implementing acts, standards)

Book today at
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