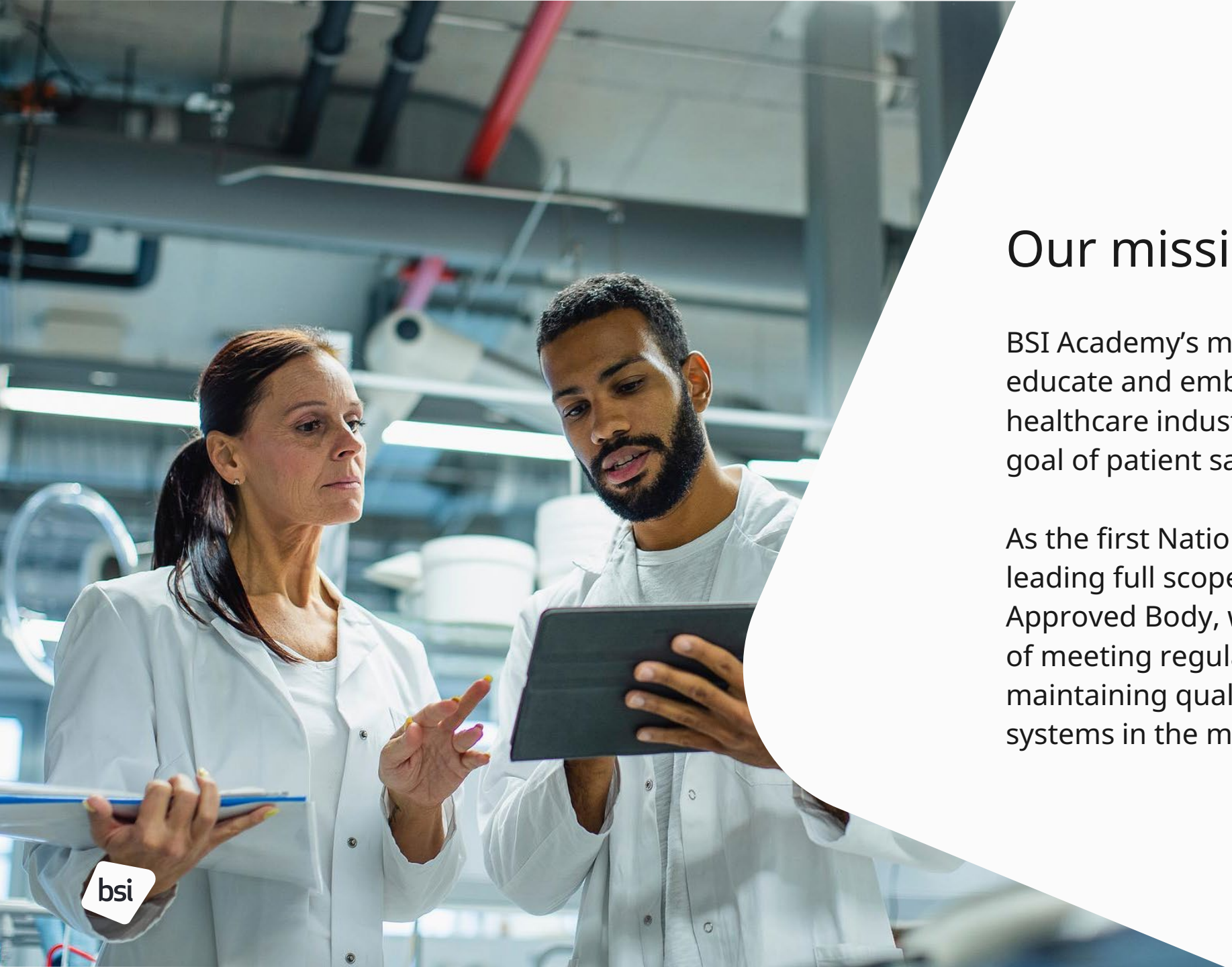
Healthcare and Medical Devices

Courses and qualifications available from the BSI Academy



Our mission

BSI Academy’s mission is to standardize, educate and embed knowledge across the healthcare industry, with the ultimate shared goal of patient safety.

As the first National Standards Body and leading full scope Notified Body and UK Approved Body, we understand the challenges of meeting regulatory requirements and maintaining quality management systems in the medical sector.

Medical Devices

Our training portfolio provides an in-depth understanding on key topics regulating medical devices, IVDs and QMS to increase your knowledge on compliance, implementation, and maintenance of regulatory requirements.

Start your learning journey with BSI and grow your knowledge demonstrating competence and compliance with the regulatory landscape, while increasing your organization's knowledge pool.

BSI training and certification services are available for all regulatory schemes. We are:

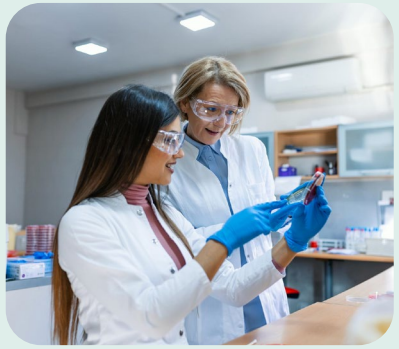
- A full scope Notified Body
- A full scope UK Approved Body
- A national Standards Body
- An accredited ISO 13485 Certification Body
- A recognized Auditing Organization under the Medical Device Single Audit Program
- A globally recognized Certification Body

Medical Device Regulation (MDR)

In Vitro Diagnostic Regulation (IVDR)

Quality Management ISO 13485

CE Marking

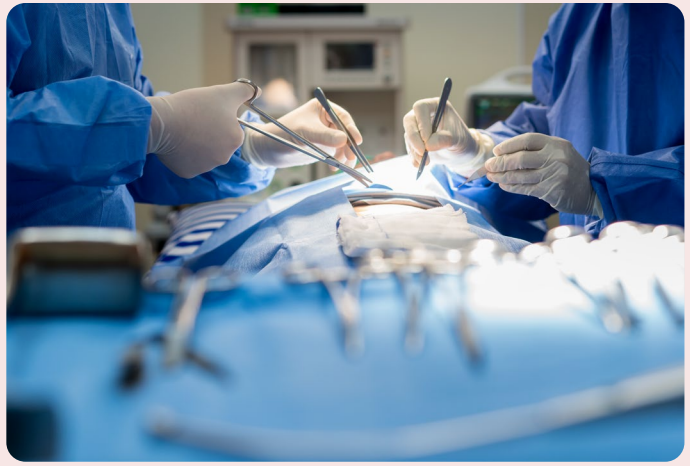


Specialized courses

Medical Device Regulation (MDR)

The European Medical Device Regulation (MDR) replaced the MDD and the AIMDD and entered into force on 25 May 2017 with 26 May 2021 as date of application.

Browse our range of courses designed to support your knowledge around these key topics.



Requirements of MDR for CE Marking

Learn about the key requirements, concepts, and the overall process for CE marking under the MDR.

Requirements of the MDR On-demand eLearning

This on-demand course is designed to increase your understanding of MDR key requirements to place your device on the market.

Implementation of MDR for CE Marking

Find out best practices to implement a compliant QMS and prepare a thorough Technical Documentation package to obtain CE mark for your medical device.

Introduction to Medical Device Software

Increase your understanding of medical device software lifecycle processes, classification rules and development activities to meet regulatory requirements.

Technical Documentation for the MDR

This one-day intensive course increases your understanding on key requirements for technical documentation for medical devices, in accordance with the MDR.

EU Medical Device Regulation (MDR) 2017/745 – QMS Auditor

This course is designed to give you insights into how Notified Bodies may perform a MDR QMS compliance audit, using the topics of a typical MDR audit agenda as the basis.

Earn a BSI MDR qualification, validating your knowledge and expertise

bsi Medical Devices Regulation PRACTITIONER

bsi Medical Devices Regulation PROFESSIONAL

In Vitro Diagnostic Regulation (IVDR)

The IVDR replaced the IVDD and came into force in May 2017, with May 2022 as date of application.

Browse our range of IVDR courses designed to grow your knowledge and confidence in this area.

Awareness of the IVDR

Make your teams aware of how the IVDR prioritizes safety, effectiveness, and the highest standards of public health within the EU.

Requirements of the IVDR

This course is designed to increase your understanding of IVDR key requirements to place your in vitro diagnostic medical device on the market.

Implementation of the IVDR for CE Marking

Designed to guide you through IVDR requirements implementation to obtain and maintain the CE mark for in vitro diagnostic medical devices. Learn more about IVD classification rules and conformity assessment routes. Increase your knowledge on General Safety and Performance Requirements in product development, performance evaluation and clinical evidence.

Technical Documentation for IVDs

This one-day intensive course increases your understanding on key requirements for technical documentation for IVDs, in accordance with IVDR requirements whilst increasing quality.

Earn a BSI IVDR qualification, validating your knowledge and expertise

bsi IVD Regulation PRACTITIONER

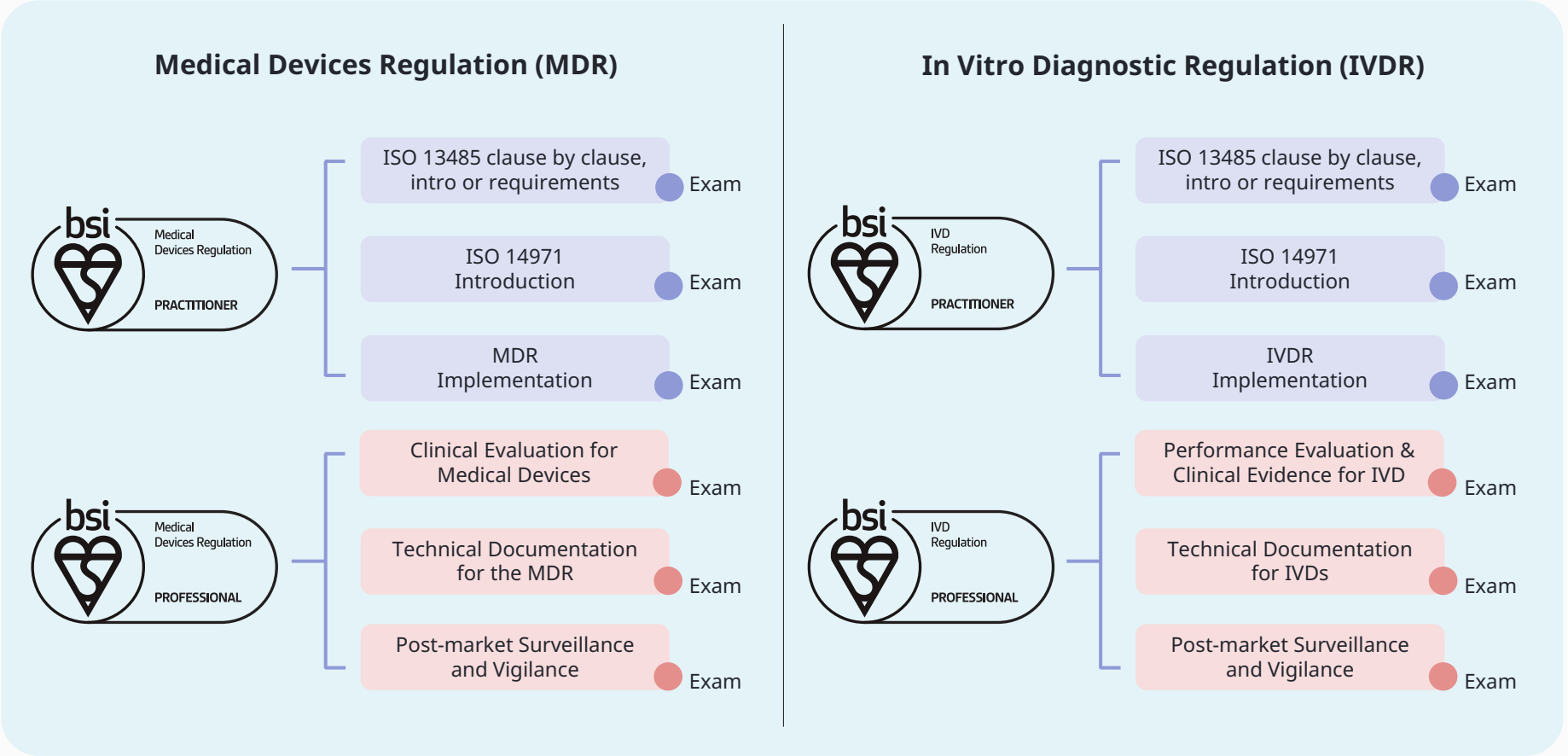
bsi IVD Regulation PROFESSIONAL

MDR and IVDR qualification pathways

Fostering high-level knowledge of the medical regulatory landscape is crucial to implementing and maintaining continued compliance with MDR and IVDR requirements.

Take a positive step towards demonstrating this competence with a BSI Medical Devices Qualification.

By using Mark of Trust, your organization's reputation and standing is enhanced, proving your high level of skills, commitment to excellence and greater expertise.



Note: Additional BSI qualification pathways are available for ISO 13485 Quality Management and more. Get in touch.

Quality Management ISO 13485

Demonstrate your ability to provide safe medical devices and services that consistently meet customer demands and applicable regulatory requirements.

Browse our range of courses and qualifications.

ISO 13485:2016 Awareness eLearning

Understand what ISO 13485 is and how it maintains patient safety. This short course considers how you are a vital piece of the jigsaw and what you can do to help your organization.

Introduction to ISO 13485 Medical Devices

Explore ISO 13485:2016 requirements and discuss key principles and its interaction with ISO 9001 and with European Regulations (MDR and IVDR).

ISO 13485:2016 Requirements eLearning

Designed to increase your knowledge on the requirements of ISO 13485:2016 Quality Management System Standard, key principles and interaction with ISO 9001:2015.

ISO 13485:2016 Clause by Clause

Increase your understanding of ISO 13485 scope, structure and requirements and identify the systems needed to implement an effective QMS in your organization.

Implementing ISO 13485:2016

Learn to effectively implement a QMS according to ISO 13485, including the key concepts to understand, develop and implement a QMS.

Internal Auditor ISO 13485:2016

Increase your knowledge on ISO 13485:2016 to increase effectiveness your organization's QMS and learn best practices to improve your QMS audit process.

ISO 13485:2016 Lead Auditor

Increase your knowledge and develop additional skills to plan, conduct, report and follow-up a compliant QMS audit.

Earn a BSI ISO 13485 qualification, validating your knowledge and expertise

bsi ISO 13485 Internal Auditor CERTIFIED PROFESSIONAL

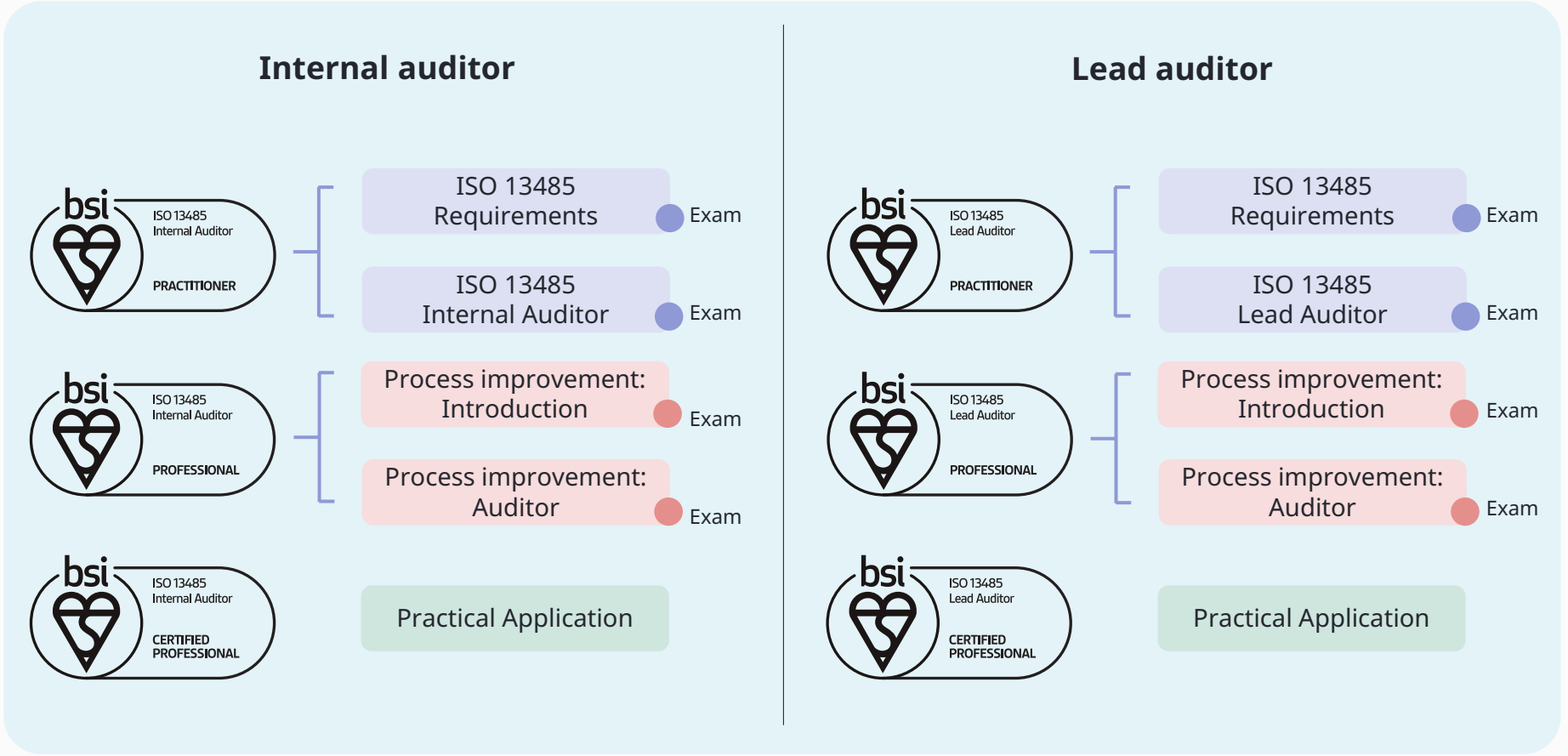
bsi ISO 13485 Lead Auditor CERTIFIED PROFESSIONAL

ISO 13485 auditor qualification pathways

Our auditor qualification pathways allow you to showcase your expertise by earning a BSI Mark of Trust.

The Mark of Trust showcases your achievements on your professional profile.

By using Mark of Trust, your organization's reputation and standing in a competitive marketplace is enhanced, proving the high level of skills, commitment to excellence and greater expertise within the organization.



Note: Additional BSI qualification pathways are available for MDR, IVDR and more. Get in touch.

CE Marking

Given the stringent and evolving regulatory requirements, to place a medical device on the market may be challenging.

Browse our range of courses designed to build knowledge and confidence in this area.

Requirements of the MDR for CE Marking

Learn about the key requirements, concepts, and the overall process for CE marking under the Medical Devices Regulation (MDR).

Implementation of MDR for CE Marking

This course will guide you through MDR implementation. Find out best practices to implement a compliant QMS and prepare a thorough Technical Documentation package to obtain CE mark for your medical device.

Requirements of the IVDR

Increase your understanding of IVDR key requirements to place your in vitro diagnostic device on the market.

Implementation of the IVDR for CE Marking

Designed to guide you through IVDR requirements implementation to obtain and maintain CE mark for in vitro diagnostic medical devices. Learn more about IVD classification rules and conformity assessment routes. Increase your knowledge on General Safety and Performance Requirements in product development, performance evaluation and clinical evidence.

Implementation of IVDR for CE Marking On-demand eLearning

This course will guide you through IVDR implementation. Find out best practices to implement a compliant QMS and prepare a thorough Technical Documentation package to obtain CE mark for your in vitro diagnostic medical device.

Specialized courses

Introduction to Pharmaceutical Good Manufacturing Practice (GMP)

This one-day course will help in gaining understanding of pharmaceutical GMP's fundamental principles and key requirements.

Pharmaceutical Good Distribution Practice (GDP)

Increase your understanding on GDP key aspects for pharmaceutical industry and on how to maintain compliance in the distribution system.

ISO/IEC 17025 Requirements for the Competence of Testing and Calibration Labs

Make your teams aware of what requirements of ISO/IEC 17025 are and why is it important to ensure good laboratory practices.

Post-Market Surveillance and Vigilance under MDR and IVDR

Increase your knowledge on the post-market surveillance and vigilance system requirements under the MDR and IVDR.

ISO 14971:2019 Risk Management for Medical Devices: Requirements

Discover the impact that ISO 14971 has on the decision-making processes in medical devices manufacturing. Learn key principles on risk management and ISO 14971 interaction with QMS standards, MDR and IVDR.

Manufacturing Process Validation for Medical Devices: Introduction to Concept and Methods

This course enables greater understanding of key requirements for manufacturing process validation for medical devices, as detailed in the European Medical Device Regulation (MDR) and ISO 13485:2016 requirements. The aim of the course is to increase your knowledge on evidence needed for manufacturing processes validation.

Clinical Evaluation for Medical Devices

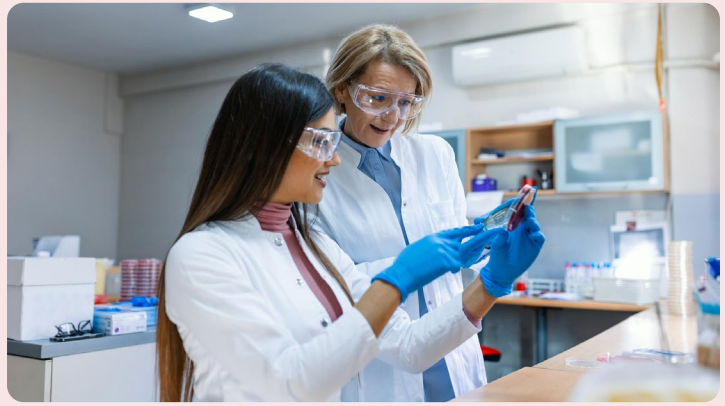
This course focuses on the clinical evaluation process including key requirements, principles, development stages, documentation, and related post-market activities. The course includes interactive activities to test your knowledge on clinical evaluation.

Medical Device Single Audit Program: fundamentals and readiness

Increase knowledge and skills required to successfully host an Medical Device Single Audit Program (MDSAP) within your organization. Gain in depth knowledge on MDSAP structure, scope, and key differences from ISO 13485 audits.

Performance Evaluation and Clinical Evidence for In Vitro Diagnostics (IVDs)

Increase your understanding of performance evaluation and clinical evidence for IVD medical devices and their interaction with product development lifecycle and IVDR requirements.



Learn in a way that works for you

Access flexible learning in a format that works for you.

We understand that people learn in different ways, so we've devised a range of delivery formats to suit all needs.

Whether you prefer learning at your own pace through distance learning or enjoy the challenge and interaction in classroom-based learning – we can provide a format you will be comfortable with.

Live online training
Learn from the comfort of your home, for convenience

On-demand eLearning
Self-paced, online, available 24/7 – for complete flexibility

Classroom-based training
Convenient location and dates, in-person with like-minded learners

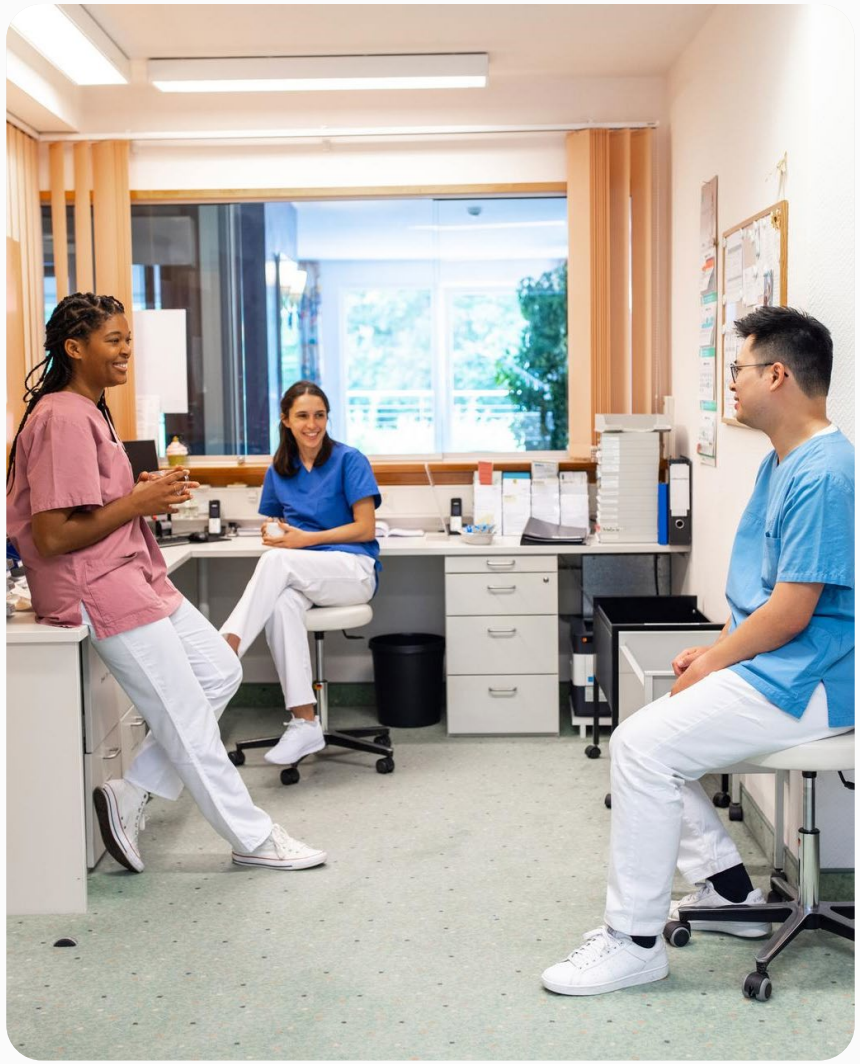
BSI benefits

- Trained 70% of the top 100 medical device companies
- Internal expertise
- Global scale
- Medical Device and IVD Regulations qualification pathways

“Very engaging, personable, and organised session. I like the real-world examples and the interactive learning.”

BSI course delegate

Progress towards your ideal future



Digital trust and information resilience

Interoperability of patient data across platforms and technologies has rapidly become an enabling aspect of healthcare provision – particularly in primary care – which is crucial to ensure seamless and connected patient pathways.

Gain the knowledge and skills you need to build resilience around information security.

Health, safety and well-being

Health, safety and well-being underpins all activity in the healthcare industry and is one of the main issues for teams at every level to address. Creating a safer workplace and reducing the levels of work-related injuries is a high priority.

Gain the competencies to minimize occupational and health risks to all.

Sustainability

A responsible healthcare organization has developed appropriate environmental, social, and governance practices. Give complete confidence to your customers, employer and supply chain that you have the desired skills in sustainability.

We can help you make a difference to issues that are important to your organization.

Quality and business excellence

Learn the systems, tools and techniques to implement (inc. lean six sigma), leading to improved organizational performance, streamlining processes, increased customer satisfaction, and competitive advantages.

Our courses and qualifications can help you in this practice area.

Browse our full range of courses