Learn in a way that works for you:

Classroom-based

Live online

On-demand eLearning

BSI Academy

Healthcare and Medical Devices training 2023

Contents

Progress towards your ideal future

At the BSI Academy, our focus is on supporting you to build knowledge and skills to add more value to your organization, whilst developing your career.

I'm proud to be part of the BSI team which provides access to impactful learning and development allowing you to develop and grow.

We look forward to support your learning journey with BSI.

Chris Wright
Commercial Learning Director, BSI Academy

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

As 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 Medtech sector.

BSI Benefits

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

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 training journey with BSI and grow your knowledge demonstrating competence and compliance with the regulatory landscape, while increasing at the same time your organization knowledge pool!

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 (MDSAP)
- A globally recognized Certification Body

Talk with us: 0345 086 9000

Medical Device Regulation (MDR) courses

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.

Hover and click on the course of your interest to be redirected to the related webpage

In Vitro Diagnostic Regulation (IVDR) Courses

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

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.

Requirements and Implementation of IVDR for CE Marking

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

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.

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ISO 13485 Courses

ISO 13485:2016 Requirements
On-Demand 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

This two-day course has been designed to provide an in depth understanding of ISO 13485:2016.

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

This two-day course has been designed to increase your knowledge on how to effectively implement a Quality Management System according to ISO 13485:2016 requirements. The course introduces key concepts to understand, develop and implement an effective QMS.

Internal Auditor ISO 13485:2016

This intensive two-day course is intended for medical device quality professionals aiming to increase their knowledge on ISO 13485:2016 to increase effectiveness of their organization QMS for internal auditing purposes. Learn best practices to improve your QMS audit process compliance to ISO 13485:2016 and ISO 19011:2018.

ISO 13485:2016 Lead Auditor

The course focuses on key principles and practices for effective Quality Management System audits according to ISO 13485:2016 and ISO 19011:2018. Experienced instructors will guide you throughout the audit process, from its management to results reporting. Increase your knowledge and develop additional skills to plan, conduct, report and follow-up a compliant QMS audit.

Introduction to ISO 13485:2016 Medical Devices

Increase your understanding of ISO 13485:2016 and its relevance for medical devices manufacturers QMS implementation. The course explores ISO 13485:2016 requirements by discussing key principles and its interaction with ISO 9001:2015 and with European Regulations (MDR and IVDR).

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CE Marking courses

Requirements of the MDR for CE

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.

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.

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.

Requirements of the IVDR

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

Requirements and Implementation of IVDR for CE Marking

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

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Specialized courses

ISO 14971:2019 Risk Management: Requirements On-demand eLearning

This on-demand intensive course is designed to increase your understanding of ISO 14971:2019 impact on decision-making in medical devices manufacturing processes.

It helps medical device professionals understand how ISO 14971:2019 can improve their business and risk management efforts.

Introduction to Pharmaceutical Good Manufacturing Practice Training (GMP)

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

This training is intended to provide learners with an introduction to pharmaceutical GMP (PIC/S), regulatory environment and product realization through market authorization, manufacturing, and lifecycle processes.

ISO 14971:2019 Risk Management for Medical Devices: Requirements

This one-day intensive course increases your understanding on the impact that ISO 14971:2019 has on decision-making processes in medical devices manufacturing. The course is intended to provide key principles on risk management and ISO 14971 interaction with QSM standards and European Regulations (MDR/IVDR).

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.

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

This one-day intensive 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.

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

Designed to increase your understanding of performance evaluation and clinical evidence for In Vitro Diagnostic medical devices and their interaction with product development lifecycle and IVDR requirements.

Pharmaceutical Good Distribution Practice (GDP)

This one-day course covers the key aspects of GDP for pharmaceutical manufacturers, wholesalers, secondary packagers, logistics companies and distributors of pharmaceutical products.

You will increase your understanding on GDP key aspects for pharmaceutical industry and on how to maintain compliance in the distribution system

Post-Market Surveillance and Vigilance under MDR and IVDR

This one-day training course has been designed to increase manufacturers' knowledge on the post-market surveillance and vigilance system requirements under the MDR and IVDR.

Remote Auditing

The course covers processes and procedures required to conduct remote audits, including the use of information and communication technology (ICT) to optimize remote audits effectiveness and efficiency while maintaining audit process integrity

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.

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.

Medical Device Single Audit Program: fundamentals and readiness

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

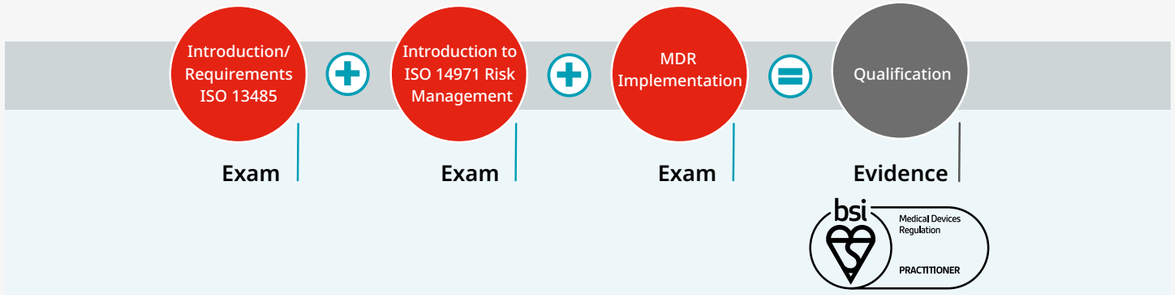
Talk with us: 0345 086 9000

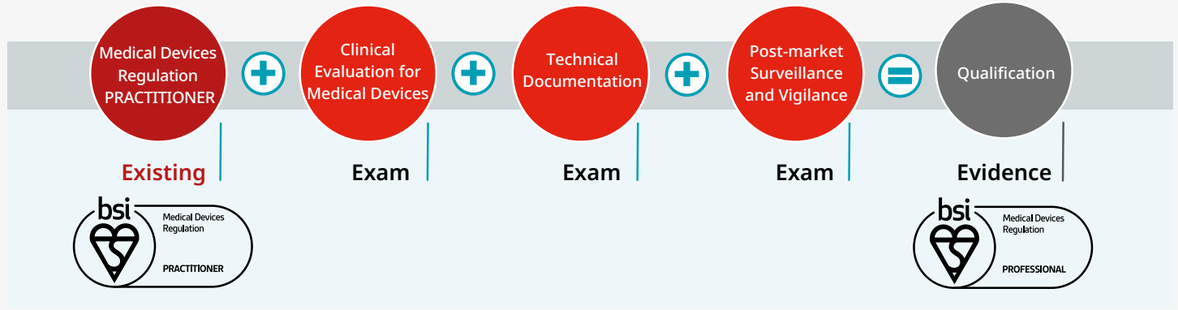
Qualifications and career pathways

BSI Medical Devices Qualifications

To foster high-level knowledge on Medtech regulatory landscape is crucial to implement and maintain continued compliance with MDR and IVDR requirements. Take a positive step towards demonstrating this competence by completing a BSI Medical Devices Qualification and obtain a recognized Mark of Trust.

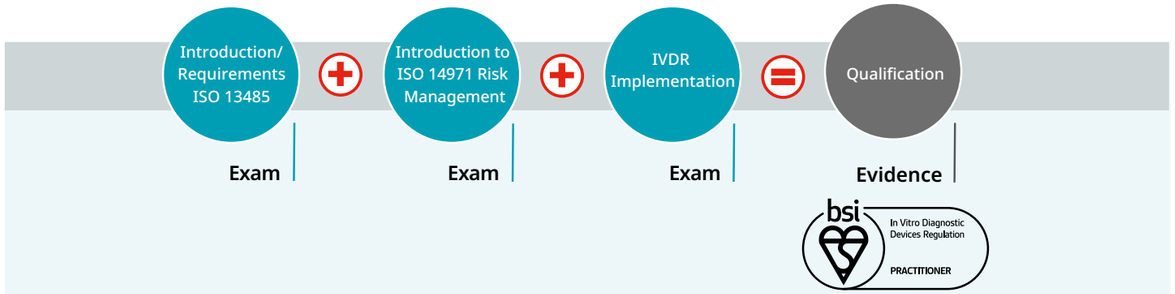
BSI Medical Device Regulation Qualifications

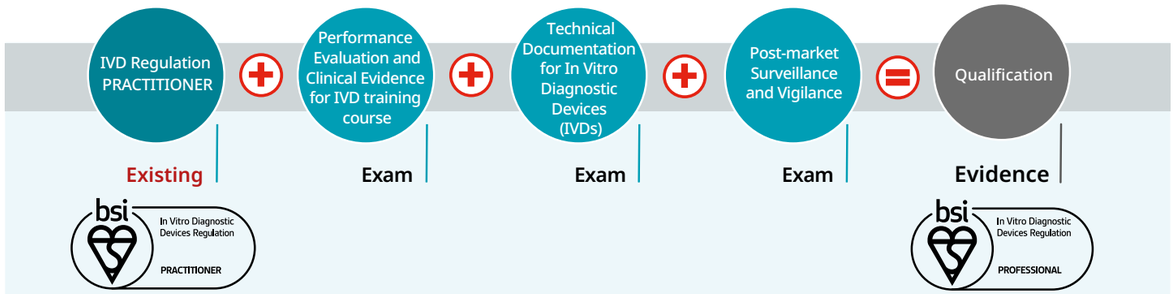




Find out how to validate your skills with a BSI qualification: bsigroup.com

BSI In Vitro Diagnostic Devices Regulation Qualifications





Auditor and Lead Auditor Qualifications available for:

- ISO 9001
- ISO 14001
- ISO 45001
- ISO 27001
- ISO 13485
- ISO 22301
- ISO 20000
- ISO 50001

View all auditor qualifications

Contact us now to talk through your requirements: 0345 086 9000

The Covid-19 pandemic has accelerated the transition to digital healthcare provision. Facing unprecedented demand, interoperability of patient data across platforms and technologies have rapidly become an enabling aspect of healthcare provision - particularly in primary care – which is crucial to ensure seamless and connected patient pathways.

With our range of digital trust courses and qualifications, we can help you gain the knowledge and skills you need to build resilience around your information security management.

New to 2023 – ISO/IEC 27001 has changed.

ISO/IEC 27001 has been updated to reflect the evolution of business practices such as remote working and has simplified how organizations map the controls for different stakeholders. Our range of courses will provide you with the knowledge required to update and manage your Information Security Management System (ISMS) when certifying to ISO/IEC 27001:2022.

Find out more

Digital trust

Information security ISO/IEC 27001

Protecting personal records and commercially sensitive information is critical. ISO 27001 helps you implement a robust approach to managing information security (infosec) and building resilience.

Cloud security

Our training helps manage cloud security risk. From cloud control implementation and auditing techniques to defining roles and responsibilities for data in the cloud, we'll help you gain confidence in cloud services.

Cyber security

Accredited training courses that can help you get the knowledge and skills needed to build resilience around information security and data management. From beginner to advanced courses, we've got you covered.

Privacy and data protection

In today's changing regulatory landscape, make sure you're best prepared to protect personal information and become a recognized privacy professional.

Digital forensics

We offer a range of specialist training courses around eDiscovery and digital forensics, to enhance your knowledge and support you to professionally develop.

Business continuity ISO 22301

Learn about a best practice framework for identifying potential threats, evaluating their impact and developing capability to minimize the impact of disruption.

Coming soon: Internet of Things (IoT) Fundamentals

Contact us now to talk through your requirements: 0345 086 9000

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. Workers can operate in high-risk environments and confined spaces or do physically demanding work so creating a safer workplace and reducing the levels of work-related injuries is a high priority.

We can support you with a range of courses and qualifications to help you gain the confidence and competencies to minimize occupational and health risks to all stakeholders.

Health and safety ISO 45001

Explore training courses covering:

- Requirements
- Implementation
- Internal Auditor
- Lead auditor
- Management Briefing

Psychological health and safety at work ISO 45003

Learn how to manage psychosocial risk across your organization as part of your overall occupational health and safety management system.

Coming soon

- Core knowledge
- Energy
- Human factors
- Management systems
- Transport
- Digital
- High hazard
- Incident management
- Occupational health
- Workplace

Contact us now to talk through your requirements: 0345 086 9000

Quality management and business excellence

Quality and business excellence training will provide you with an awareness of systems, tools and techniques to implement and audit against a variety of standards.

Improved organizational performance, increased customer satisfaction and competitive advantages can be gained through training and qualifications in this practice area.

Quality management ISO 9001

Explore courses covering:

- Requirements
- Implementation
- Auditor
- Lead auditor
- Management Briefing

Lean Six Sigma

Lean Six Sigma is a two-staged approach which drives continual improvement in organizations and strives towards greater than 99% efficiency. Learn to keep your business processes lean and boost customer satisfaction in the process.

Asset management ISO 55001

Learn about how to establish and manage an Asset Management System to improve operating results, performance and improve your bottom line.

Business continuity ISO 22301

Learn about a best practice framework for identifying potential threats, evaluating their impact and developing capability to minimize the impact of disruption.

Collaborative Relationships ISO 44001

Learn how to challenge and innovate to get the best out of partnerships and deliver real benefits – achieve greater efficiency.

Facility management ISO 41001

Looking to embed consistent and effective Facility Management? Learn how your organization can improve FM performance and manage its risks, whilst increasing quality.

Risk management ISO 31000

Whether you work in a public, private or community enterprise, you can benefit as it applies to most business activities including planning, management operations and communication processes.

Service management ISO 20000

Internationally recognized, ISO 20000 is the best practice framework for a service management system that helps you to provide a consistent, reliable service.

Contact us now to talk through your requirements: 0345 086 9000

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 and competence in sustainability.

With a BSI qualification or training course you can demonstrate that you have the aptitude to help make a difference to issues that are important to you and your organization.

New to 2023

Sustainability evaluator

Explore key topics using our sustainability evaluator to assess where you are in your journey and discover what comes next.

Get started

Carbon reduction hub

Plan the steps your organization needs to take to reduce its carbon footprint and achieve the UK's net zero goals.

Explore the hub

Sustainability

Carbon neutrality PAS 2060

Carbon neutrality means not adding new greenhouse gas emissions to the atmosphere. Discover our training in this area and help your organization on the Road to Net Zero.

Energy management ISO 50001

Learn how to establish, implement and maintain an Energy Management System using a range of technical and non-technical tools and techniques.

Environmental management ISO 14001

Environmental management is no longer a moral choice but a business necessity. An Environmental Management System helps you drive sustainable growth, stimulate innovation and gain access to new markets.

Sustainable events management ISO 20121

Sustainability Management for Events turns concepts into common sense solutions. Gain skills to design, implement and maintain a management system to deliver immediate results.

UN SDGs

This course will help you understand the purpose and gain awareness of the United Nations (UN) Sustainable Development Goals (SDGs) for your organization.

Coming soon

- Social accountability
- Energy
- Institutional governance
- Regulated qualifications
- Green finance
- High hazard
- Supply chain
- Modern slavery

Courses and qualifications in sustainability View all sustainability courses here

Governance, Risk and Compliance

Our Governance, Risk and Compliance (GRC) courses will provide you with an awareness of the processes you can implement to help your organization achieve business objectives and act with integrity.

Gain the knowledge and skills needed to embed good business practices into everyday life - enabling your organization to seize opportunities, stay ahead of uncertainty, and meet stakeholder expectations.

Business continuity ISO 22301

Learn about a best practice framework for identifying potential threats, evaluating their impact and developing capability to minimize the impact of disruption.

Risk management ISO 31000

Whether you work in a public, private or community enterprise, you can benefit as ISO 31000 to most business activities including planning, management operations and communication processes.

Facility management ISO 41001

Looking to embed consistent and effective Facility Management? Learn how your organization can improve FM performance and manage its risks, whilst increasing quality.

Modern slavery

Gain awareness and knowledge of modern slavery and modern slavery practices, introducing a risk-based approach to managing the risk of modern slavery outlined in BS 25700.

Social Accountability SA8000

Learn the fundamentals of SA8000 and how to audit, implement, or manage an SA8000 aligned management system.

Sustainability

Give complete confidence to your customers, employer and supply chain that you have the desired skills and competence in sustainability.

Delivering Inclusive Products and Services

Learn more about vulnerability and inclusion in the workplace, and be able to identify individuals in a vulnerable situation, identifying the risk factors that may give rise to vulnerability.

Remote Auditing

Discover the processes and procedures required to perform remote audits, including the use of ICT to optimize the audit effectiveness and efficiency and support and maintain the integrity of the audit process.

Contact us now to talk through your requirements: 0345 086 9000

Delivery formats

We understand that different people learn differently, so we've devised a series 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.

Classroom-based training

Classroom training gives learners access to a world class expert and the ability to ask questions in real time. It helps those who feel more comfortable learning as a group. It promotes peer to peer learning which is a very powerful tool in the learning and development sphere. The accelerated learning techniques that our tutors utilize ensure that knowledge and skills are developed throughout your learning journey.

Virtual instructor led training

With BSI's live online training, you can take the same high-quality classroom course with the same expert tutor, simply delivered in a virtual environment, regardless of where you're located.

On-demand eLearning

Our eLearning courses are great for learners that need an introduction or refresher on a particular topic. eLearning is a self-directed, interactive learning experience - at a time, place, and pace that best suits you.

Our growing eLearning offering includes:

- Implementation of the IVDR for CE Marking
- Requirements of the MDR
- ISO 13485 Requirements
- ISO 14971 Risk Management for Medical Devices: Requirements
- PAS 2060 Carbon neutrality
- BS 8001 Circular economy
- ISO 9001 Quality management
- ISO 14001 Environmental management
- ISO 22301 Business continuity
- ISO/IEC 27001 Information Security
- ISO 27002 Information security controls
- ISO 45001 Health and safety
- ISO 45003 Psychological health and safety
- ISO 50001 Energy management
- Plus, sector specific eLearning including Medical devices and Food and Retail

Distance learning

Distance learning gives learners flexibility to learn at their own pace, typically over several months. On hand are our team of expert tutors who feedback on submitted modules to support learners as they progress through the materials on their learning journey.

Adaptive learning

Adaptive learning uses state of the art AI technology and high-quality video tutorials along with personalized learning analytics to support reflective practice. Delegates have access to training materials for 12 months meaning you can learn at a pace that is comfortable for you.

Hybrid learning

Hybrid learning is an educational model where some students attend class in-person, while others join the class virtually from home using computer, video and audio technology.

Webinars

Our free webinars share relevant sector specific information to keep you informed and up to date.

Contact us now to talk through your requirements: 0345 086 9000

Why partner with the BSI Academy?

Great businesses need great people.

74%

of employees feel like they're not reaching their full potential

40%

of employees with poor training leave their job within the first year

58%

of workers say training and development is the most important workplace policy

Turn our experience into your expertise.

70%

of the top 100 medical device companies were trained by us

9/10

rating regularly awarded to our tutors

Chunfeng Li, Trauson

"We needed training on QMS requirements, so our first consideration was our Notified Body. We think BSI is professional and has expertise with ISO 13485."

Craig Hardingham, Sweco UK & Ireland

"We have a great relationship with BSI. Their collaborative approach has supported us in delivering our development – at a business level and for our people individually."

Ekaterina Serban Robert Bosch, Power Tools GMBH

"I would like to thank you for delivering a fantastic online course. The content was great and very relevant. The tutor was so enthusiastic and made the training both interesting and enjoyable!"

Denise Hoarty, Unilever

"Excellent course, all of my objectives were fulfilled. It has filled the gaps in my knowledge for implementing a QMS."

Find us on:

LinkedIn

BSI Academy
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP

T: 0345 086 9000
E: training@bsigroup.com