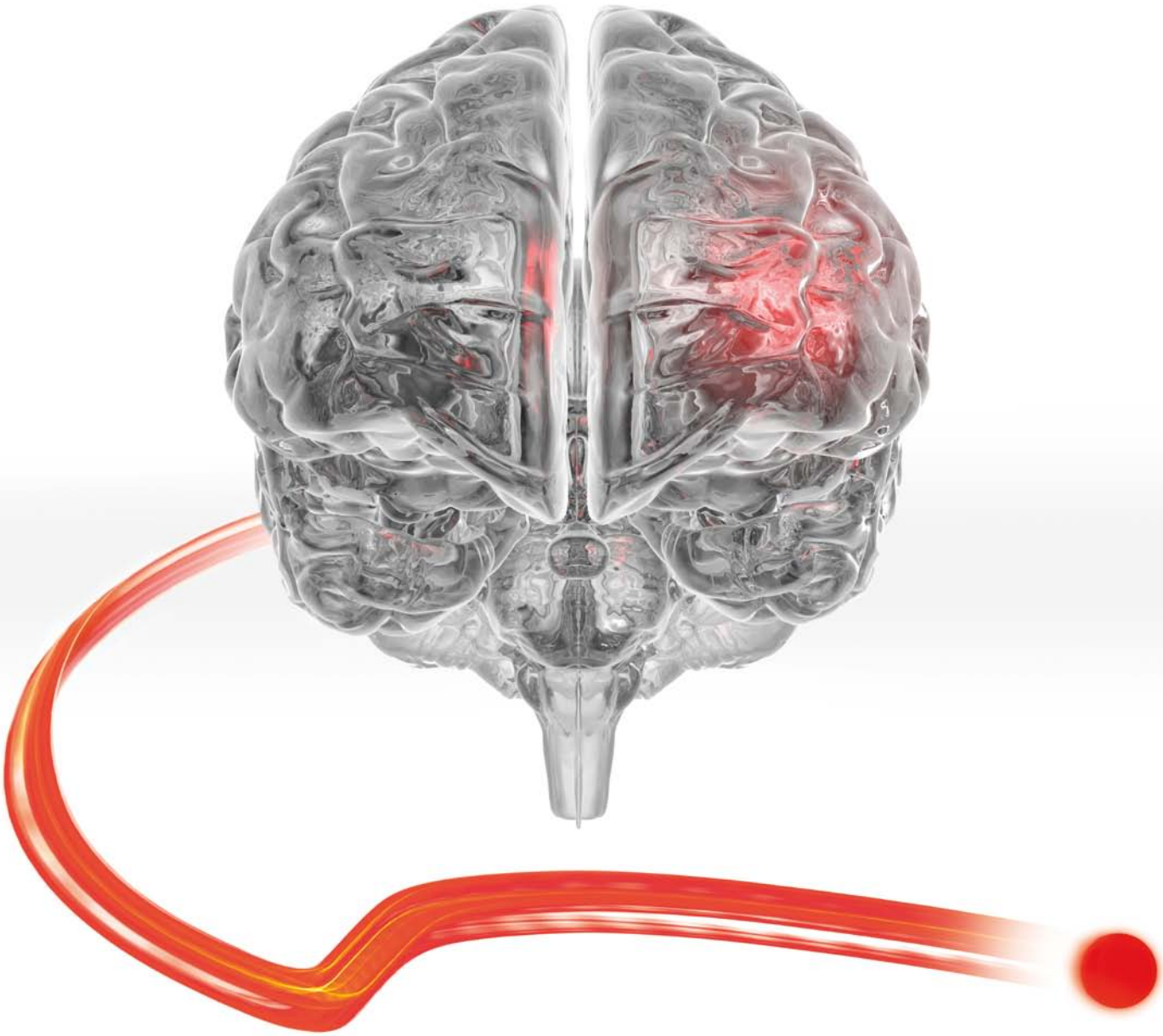


Turning our experience into your expertise

Medical devices training

bsi.

...making excellence a habit.™

A leading training academy.

Annually we train in excess of 4000 people. More than 70% of the top 100 medical device companies were trained by us and our technical trainers have a combined industry and regulatory experience of over 546 years.

- **World-leading industry subject matter experts**, over 200 BSI Medical Device product and regulation experts.
- **Course instructors are active practitioners in their subjects**, ensuring the latest developments are fully understood.
- **State of the art courses**, representing up-to-date thinking on the current and possible future interpretations of the directives, standards and guidance.
- **Accelerated learning philosophy** – you don't just sit and listen, you experience the subject. You participate in hands-on exercises, case studies, group work, mock real life situations and learning aids including photos, charts, games and quizzes.
- **On-line, public or in-house course** – its your choice. We schedule public courses for you to book onto or if you prefer to have a group of employees attend a course together, choose in-house. Courses can be customised to your requirements.
- **Cost efficient** – A BSI training course can provide you with the knowledge to save significant time and money in bringing your product to market.
- **Make excellence a habit** – BSI training will prepare you to take the excellence habit back to your business.

medicaldevices.bsigroup.com/training

Our venues

We deliver five star learning at first class venues. Venues are selected specifically to make sure you learn in the best possible environment with great facilities, refreshments and quality accommodation. This way you can focus on and maximize your learning experience. Also, any of our public courses can be tailored to your specific needs and delivered at your premises making it even more convenient for you.

99% of course delegates say they would recommend BSI. Here are some of their reasons for doing so:

- Experience and breadth of training
- Brand association
- Choice of course style
- Ease of booking
- Quality course material
- Reputable venues

Remember if you want a training course to be run at your place of work, please talk to our training team on +44 (0)845 086 9000

99% of course attendees would highly recommend BSI Training

Medical device training courses.

CE marking

Introduction to CE marking

Attend Introduction to CE marking course and start making informed decisions with regards to meeting the requirements of the EU Medical Devices Directives. On completion , you will be able to identify the steps required to reduce the risks and uncertainty in the EU regulatory process and thus bring products to the EU market more quickly.

Course duration: 1 day

Medical Devices CE marking

The medical devices CE marking course is designed to provide participants with the knowledge to assist their companies in getting products to market quickly. You will gain knowledge of the requirements of the Medical Device Directive and the CE marking approach. Participants will be able to provide leadership for their organizations when placing medical devices on the market in the European Union.

Course duration: 3 days

Introduction to CE marking for the In Vitro Diagnostics Directive

This BSI course has been designed to introduce the In Vitro Diagnostics Directive (IVDD), the types of product covered by the Directive and the regulatory framework required for placing IVD products on the European market. Participants will gain knowledge about the directive and the development of IVD products as well as their on-going maintenance to achieve continued regulatory compliance throughout the lifecycle of the product.

Course duration: 1 day

Application of the In Vitro Diagnostics Directive

Application of the In Vitro Diagnostics Directive course has been designed to enable you to explore the IVD Directive, gain a greater understanding of the requirements and thus enable your IVD devices to be placed on the European market efficiently.

You will be able to apply the requirements of the directive to create technical documentation to support the product throughout its lifecycle.

Course duration: 3 day

"This course was excellent. The tutor delivered the course at a good pace pitched at an appropriate level"

Michael Dibbens,
St Thomas' Hospital

ISO 13485

Introduction to ISO 13485 Medical Devices

BSI's Introduction to: ISO 13485 course has been designed to provide an insight in to the use of ISO 13485 as the basis for a Quality Management System implemented by medical device manufacturers. Time will be spent during the course reviewing requirements of ISO 13485 and making comparisons to ISO 9001 and the FDA's Quality System Regulation. In addition to this, participants will also gain an awareness of the relationship between ISO 13485 and ISO 14971, Application of Risk Management to Medical Devices.

Course duration: 1 day

Implementing ISO 13485 Medical Devices

BSI's Implementing ISO 13485 course has been designed to provide you with the knowledge and process steps to enable them to effectively implement a Quality Management System in line with the requirements for ISO 13485 certification. The course introduces the concepts needed to understand, develop, and implement a quality management system.

Course duration: 2 days

Internal Auditor ISO 13485 Medical Devices

BSI's Internal Auditor ISO 13485 course is intended for medical device quality professionals aiming to build on their current knowledge of ISO 13485 and evaluate the effectiveness of the quality management system in their organization. This intensive course teaches the principles and practices of effective quality management systems process audits in accordance with the ISO 13485 and ISO 19011. An experienced instructor guides students through the internal audit process, from planning an audit to reporting on audit results and following up on corrective actions.

Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, and group workshops.

Course duration: 2 days

Lead Auditor ISO 13485 Medical Devices

BSI's Lead Auditor ISO 13485 course teaches the principles and practices of effective quality management systems and process audits in accordance with ISO 13485 and ISO 19011, "Guidelines for Quality and/or Environmental Management Systems Auditing." Experienced instructors guide students through the entire audit process, from managing an audit programme to reporting on audit results. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

Course duration: 5 days

Book online at medical.devices.bsigroup.com/training or call +44 (0)845 086 9000

Specialist courses

Medical Devices Risk Management ISO 14971

This course is designed to provide participants with an understanding of the impact that ISO 14971 has on the decision making process at medical device manufacturing firms. This course helps medical device professionals gain an understanding of how ISO 14971 can improve their business and risk management efforts. Participants will also understand how ISO 14971 applies to ISO 13485.

The training includes exercises, and participants will have the chance to ask questions about how ISO 14971 and risk management apply to their organizations.

Course duration: 1 day

Writing Technical Files for Compliant Devices

BSI's Writing Technical Files for Compliant Devices course is designed to support manufactures by confirming current regulatory requirements of technical documentation. The aim of the course is to speed up the certification process and enable manufacturers to sell compliant devices within the European Union.

On completion of the training you will be able to identify and locate all regulatory requirements and guidance documentation necessary to write procedures enabling the creation and maintenance of compliant technical files and design dossiers.

Course duration: 1 day

Clinical Evaluation for Medical Devices

BSI's Clinical Evaluation for Medical Devices course is designed to support manufacturers by confirming the information necessary to demonstrate clinical safety and performance of their product in accordance with the requirements of the European Medical Devices Directive.

On completion of training, manufacturers will be able to determine if a clinical trial is required, prepare a clinical evaluation report including literature review and determine requirements for post-market clinical follow-up and post-market surveillance to support continuing compliance.

Course duration: 1 day

Post-Market Surveillance and Vigilance

Post-market surveillance including clinical follow-up, complaint and vigilance handling, impacts on all aspects of the Quality Management System. Proactive and reactive sources of information are a regulatory requirement to be incorporated in your post-market surveillance procedures applicable to all products. Obtaining the right postmarket information will ensure continued compliance with the directives and identify consumer needs enabling continued product development.

BSI's Post-Market Surveillance and Vigilance course is designed to help you identify the requirements of the European Medical Device Directives , standards and guidance documents to enable effective implementation of a post market surveillance system.

Course duration: 1 day

Process Validation for the Medical Device Industry

BSI's Process Validation for the Medical Device Industry course has been designed to help manufacturers gain awareness of quality requirements regarding validation and the nature of "special processes". Learn the generally accepted principles of validation, and introduce how-to-do methods of installation, operational, and process qualification.

Course duration: 1 day

Device-Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process

This specialized course has been designed to provide manufacturers with the knowledge and skills to interpret the requirements of the drug consultation process for devices containing ancillary medicinal substances. The course will provide guidance on how to reduce risks and uncertainty in the EU regulatory process.

The course focuses on determination of the applicable European legislation for borderline products, and provides insight into further information and guidance related to the distinction between medical devices and medicinal products. and examines devices incorporating derivatives of human blood or plasma.

Course duration: 1 day

CE marking Medical Devices with Software

When it comes to creating, testing, and maintaining software, there are often grey areas. However, when your software applies to a medical device, the steps you take to define, classify, develop, and test your software become critical to both your business and patient health. Achieving and maintaining a CE mark for your medical software is essential to keeping your product marketable.

For those organizations that are unsure how the medical device directives apply to their software, how their software is classified, and how to develop and maintain it with a CE mark in mind, this course will help you evaluate your software and processes so you can know what to do during the life-cycle of your software to meet the Medical Device Directives and get on track.

Course duration: 1 day

Medical Devices Utilizing Materials of Animal Origin: Practical Guidance on the Legislative Approval Process

This one day course has been designed to provide manufacturers with the knowledge and skills to interpret the regulatory requirements relating to materials of animal origin, including those for which a TSE risk is expected.

This course will provide guidance on how to reduce risks and uncertainty in the EU regulatory process; gain an appreciation of typical hazards associated with animal tissues & derivatives; justifications needed to use these materials and awareness of common mistakes to avoid in sourcing, collection and handling to ensure delays are minimized.

Course duration: 1 day

Fast and experienced routes into global markets.

Be prepared

In the competitive medical device market place, ensuring that product development meets all regulatory requirements is essential. Understanding and consideration of the complicated clinical and regulatory requirements early in the product lifecycle could ensure your company gains the competitive advantage. Consolidated clinical and regulatory planning will assist your company to maximise resources and minimise time to market.

Worldwide access

Our partnership approach offers a wide range of proven regulatory and quality management programmes that work together for full international compliance. Our QMS solutions include: ISO 13485, ISO 9001, ISO 14001 and many more.

BSI partner with international regulators to help you get your products approved in the USA, Canada, Japan, Australia, Hong Kong, Russia and Taiwan.

CE marking: speed-to-market

Clients work with us because we understand the challenges medical device manufacturers face in getting compliant products to market quickly.

CE-90 Standard: Our standard service, is completed within 90 days from submission, giving you predictability for accurate planning.

CE- FastTrack: Our FastTrack programmes deliver the speed-to-market you need to be competitive and move ahead of the competition. The aim is review completion in 45 days from submission with a choice of options:

- CE-45 Standard: 45 day service
- CE-Onsite: The review service is conducted at your premises, allowing for a faster time-line and dynamic communication.
- CE-Dedicated: Your review will be conducted remotely, your Product Expert will be able to arrange flexible schedules with you.

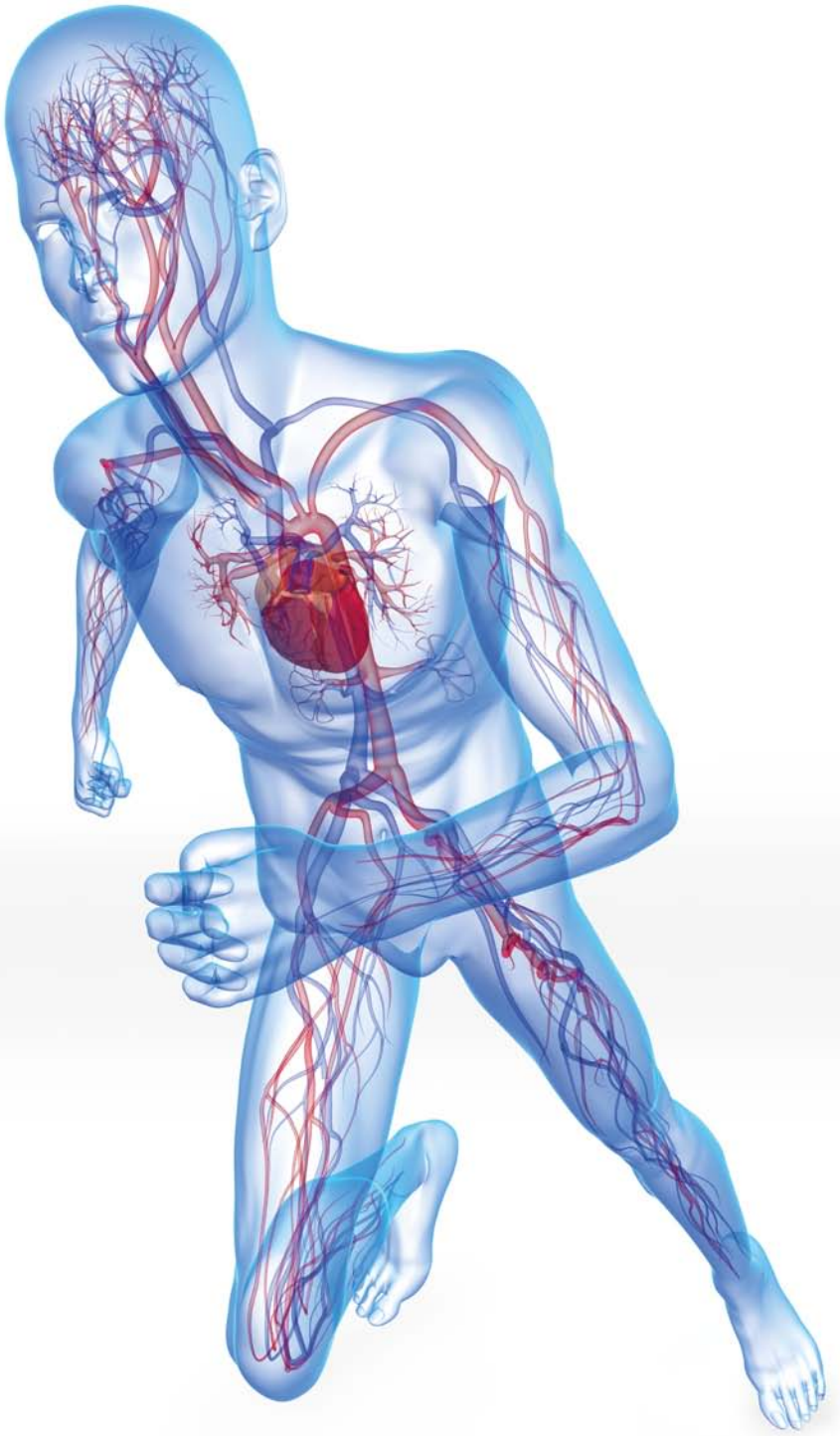
Seamless transfer to BSI

If you decide to transfer your certification to BSI, we can offer a seamless exercise with comprehensive support and the absolute minimum level of disruption. With expertise encompassing the full range of industry sectors and management system standards.

Certification support

Throughout the certification process and beyond we can continually help you by providing:

- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
  - On-line, we have an increasing number of short courses running via distance learning
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards.



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book your course now.
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ISO 13485 QMS Auditing

CE marking

Health Canada CMDCAS

Japan PAL

FDA 510k Third-Party Review Programme

FDA Accredited Persons Inspections

Australia EU CAB

Hong Kong CAB

Russian Registration Certification

Taiwan TCP

Training courses

- CE marking for AIMD, MDD and IVD
- ISO 13485 QMS
- Medical Devices Risk Management ISO 14971
- CE marking Medical Devices with Software
- Compiling and Maintaining Technical Files and Design Dossiers
- Clinical Evaluation for Medical Devices
- Device - Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process
- Process Validation for the Medical Device industry
- Post Market Surveillance and Vigilance
- Medical Devices Utilising Material of Animal Origin.

Your partner in worldwide compliance: Call BSI today on +44 (0)845 086 9000 or visit medicaldevices.bsigroup.com – to start your partnership

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