Quality Management System (QMS) Certification

Understanding Medical Device QMS Certification

Medical device manufacturing is one of the most regulated sectors in which significant quality systems and product requirements must be satisfied. The regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose.

"Successfully certified organizations are able to demonstrate the effective interconnectivity of their processes. It is essential to be able to demonstrate how outputs from complaints, for example, feed into management review, improvement processes, Technical Documentation and risk management updates, to name a few."

Teresa Perry
Global Quality and Accreditation Manager – Medical Devices

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...making excellence a habit.™

Introduction to a medical device QMS

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

What is ISO 13485?

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 previous version of ISO 9001, ISO 9000:2008 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; therefore it is more prescriptive in nature and requires a more thoroughly documented QMS.

ISO 13485 was written to support medical device manufacturers in designing a QMS that establishes and maintains the effectiveness of their processes. It ensures the consistent design, development, production, installation and delivery through to disposal of medical devices that are safe for their intended purpose.

BSI's approach to excellence

BSI selects and recruits professionals to conduct ISO 13485 audits. Candidates must have design, manufacturing or process knowledge in addition to general knowledge on use of medical devices. Our assessment staff come to BSI with exceptional real industry experience. They then go through rigorous internal training and BSI qualification processes including best practice quality systems auditing techniques, understanding critical manufacturing processes and interpretation of regulatory compliance expectations.

BSI auditors are experts in current state-of-the-art and are constantly trained on new requirements and future changes. BSI is always looking ahead to ensure that our clients are prepared and well placed for future changes to compliance and the regulatory landscape

"As I look over the 20 years that 3M Unitek and BSI have worked together, it has been a very satisfying part of my career. The professional and collegial atmosphere BSI brings to these audits strongly encourages us to want to continually improve our quality management system. Please convey my great appreciation to you and your colleagues for this."

Jerry Horn, PhD
Manager, Quality and Regulatory
3M Orthodontic Products

A medical device manufacturer's quality management system is the foundation for maintaining regulatory compliance, driving improvement and effectiveness, and achieving stakeholder confidence in the manufacturer and their products.

High performing organizations expect ISO 13485 auditing to be thorough, competent, relevant and challenging of the manufacturers' QMS. Effective auditing provides significant benefits for the manufacturer.

The beneficial outputs of an effective audit include:

- **Meaningful feedback** on the effectiveness of the quality management system

- **Confidence in compliance** with regulations

- **Identification** of areas requiring attention

- **Detection** of areas of non-compliance and risk

- **Reporting and certification** that is valuable and recognized

Risk Management ISO 14971

Risk management is a key component and requirement for ISO 13485 certification. ISO 14971 is a risk management system standard, which was designed to be compatible with ISO 13485. It helps manufacturers meet the increasing global requirements and expectations to implement not only quality, but full risk management systems throughout the entire life cycle of the medical devices they manufacture.

ISO 14971 satisfies the risk management requirement for IEC 60601-1 for medical electrical equipment and systems. It is a helpful tool for manufacturers in identifying and controlling the risks associated with their medical devices, but also evaluating interactions with other devices. Increasingly, ISO 14971, in the footsteps of ISO 13485, is becoming an international requirement for medical device manufacturers to meet regulatory expectations globally.

Medical Device Single Audit Program

The Medical Device Single Audit Program (MDSAP) allows a single audit of a medical device manufacturer's QMS which satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations (AO), such as BSI, authorized by the participating Regulatory Authorities (RA) to audit under MDSAP requirements.

MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

A BSI MDSAP Audit can also be combined with assessment for CE and ISO 13485.

MDSAP audits can be performed by a recognized MDSAP AO, such as BSI, which has performed MDSAP audits worldwide and issued a significant number of global sites with MDSAP certifications; we are currently processing many more.

bsigroup.com/mdsap

The importance of ISO 13485

ISO 13485 is important to designers, manufacturers, and distributors of medical devices. In addition, suppliers and service providers can enhance an organization's marketability as more and more manufacturers require certification in order to do business with a vendor.

When it comes to medical device manufacturing, patient safety greatly depends on the quality and consistency of medical products, and ensuring effectiveness, control and maintenance of your QMS is critical to customers, stakeholders, patients and users, and regulatory agencies.

The value of ISO 13485 is not just in the implementation, but also in providing a tool for a thorough audit to test the effectiveness of the system. It provides the manufacturer with a higher level of confidence in the ability to consistently achieve and maintain compliance with regulatory requirements. It can also help to minimize surprises and failures which might adversely affect patient safety and damage a manufacturer's reputation.

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

By Royal Charter

When it comes to medical device manufacturing, patient safety greatly depends on the quality and consistency of medical products.

ISO 13485 and CE marking

ISO 13485 is the best internationally-accepted model a medical device organization can implement to help demonstrate compliance to laws and regulations of the medical device industry. ISO 13485 is the quality management system standard accepted as the basis for CE marking medical devices under European Directives and Regulations.

Although ISO 13485 certification is not mandatory for CE marking medical devices under the European Medical Device Directives (AIMDD, MDD, IVDD), it is harmonized, which allows the presumption of conformity to the Directives.

ISO 13485 is also not mandatory for CE marking under the European Medical Device Regulations (MDR, IVDR). Although there are currently no standards harmonized to the Regulations, ISO 13485:2016 remains a state-of-the-art document. BSI, as one of the leading Notified Bodies for CE marking, can verify medical device manufacturers' selection of the most efficient conformity assessment routes to achieve CE marking.

Where to find more information

BSI has developed a suite of materials, including webinars, whitepapers and training courses to help you understand ISO 13485.

bsigroup.com/ISO-13485

Your path to certification

BSI provides a full range of services to support your path to certification. BSI's business development team can help you and your organization fully understand the ISO 13485 certification process and its available guidelines. We provide training courses that can support you in developing you develop a thorough understanding of the complexities of complying with the standard, as well as the laws and regulations the standard helps to address.

Once a medical device QMS has been developed and implemented, a BSI Client Manager can conduct a rigorous assessment of the system against the requirements. Upon satisfactory completion, BSI will issue a certificate to the standard, which you can then use to promote your business and accredited products, providing globally-recognized evidence of your company's commitment to quality systems and maintaining patient safety.

Key activities for ISO 13485

Get top management involved

Top management involvement is a requirement for ISO 13485. Involvement must be demonstrated by providing evidence of its commitment to the standard by determining customer requirements, establishing a quality policy, and ensuring relevant, useful, and measurable objectives. Top management needs to focus on responsibility, representation, communication, and review of medical devices.

> The third revision of ISO 13485 does **NOT** align with the revised structure of ISO 9001:2015. For those medical device manufacturers who hold dual certification, you will need to be aware and plan your internal procedures to take into account the differences.

Adopt the process model

Rather than focusing on each individual clause of the standard, read the requirements in terms of inputs and outputs. ISO 13485 uses the *Plan, Do, Check, Act* methodology; each key area of the standard, such as quality system, management responsibility, resource management, product realization, and measurement, must be read in terms of inputs to the requirement (i.e. resource requirements) and outputs to the requirement (i.e. measurements). Only through careful study and understanding of the process model can you achieve this effective thinking approach.

Inputs such as the following could be considered:

- Regulatory requirements
- International or national standards
- Customer product or service requirements including:
  - usability requirements
  - customer complaints
  - feedback
  - benchmarking
  - market trends, statistics and forecast information

Examples of activities to process these inputs include:

- Design and development process
- Risk management
- Management review
- Complaint investigations
- Corrective action or preventive action

As an output, your organization can consider such things as decisions and actions related to:

- Design and development of new product
- Existing product redesign
- New or revised labelling
- Advisory notices or other actions
- Risk management reports/files
- Improvement
- Quality planning
- Policy, process or procedure revision

Conducting an internal audit

When an organization adopts ISO 13485, it commits to establishing, documenting, implementing, and maintaining a QMS, which includes a commitment to an effective internal audit program. There are four steps to conducting a complete and effective internal audit.

Plan

Planning is an important component to the ISO 13485 standard. Organizations must consider product realization, ISO 13485 in its entirety, and QMS requirements established by the organization. This is in addition to all of the activities related to the product, such as planning of the product, customer requirements, design, purchasing, production, storage, and measuring, and any additional requirements.

Do

Conducting internal audits is one of the biggest areas of non-conformity seen in support of the ongoing process over time. As costs rise and enthusiasm for an effective system fades, organizations begin to falter. However, in order to maintain an effective quality management system, an organization must press on and conduct its internal audit plan.

Check

Once an internal audit is conducted, the results are reported, and actions to correct deficiencies must be processed immediately. Any causes for non-conformities must be eliminated.

Questions to consider are:

• Have deficiencies been corrected?

• Were they corrected effectively and in a timely manner?

• Were the causes well understood and eliminated?

• Were there any trends noted in the process or in the product?

Act

The final step in conducting an effective internal audit focuses on understanding and measuring the effectiveness of the actions taken, and understanding and measuring the effectiveness of the internal audit process.

Questions to consider here are:

• Do we need more people?

• Do we have the right people?

• Are the people trained effectively?

• Are we seeing and understanding the right areas of the organization to detect the issues and corrections that will make our devices safer and prevent defects from getting on the market?

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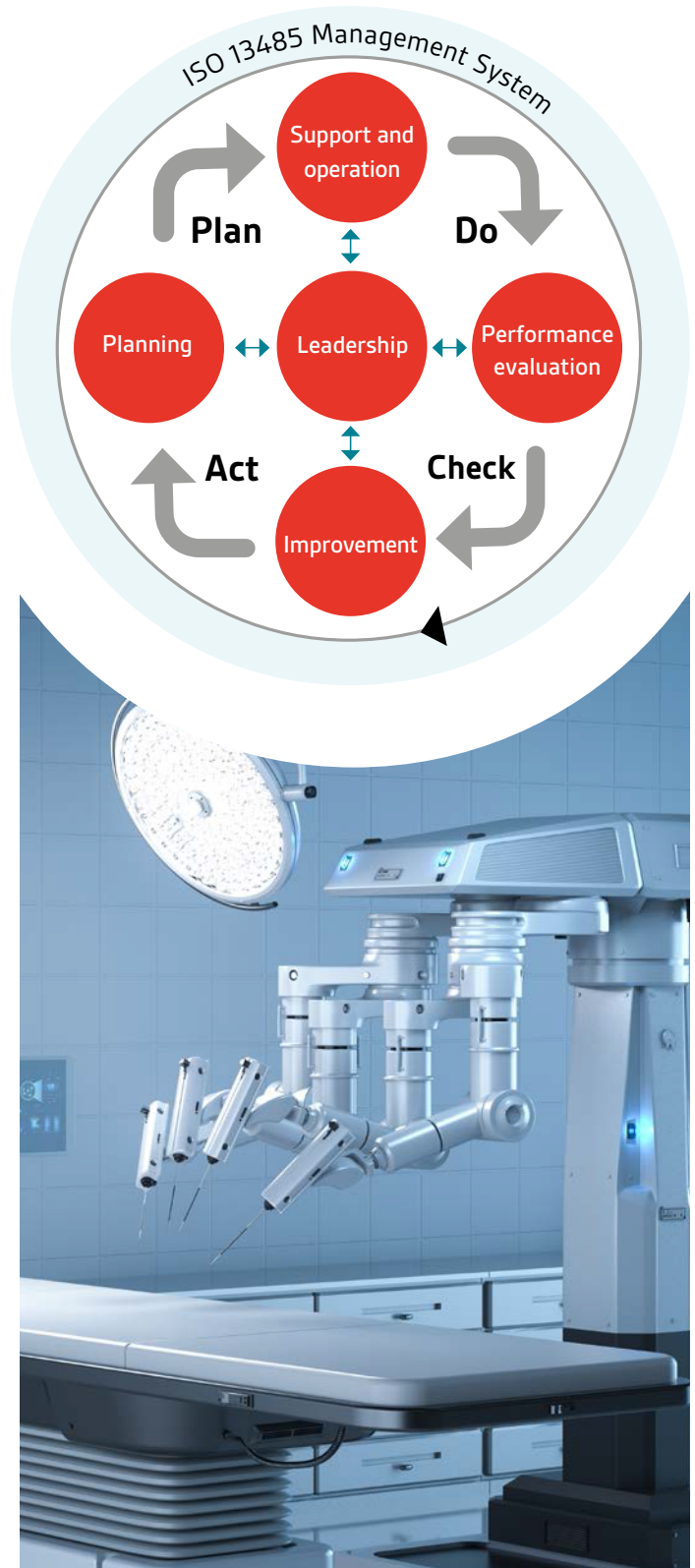
ISO 13485 training courses

ISO 13485 Clause by Clause

This course has been designed to provide an in depth understanding of ISO 13485. On completion participants will be able to apply knowledge of the ISO 13485 standard to the development an ISO 13485 compliant quality management system and to maintain on going certification of their organization.

Course duration: 2 days

Implementing ISO 13485 Medical Devices

BSI's Implementing ISO 13485 course provides you with the knowledge and process steps 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 "Guidelines for Quality and/or Environmental Management Systems Auditing." The tutor guides students through the internal audit process, from planning an audit to reporting on audit results and following up on corrective actions.

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. Tutors guide students through the entire audit process, from managing an audit programme to reporting on audit results.

Course duration: 5 days

ISO 13485:2016 Transition

This comprehensive course introduces you to the new requirements and explores the changes between ISO 13485:2003/EN ISO 13485:2012 and the latest standard.

With greater attention on the organization's ability to meet applicable customer and regulatory requirements, ISO 13485:2016 focuses on the entire supply chain of the medical device industry, with added emphasis on risk management.

You'll be able to identify the gaps in your current Quality Management System (QMS) and start planning your transition and certification to comply with ISO 13485:2016.

Course duration: half day.

ISO 13485:2016 Auditor Refresher

Are you an existing auditor with knowledge of ISO 13485 wishing to update your audit programme in line with ISO 13485:2016? This course will refresh your auditing techniques and help you prepare to audit against requirements.

With a transition period of 3 years, it's important to get up to speed so you can ensure your organization is ready to comply with new requirements. Through audit scenarios, you'll identify opportunities for improvement and build on your reporting skills.

Course duration: half day.

To book your course visit:
bsigroup.com/training
or call us on: **+91 80815 80815**

Five reasons to make BSI your Notified Body

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group is a global network of over:

5,000 people	supported by	**12,000** industry experts	in more than	**193** countries

Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

Confidence and robust reviews

Our comprehensive review process combined with our world-leading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

How can BSI support your product launch?

Be prepared

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized Certification Body in Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Talk to our experts today
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