

Quality Management  
System Certification



# Understanding Medical Device Quality Management System (QMS) certification

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The medical device manufacturing sector 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.

ISO 13485:2016 was published in March 2016. Go to our revision page to find out differences between ISO 13485:2003 and the new standard.

[bsigroup.com/ISO13485revision](https://www.bsigroup.com/ISO13485revision)

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The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a quality management system (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. Thus 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, 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 or manufacturing or process knowledge and general knowledge on use of medical devices. Our assessment staff come to BSI with exceptional real industry experience and then go through rigorous internal training and BSI qualification processes including best practice quality systems auditing techniques, understanding critical manufacturing processes, interpretation of regulatory compliance expectations.

BSI auditors are experts in current state-of-the-art requirements and are constantly trained on new requirements and future changes. BSI is always looking forward and ensuring our customers are prepared and well placed for future regulatory and compliance concerns.

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, Ph.D., Manager, Quality & Regulatory 3M Orthodontic Products



A medical device manufacturer's quality management system is the foundation for maintaining regulatory compliance, driving improvement, effectiveness and achieving stakeholder confidence in the manufacturer and their products. The requirements of ISO 13485 provide the model quality management system building blocks of success.

High performing organizations expect ISO 13485 auditing to be thorough, competent, relevant and challenging of the manufacturers quality management systems; effective auditing drives significant benefits to 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
- Confirmation that best practice is achieved
- Detection of areas of non-compliance and possible 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, and 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 not only 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) is an international initiative led by Regulatory Authorities (RA) to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that would be accepted by multiple regulators to address QMS/GMP requirements.

Health Canada announced in December 2015 the requirement for medical device manufacturers to transition from CMDCAS to MDSAP to place devices into Canada. From January 1, 2019 Health Canada will only accept MDSAP for manufacturers who market their devices in Canada, hence, manufacturers will need to transition from ISO 13485 Certification issued by a CMDCAS recognized registrar to MDSAP Certification issued by an AO.



# 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 quality management system 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 a higher level of

confidence in the ability to consistently achieve and maintain compliance with regulatory requirements. Also it can help to minimize surprises and failures which might adversely affect patient safety and damage a manufacturer's reputation.



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## 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.

Although ISO 13485 certification is not a direct requirement for CE marking medical devices under the European Medical Device Directives, it is recognized as a harmonized standard by the European Commission. Therefore compliance with ISO 13485 provides a presumption of conformity with the basic European Union (EU) quality assurance requirements for CE marking (additional EU requirements apply). 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.

### Start to plan your transition to ISO 13485:2016

Users of this key medical device standard should start planning and obtain information from their Certification Agency or Notified Body in order to begin to develop suitable transition plans.

The international working group has proposed a work plan for development of a mapping document to support users who chose to adopt new versions of both ISO 13485 and ISO 9001. There will not be an updated version of ISO 14969 - Guidance on the application of ISO 13485:2003. However, the alternative proposal is a handbook which would provide users with relevant guidance and interpretation of the requirements of ISO 13485:2016.

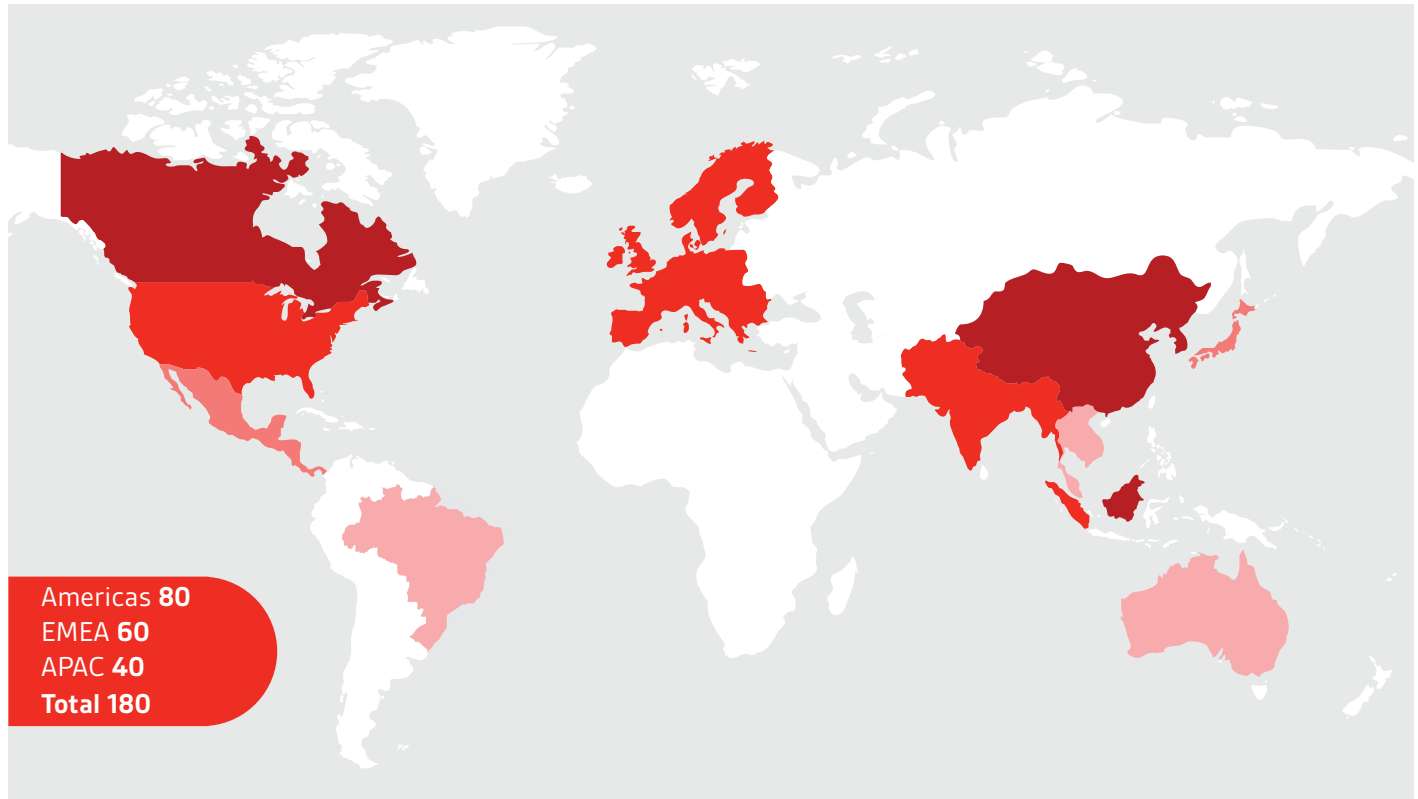
### Where to find more information

BSI is developing a suite of materials, including webinars, whitepapers and training courses to help make transition as smooth as possible.

[bsigroup.com/ISO13485revision](https://bsigroup.com/ISO13485revision)

# BSI offer you excellence locally

## Worldwide Medical Device QMS assessors

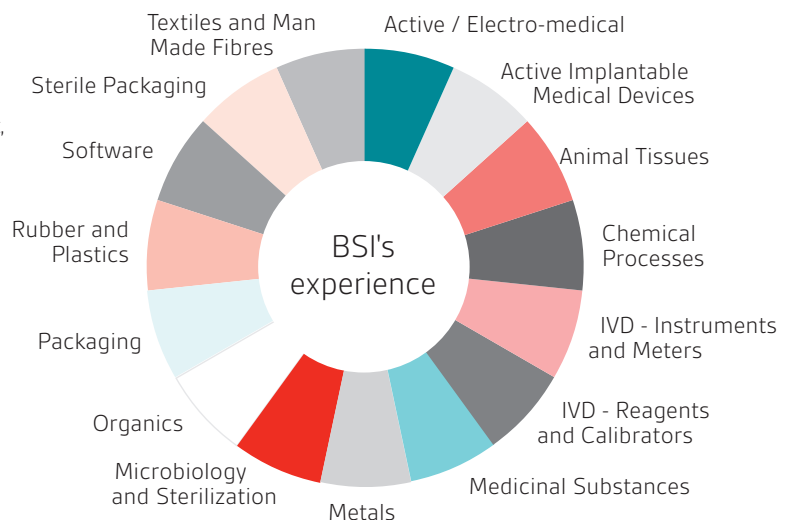


## BSI's experience

Whether a medical device manufacturer is a single site, a one-person start up or a multinational corporation, a BSI ISO 13485 Certification indicates to all stakeholders that a medical device manufacturer is not looking for short-cuts or easy routes to market, but, that they are a manufacturer fully committed to quality and compliance with regulatory requirements.

There is more concern today than ever about the integrity and regulatory value of ISO 13485 certifications. A BSI ISO Certification stands up to regulatory scrutiny, has broad recognition and a high reputation consistent with the high demands of the industry leaders who select to be certified by BSI.

BSI ISO 13485 Certification is one component of the comprehensive portfolio of quality management assurance services that BSI provides medical device manufacturers, services that include quality and regulatory training, CE marking, CMDCAS certification and MDSAP.



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# Your path to certification

BSI provides a full range of services to support your path to certification. BSI's business development staff can help you and your organization understand each phase of the assessment and certification process to ensure you fully understand the ISO 13485 certification process and its available guidelines. We provide training courses that can help 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 quality management system 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 products as an objective, accredited, and globally-recognized evidence of your company's commitment to quality systems and maintaining patient safety.

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## Key activities for ISO 13485

### Get top management involved

Top management involvement is a requirement for ISO 13485 and must be clearly 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, as well as focusing on responsibility, representation, communication, and review of medical devices.

The 3rd 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 start to consider and develop transition plans to allow for a smooth migration to the new versions of the standards.

### 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, and 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.

#### Important questions to consider for inputs are:

- Who does this process?
- How are they trained?
- What records are kept?

#### Important questions to consider for outputs are:

- How are customer concerns captured?
- How are regulatory requirements met?
- How are they summarized?
- Who receives the summary report?
- What metrics are outputs of the process?
- How are these reviewed or monitored?

# Conducting an internal audit

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

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## Plan

Planning is an important component to the ISO 13485 standard. Organizations must consider product realization, ISO 13485 in its entirety, and quality management system 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.

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## 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.

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## Check

Once an internal audit is conducted, the results are reported, and actions to correct deficiencies must be processed immediately and any causes for nonconformities 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?

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## Act

The final step in conducting an effective internal audit is focusing 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 and see the corrections that will make our devices safer and prevent defects from getting on the market?



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# ISO 13485 training courses

## ISO 13485:2016 Requirements (TPECS)

BSI's "ISO 13485:2016 Requirements" competency-based 2-day course teaches a general understanding of the concepts of the ISO 13485:2016 standard and how the requirements impact the day-to-day operations of organizations in the Medical Device industry.

**Course duration: 2 days**

## ISO 13485:2016 Internal Auditor (TPECS)

BSI's "ISO 13485:2016 Internal Quality Systems Auditor" competency-based 3-day course teaches a general understanding of the concepts of the ISO 13485:2016 standard and the principles and practices of effective internal audits in accordance with ISO 19011, "Guidelines on Auditing Management Systems".

**Course duration: 3 days**

## ISO 13485:2016 Lead Auditor (TPECS)

BSI's "ISO 13485:2016 Lead Auditor" competency-based 4-day course teaches a general understanding of the concepts of the ISO 13485:2016 standard and the principles and practices of leading management systems and process audits in accordance with ISO 19011, "Guidelines on Auditing Management Systems".

**Course duration: 4 days**

## ISO 13485:2016 Transition & Auditor Refresher Training

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

Discover the latest requirements and explore the changes since ISO 13485:2003 and EN 13485:2012. You'll refresh your auditing techniques and be able to identify the gaps in your current Quality Management System (QMS).

**Course duration: 1 day**

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**Your resource in worldwide compliance: Call BSI today on 1 800 862 4977  
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