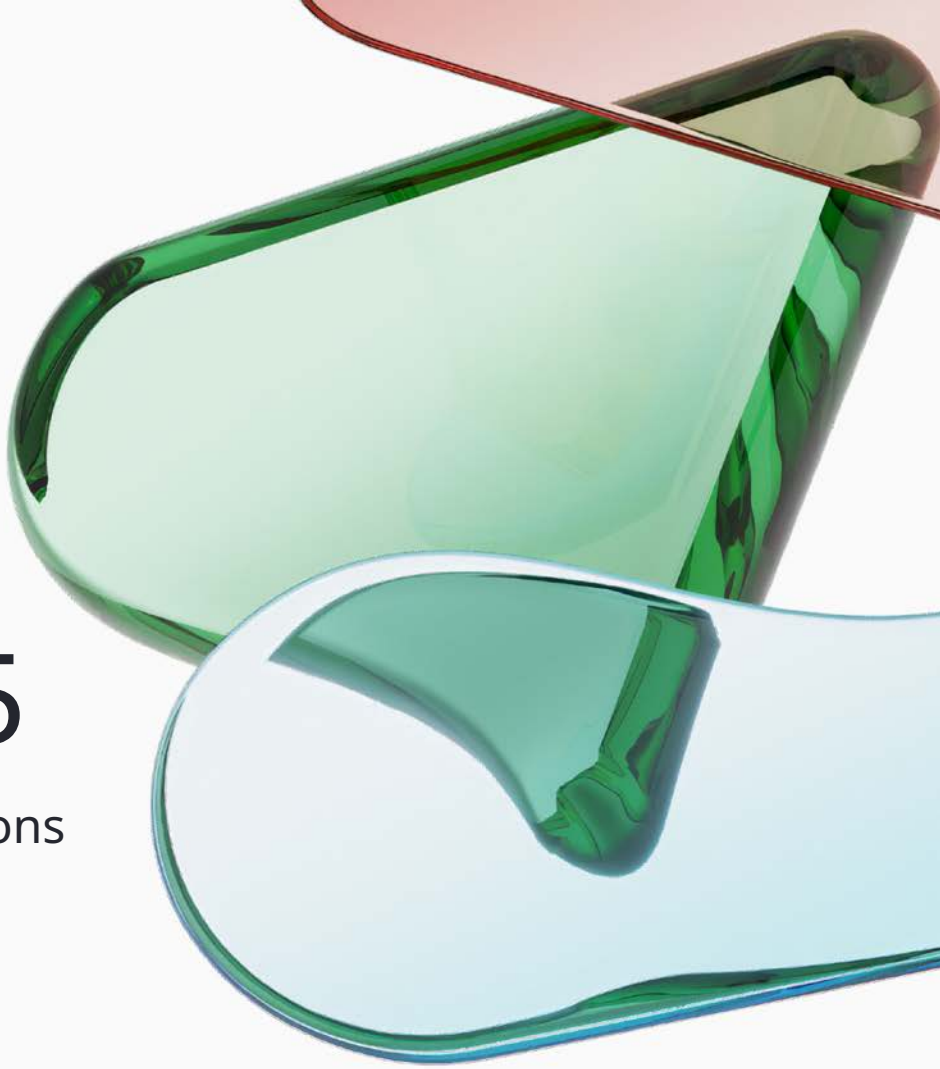
Your partner
in progress



ISO 13485

Frequently asked questions

What is ISO 13485 Quality Management System Certification?

A ISO 13485 is a harmonised internationally recognized standard that specifies requirements fora quality management system (QMS) of organisations involved in one or more stages of the life-cycle of a medical device or providers of products or services to such organisations.

It provides a framework for organisations to establish and maintain processes that ensure the consistent design, development, production, distribution, installation, servicing, final decommissioning or disposal of safe and effective medical devices, as well as requirements for suppliers or external parties producing products or services to such organisations. The supplier or external parties providing product or services to such organisations can voluntarily choose to conform to the requirements of ISO13485 or can be required by contract to do so.

As a result compliance with ISO 13485 demonstrates a commitment to safety, and quality throughout the entire product lifecycle. Adopting ISO 13485 also provides a practical foundation for your quality management system to incorporate applicable regulatory requirements, such as EU-MDR and EU-IVDR. Global jurisdictions have regulatory requirements for the application of quality management systems by organizations performing activities within a variety of roles in the supply chain for medical devices.

BSI is an accredited Conformity Assessment Body for Quality Management Systems. We conduct QMS assessments and provide certification for ISO 13485.

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How to get ISO 13485 Certified?

A Becoming ISO 13485 certified involves a number of key steps to ensure your organization complies with the standard's requirements.

After your application with BSI is completed, a QMS auditor will conduct an initial two-stage assessment of your Quality Management System:

At Stage 1

We will review the completeness of your QMS documentation to ensure it meets the requirements of ISO 13485. You will receive a report identifying any areas where the system does not meet requirements and requires corrective actions. The audit will also determine your readiness for Stage 2 and the report will include a plan for this next part of the audit.

At Stage 2

We will review the implementation of your QMS to check that it meets the ISO 13485 requirements in practice through processes and activities sampling. You will receive a report identifying any non-conformities and a recommendation for certification or for further audit in the event of major non-conformities being identified.

After the Stage 1 and 2

The audits have been completed and a recommendation is made, a BSI final review is conducted and then the certificate will be issued. ISO 13485 certification has 3-years validity and is maintained through annual surveillance audits and renewed following a successful recertification audit in the third year.

For more information about the ISO 13485 Standard, and how to become certified visit our **dedicated webpage**.

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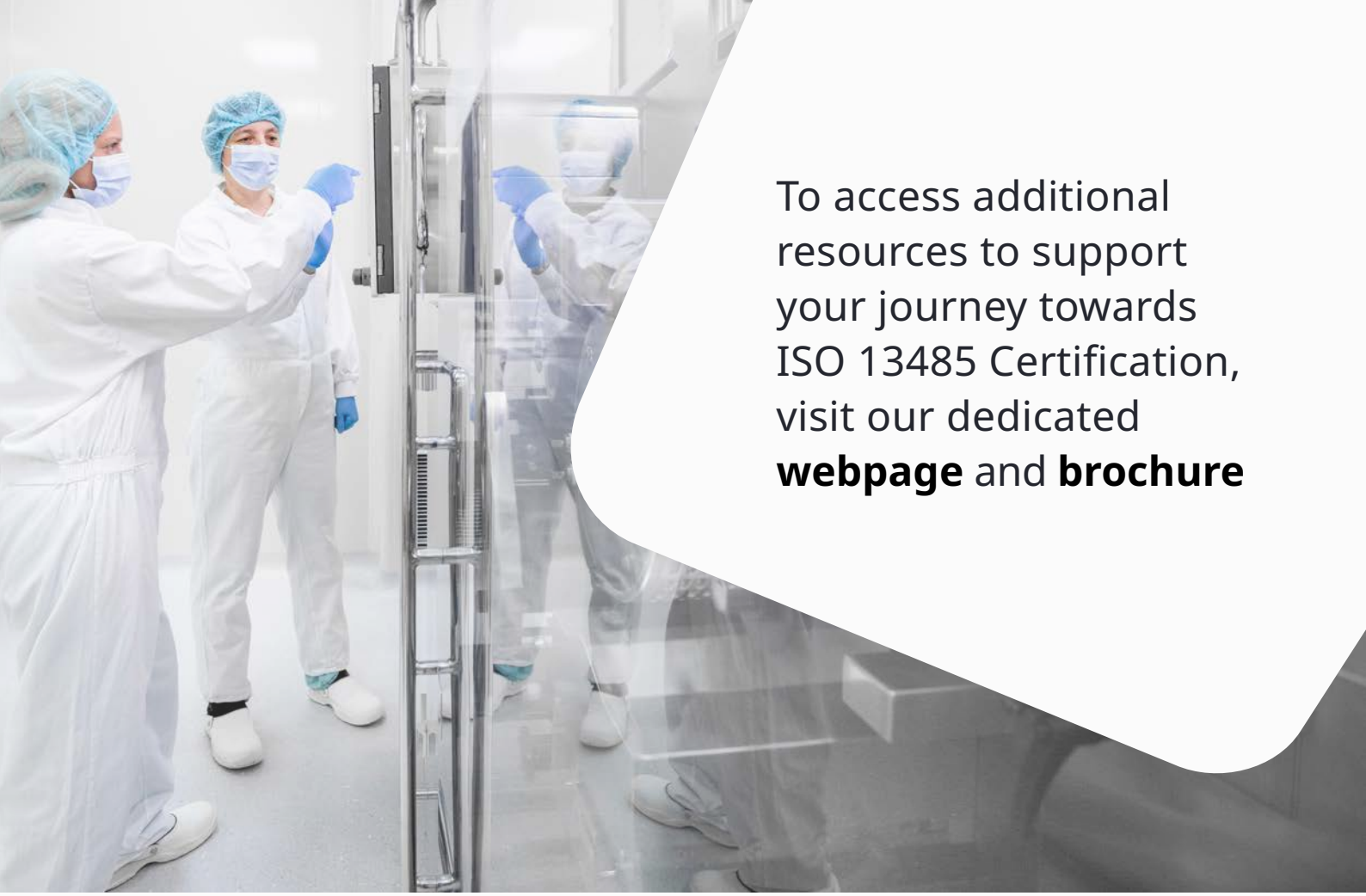


To access additional resources to support your journey towards ISO 13485 Certification, visit our dedicated **webpage** and **brochure**

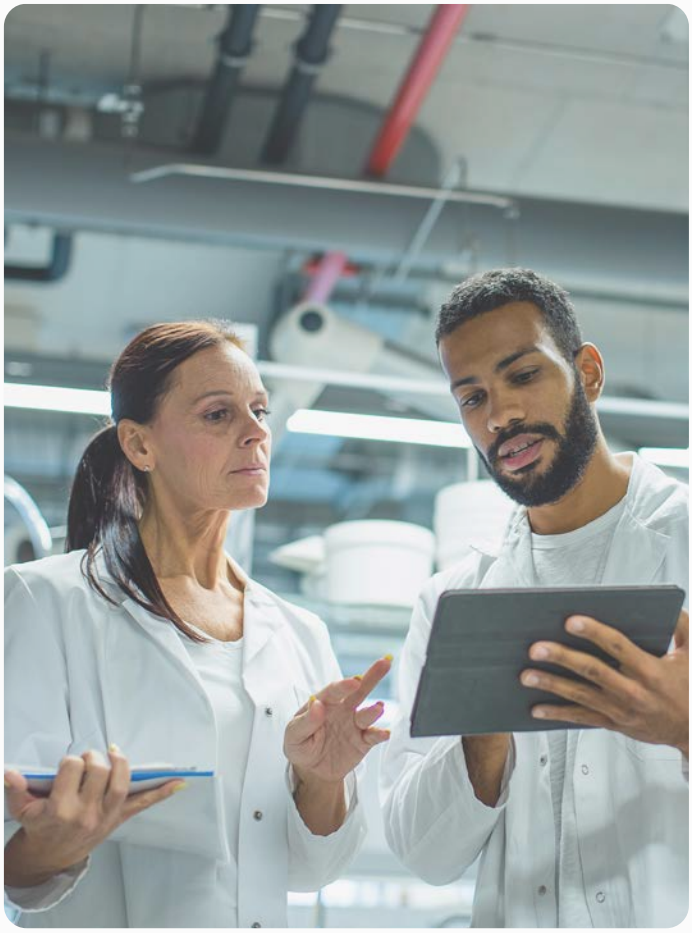
How do I implement ISO 13485?

A Implementing ISO 13485 involves creating a clear, documented process to establish a robust Quality Management System tailored to medical device manufacturing.

To implement ISO 13485, you will need to thoroughly understand the requirements of the ISO 13485 Standard to grasp its provisions and expectations.

Implementing ISO 13485 requires dedication, time, and collaboration:

To increase your ISO 13485 knowledge we encourage you to also register to BSI Training Academy **ISO 13485 courses** and to read our ISO 13485 dedicated **whitepapers**.



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How long does it take to get ISO 13485 certified?

A The timeframe to achieve ISO 13485 certification can vary depending on several factors unique to each organization. The process typically involves several stages, which include:

1 **Preparation:**
Duration varies based on your organization's initial compliance level with ISO 13485 requirements. This phase may take a few months to assess gaps and develop necessary documentation.

2 **Implementation:**
Designing and implementing the Quality Management System may take around 6 to 12 months, considering the complexity of your processes and the scale of your operations. At stage 2 audit, BSI expects a minimum of 3 months of records to demonstrate implementation of the processes and if production is included in the scope that a device or prototype has been through the full manufacturing process.

3 **Internal Audits:**
Conducting internal audits and addressing non-conformities may require another 1 to 3 months.

4 **Assessment:**
Scheduling an assessment usually takes a few months so it is important to contact your certification body as soon as you have an idea of your timescales. The duration of the assessment depends on your organization's size and complexity.

5 **Certification Decision:**
After the assessment, BSI's review and decision-making process can take around 1 to 2 months, depending if a corrective action plan is required.

In total, the entire journey from preparation to certification might span approximately 12 to 24 months. However, this is a general estimate; actual durations can differ based on your organization's readiness, resources, and the efficiency of your implementation process. We work with you to facilitate a smooth certification process within these timeframes.

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