Your partner
in progress

ISO 13485

Quality Management System (QMS)

Your pathway to
QMS certification

Medical Devices Quality Management System

ISO 13485 is the harmonized standard that medical device organizations can implement to demonstrate their ability to provide safe and compliant medical devices and related services that meet both patient needs and regulatory requirements.

Adopting ISO 13485 provides a practical foundation to address the regulations and responsibilities, as well as demonstrating a commitment to the safety and quality of medical devices. This QMS standard is critical to manufacturers but also to importers, suppliers and distributors. It enhances trust in the organization and its marketability, particularly as more manufacturers require ISO 13485 certification when outsourcing certain medical device related services.

Your Conformity journey through our expertise

BSI auditors come with exceptional industry experience, which is supported and enhanced through continued internal training and qualification processes. Our auditors' expertise remains aligned with the current state-of-the-art and evolving regulatory requirements.

Working with BSI means you have a support team throughout your journey with us, including a dedicated Regional Planner and Client Manager. This team will be your main point of contact and will handle any questions or queries you may have during your certification pathway.

Regional Planner

Works with you to plan any required visits, to make sure that you meet regulatory timelines with minimal disruption to your business.

Your Planner will assign a local Client Manager for each assessment. As we have over 200 Client Managers globally, we can match you with a manager with the relevant technical competency and language.

Client Manager

Is your assessor, or auditor. They conduct on-site audits of your QMS and assesses whether to recommend your company for certification. They also provide a report including the findings of the audit to the Decision Panel.

Additionally, your Client Manager will conduct a number of surveillance audits throughout the duration of your certification with BSI.*

*** Note:** in compliance with regulatory requirements and BSI impartiality procedures, your Client Manager will periodically change.

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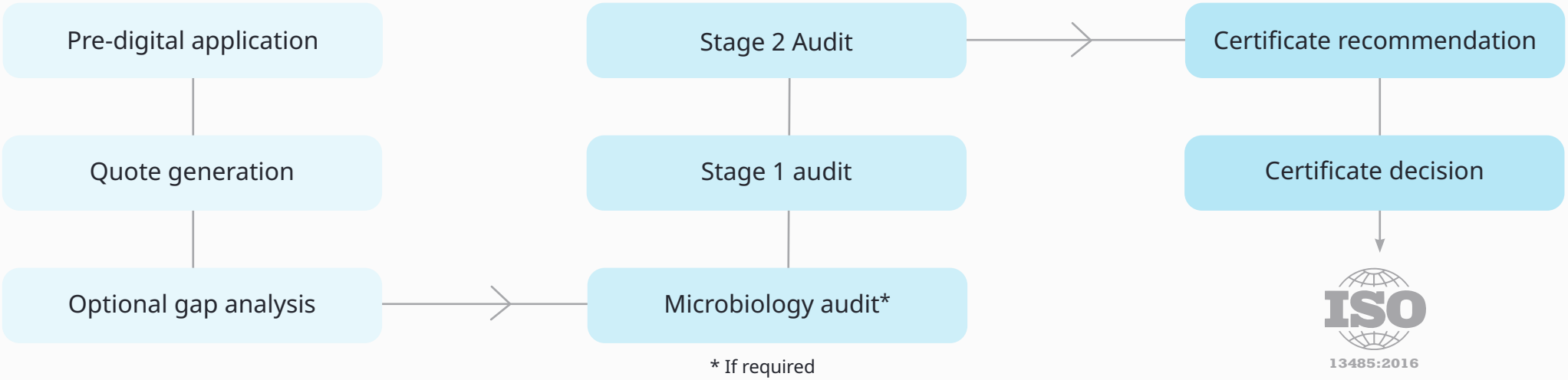
BSI ISO 13485 assessment process



* If required

There are several steps that you need to go through to achieve ISO 13485 Certification. The below details each of these steps.

Pre-digital application and quotation

After you sign the contract with us, a BSI Regional Planner will contact you to arrange the review, and you will be assigned a Client Manager.

Pre-certification assessment

While you prepare for ISO 13485 certification, BSI can conduct an optional gap analysis – also called pre-certification assessment. During this assessment, the existing processes and procedures within your organization are compared to the requirements of the standard. This helps in finding any oversights or weaknesses you can act on ahead of the Stage 1 assessment.

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Preparing your Stage 1 assessment

The period before your assessment is an opportunity to confirm that your QMS meets the regulatory requirements of ISO 13485. It is also an opportunity for you to ensure you understand the requirements, have the correct solutions in place and challenge your own processes to make sure that your systems are robust.

Stage 1 assessment

During the Stage 1 assessment, your Client Manager will review the structure of your QMS and your readiness for the Stage 2 full assessment. All findings will be discussed and summarized in an Audit Report to ensure that you are prepared for Stage 2.

Your Client Manager will perform an assessment to figure out whether you are ready for a full Stage 2 assessment. We may find areas where further work is needed ahead of the Stage 2 assessment, with the aim of ensuring that you are prepared.

During our visit, we'll summarize our findings in a report and plan for the Stage 2 assessment.

To prepare for your Stage 1 assessment, BSI offers several resources to support you:

- ISO 13485 standard and expert commentary are available on our **website.**
- You can register to **BSI Compliance Navigator** to access expert commentary and to be notified of any relevant regulatory change.
- You can visit our **ISO 13485 webpage** to access additional resources.
- BSI Academy offers a wide choice of **ISO 13485 training courses**.

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During your Stage 1 assessment, your Client Manager will:

- Make sure that you understand the standard and what it requires.
- Review your scope to ensure that it meets the requirements.
- Ensure you are ready for your Stage 2 assessment.
- Discuss and summarize their findings.

The findings will also be provided in the report, which may highlight areas that need more work ahead of your Stage 2 assessment. These are known as Non-Conformities(NCs). Receiving NCs is a normal part of the certification process and allows you to continually improve your QMS. Typically, there are around four months between the Stage 1 and Stage 2 assessments.

Non-Conformities (NCs)

NCs are raised when your QMS does not match the standard. There are two types of Non-Conformity (NC): Minor and Major.

Minor Non-Conformities: Stage 1

If you receive a minor Non-Confrormity at your Stage 1 assessment, BSI must receive a copy of your Corrective Action Plan (CAP) ahead of your Stage 2 assessment. Be aware that we will check the actions set out in your CAP have been completed at your Stage 2 assessment.

Major Non-Conformities: Stage 1

If a major Non-Conformity is identified during your Stage 1 assessment, BSI must receive a copy of your CAP. All major Non-Conformities must be effectively addressed and verified before your Stage 2 assessment can proceed.

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Preparing your Stage 2 assessment

This is the second part of your initial audit and takes place after you have successfully completed Stage 1 and addressed any nonconformities raised. Stage 2 confirms your management system is fully aligned to the standard and is fully operational within your organization. We'll evaluate the implementation and its effectiveness and make a recommendation for your formal certification.

Stage 2 assessment

During the Stage 2 assessment, your Client Manager will review the management system of your organization against the requirements of the standard. This assessment will confirm if your management system complies with the standard.

Note: If you manufacture a sterilized device, you will have to undergo a microbiology audit. This will be combined with your Stage 2 Assessment, where possible.

Your Client Manager will arrive on-site and begin with an opening meeting. Here, they will introduce themselves, discuss the process and audit agenda, and answer your questions. Your Client Manager will assess your QMS against the requirements of the standard. We will evaluate its implementation and effectiveness. They will need to observe and discuss your operational processes. The audit will end with a closing meeting, where the Client Manager will discuss the findings and outline the next steps.

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During your Stage 2 assessment, your Client Manager will:

- Gather evidence that your QMS meets the requirements of the standard, that most of the QMS has been implemented, and that it has been working for at least three months.
- Ask you to demonstrate clear monitoring, measuring, reporting and reviewing of your system against key performance objectives.
- Check that most of the manufacturing processes, including sterilization, have been verified and validated.
- Evaluate the operational control of your processes.
- Ensure internal audits and sufficient management reviews have been undertaken.
- Ensure that, where manufacturing is undertaken, at least one representative sample product or batch has passed through the full manufacturing, assembly and testing processes using the QMS established.
- Ensure most of product and process verifications and validations are complete.
- After the audit, your Client Manager will make a recommendation for the certification decision. You may need to make some final updates to your QMS after the audit. For example, additional NCs may be identified, during the Stage 2 audit which will also require a Corrective Action Plans (CAPs). Minor NCs will not delay your certification, providing you have an acceptable CAP in place. However, you must address Major NCs before BSI can issue your ISO 13485 Certificate.
- BSI will further review your organization scope to ensure it meets both the QMS activities and requirements.

Non-Conformities

Minor Non-Conformities: Stage 2

A CAP must be submitted to BSI within 15 calendar days to address Minor Non-Conformities before a decision about certifxication can be made.

It must detail the correction, root cause corrective action, timescales and functional responsibilities. This will assessed at your next visit.

Major Non-Conformities: Stage 2

If Major Non-Conformities are identified, a CAP including the correction, root cause, corrective action, timescales must be submitted to BSI within 15 calendar days. An additional assessment is then required focusing on the correction and the corrective actions taken. All Major Non-Conformities need to be addressed before a cerificate can be issued.

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Certification recommendation

On completion of a successful Stage 2 assessment, your Client Manager will make a recommendation for your formal certification. The recommendation will be made at the point of your Stage 2 assessment.

Certification decision

The Certification Panel will review the findings detailed in the audit report and decide about your certification.

Issue of ISO 13485 certificate

Assuming a positive result, BSI will issue an electronic certificate to your organization.

Post certification

Over the period of the certification cycle, we will conduct Continuing Assessment Visits (CAVs), to check that your QMS still meets the requirements of the standard.

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Continuing Assessment Visits (CAVs)

The CAV is a regular event that may be completed in stages, typically every year. Visits are planned throughout the period of certificate validity and will ensure that all elements of the QMS covered by your Stage 2 assessment are re-assessed.

Your first CAV will usually be within 10 months of your Stage 2 assessment, and then annually after that. After your first CAV, the next audit can be scheduled at the audit itself.

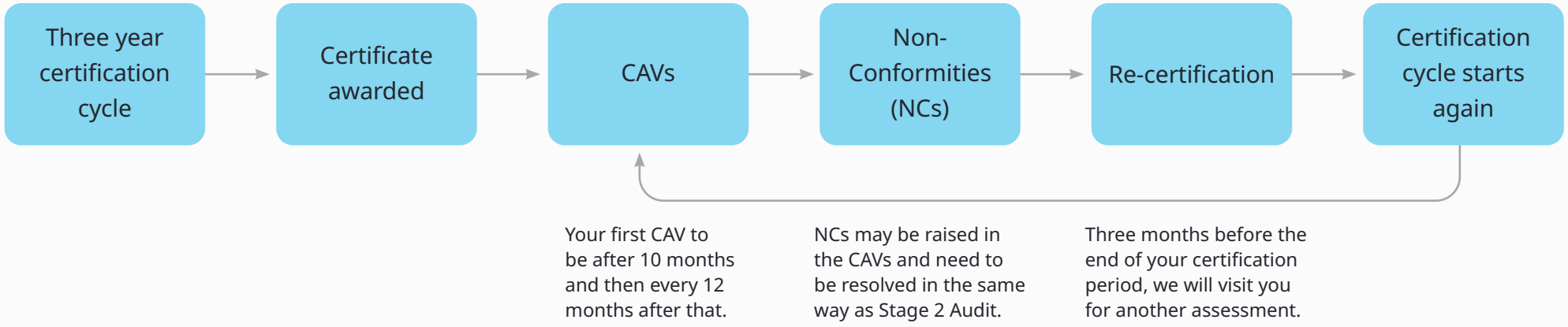
The assessments will always cover:

- System maintenance.
- Effectiveness of internal audits and follow-up actions.
- Management reviews.
- Preventative actions.
- Corrective action process.
- Customer complaints.
- Change to products, processes,system and organizational structure.

At each CAV, the following will be audited:

- Actions related to any previous Non-Conformities.
- How your QMS is performing vs. your objectives.
- The progress of new and planned activities aimed at continual improvement.
- Results from any internal audits.
- The use of marks and any other reference to certification.
- Records and processes relating to any complaint about the client that has been referred to BSI.

Certification cycle



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BSI best practice tips

1 **Objectives, scope and resources**
Clearly define and document these elements. It is essential that they are established from the outset.

2 **Top management involvement**
Early engagement of leadership, in addition to being a requirement, also significantly enhances the effectiveness of the process.

3 **Teamwork**
Key personnel across all departments must collaborate effectively and fully understand their individual responsibilities.

4 **Systems, policies, procedures and processes**
Conduct a thorough gap analysis to assess how your existing QMS aligns with the standard.

5 **Project plan**
Outline the activities and key milestones necessary for the successful implementation of the system.

6 **Adopt the process model**
Instead of focusing solely on individual clauses, interpret the requirements in terms of inputs and outputs.

7 **Collect evidence**
Ensure that sufficient documentation and records are maintained to demonstrate the effective implementation of the QMS within your organization.

8 **Conduct Internal audits**
Utilize well-trained and competent internal auditors to perform audits, enabling early identification of potential issues and opportunities for improvement.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

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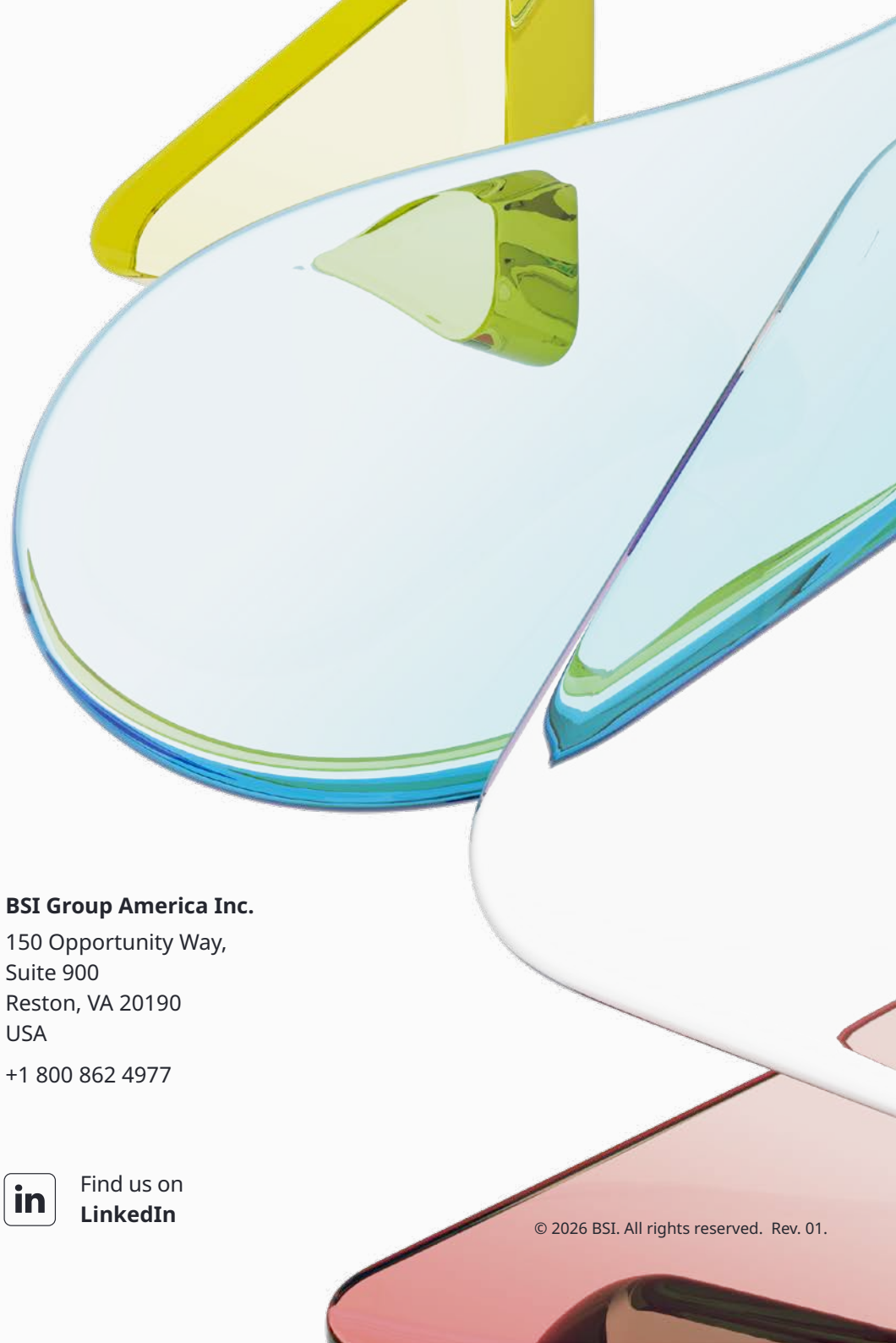

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