

ISO 7101

Management systems for quality in healthcare organizations

Self-assessment checklist

Where are you on the path to implementing your healthcare organization's quality management maturity?

An effective quality management system can support the workforce who are at the core of sustainable health and care systems. With increasing pressures, such as staff shortages, growing service demands, and rising expectations for equitable, quality care, there is a need to implement strong quality management practices.

With a mature and certified Healthcare Organization Quality Management System (QMS) in place, organizations can promote quality, health & well-being, sustainability, equity, and performance across all levels. This standard supports safe, people-centred care, and builds trust among patients, staff, and communities through implementation of co-production, continuous improvement and learning.

Introducing ISO 7101 Healthcare Organization Management

ISO 7101 is an international standard that provides a framework for establishing, implementing, maintaining, and continually improving the healthcare quality management system. It ensures your quality strategy is resilient, inclusive, aligned with service delivery goals, and prepared for future needs.

The benefits of certification

Certification to ISO 7101 demonstrates your organization's commitment to excellence in healthcare sustainability, governance, and service quality. Independent verification helps assure regulators, funders, staff, and patients that your system meets international best practices, and delivers people-centred care.



How self-assessment works

By filling in the checklist on the next few pages you can gauge what stage of maturity your healthcare organization QMS is currently at in relation to the main requirements of the standard, and what actions you can take next. No matter where you are in your healthcare quality journey, our solutions can help you move forward.

Please fill in the checklists below, each 'yes' counts as one point towards your final score and subsequent maturity range.

Snapshot of our ISO 7101 maturity scores

Early stage

0-10 Points:

Begin with ISO 7101 courses and solidify your foundational knowledge and practical skills in managing healthcare quality.

Moderate stage

11-20 Points:

Consider a BSI Gap Assessment to align your current practices with future goals, enhancing performance through standards. To achieve maturity, our courses should be key considerations.

Mature stage

21-30 Points:

Pursue ISO 7101 certification to differentiate your healthcare organization by showcasing a commitment to high-quality service delivery through a robust Quality Management System. Additionally, ongoing staff training and development will support the organization in achieving full maturity of the system.



Your healthcare QMS self-assessment checklist

Context of the organization

Yes

No

1

Has your organization identified and understood the internal and external factors that could affect its ability to achieve the intended outcomes of the healthcare QMS?

☐☐

2

Has your organization demonstrated compliance with requirements such as stakeholder mapping, management review meetings, review of agreements, action plan reports, and climate change or sustainability policies?

☐☐

3

Has your organization documented that all areas within scope operate under the central QMS, that a current statement of purpose with aims, objectives, services, and facilities is available, that quality monitoring and performance reviews exist, and that data is being tracked to support continuous improvement?

☐☐

Leadership

Yes

No

4

Has your organization documented top management discussions on workforce safety, co-production, well-being and training in confidentiality, impartiality, and privacy?

☐☐

5

Has your organization established a risk management plan with clear terms of reference, responsibilities, and authorities?

☐☐

6

Has your organization implemented a process to identify service user requirements, respond to them, and ensure compliance with mandates, laws, and regulations, supported by evidence such as patient surveys, corrective action reports, and continuous improvement plans?

☐☐

Your healthcare QMS self-assessment checklist

Planning

Yes

No

7

Has your organization developed and documented risk management plans with follow-up actions?

☐☐

8

Has your organization implemented a change management process at all applicable system levels within the scope of the QMS, supported by procedures, documents, interviews, or training records?

☐☐

Support

Yes

No

9

Has your organization established HR policies and systems that include recruitment, staffing schedules and occupational health?

☐☐

10

Has your organization documented procedures for staff induction, exit interviews, and schedules for mandatory and core training?

☐☐

11

Has your organization defined processes for communicating clinical information, managing breaches of data security, handling oral and telephone orders, and updating documents?

☐☐

12

Has your organization established procedures for identifying external partners and setting up communication channels?

☐☐

13

Has your organization documented policies for data backup, information security, risk management of IT failures, protection of documents and records, audits of clinical and nonclinical records, and the development of patient information materials?

☐☐

Your healthcare QMS self-assessment checklist

Operations

Yes

No

14

Has your organization defined processes to ensure that external suppliers meet the requirements of the QMS?

☐☐

15

Has your organization established maintenance schedules and records for equipment, machinery, and diagnostic tools that affect quality, operations, and safety?

☐☐

16

Has your organization documented the availability of potable water, ambulance services, power back-up, biomedical equipment, measuring instruments, software, reagents, consumables, medical devices, and emergency response plans?

☐☐

17

Has your organization implemented procedures for the safe handling and disposal of biowaste and toxic waste?

☐☐

18

Has your organization implemented processes to reduce waste in clinical and administrative operations?

☐☐

19

Has your organization documented procedures for services provided, patient rights, discharge notes, patient transfers, website maintenance, medicine reconciliation, and diet and nutrition support?

☐☐

Your healthcare QMS self-assessment checklist

Operations – continued

		Yes	No
20	Has your organization documented training records covering compassionate care, cultural competence, health literacy, and co-production?	<input type="checkbox"/>	<input type="checkbox"/>
21	Has your organization documented patient safety plans based on guidelines, critical incident reporting, patient identification protocols, and processes for handling ethical concerns or difficult treatment decisions?	<input type="checkbox"/>	<input type="checkbox"/>
22	Has your organization established policies and procedures for medication management, antibiotic prescriptions, operating theatre practices, anaesthetic safety, and acceptable laboratory and imaging reporting times?	<input type="checkbox"/>	<input type="checkbox"/>
23	Has your organization established infection prevention and control (IPC) policies and procedures?	<input type="checkbox"/>	<input type="checkbox"/>
24	Has your organization established procedures for preventing thromboembolism, patient falls, and pressure ulcers?	<input type="checkbox"/>	<input type="checkbox"/>
25	Has your organization established documented procedures for blood transfusions based on guidelines?	<input type="checkbox"/>	<input type="checkbox"/>



Your healthcare QMS self-assessment checklist

Performance evaluation

Yes

No

26

Has your organization identified, listed, and tracked healthcare quality indicators?

☐☐

27

Has your organization established an internal audit schedule and carried out audits?

☐☐

28

Has your top management taken an active role in the continual improvement process?

☐☐

Improvement

Yes

No

29

Has your organization defined procedures to address nonconformities and implement corrective actions?

☐☐

30

Has your organization established procedures for change management, risk management, and equipment management?

☐☐

Your score



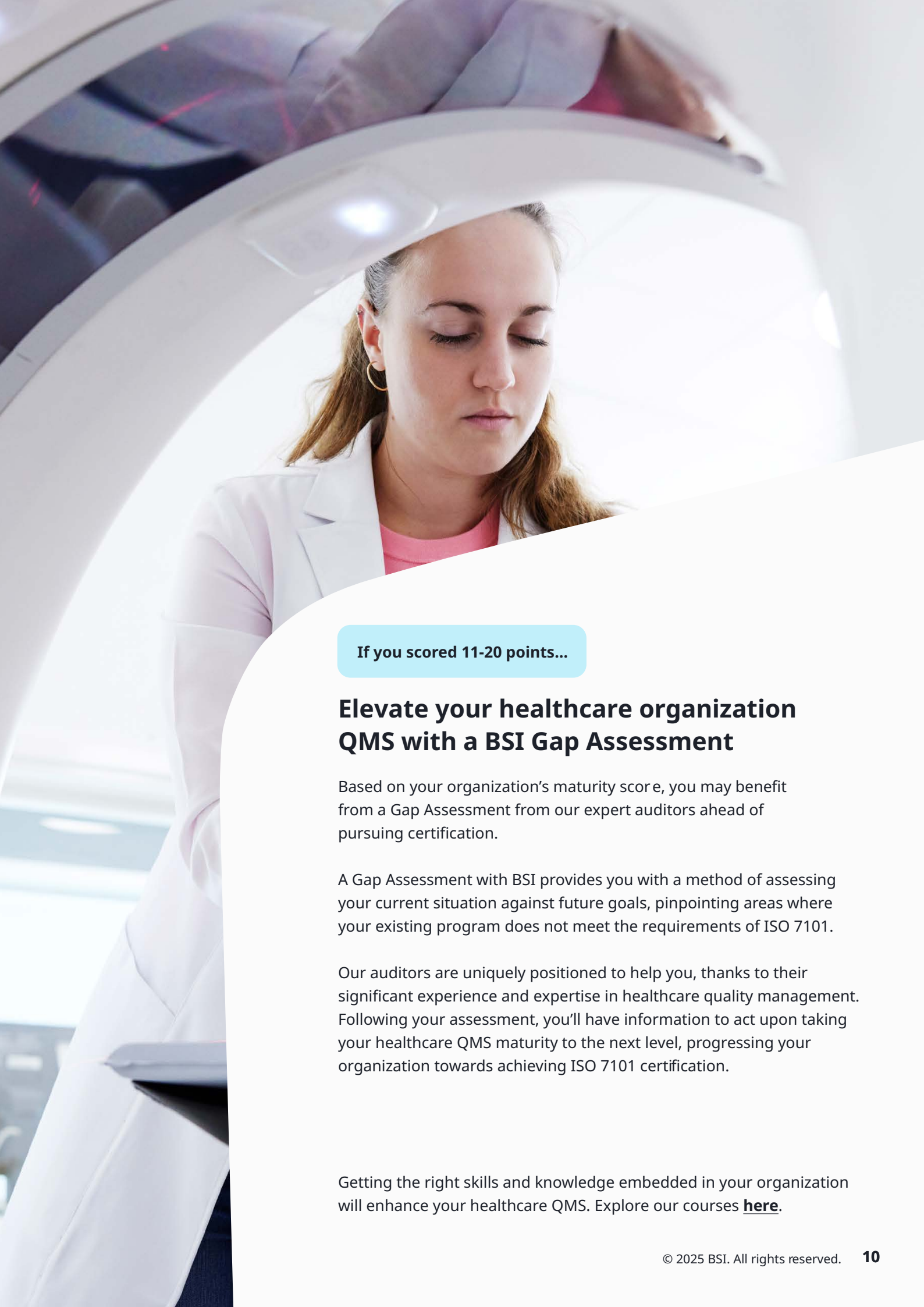
If you scored 0-10 points...

Elevate your healthcare organization QMS skills and knowledge with courses from BSI

Based on your organization's maturity score, we'd recommend exploring our dedicated healthcare QMS courses for you and your team.

Developed in conjunction with leading industry experts, our healthcare organization QMS training courses provide the most relevant and up-to-date skills and knowledge. Our courses help you to interpret and understand the standard requirements and how to audit your management system.

Wherever you are on your journey, whatever your role, we have a course to help you be more efficient at what you do.



If you scored 11-20 points...

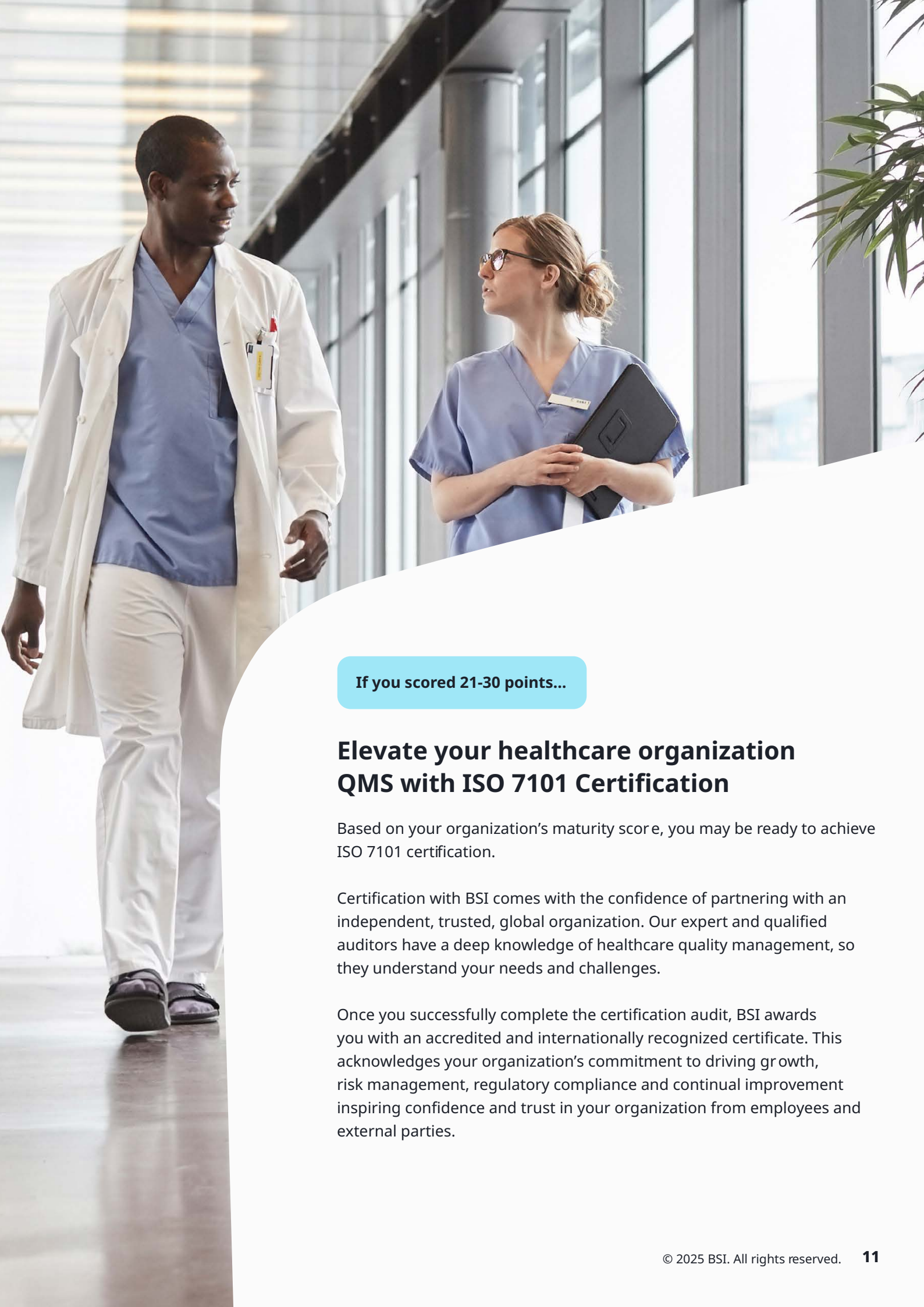
Elevate your healthcare organization QMS with a BSI Gap Assessment

Based on your organization's maturity score, you may benefit from a Gap Assessment from our expert auditors ahead of pursuing certification.

A Gap Assessment with BSI provides you with a method of assessing your current situation against future goals, pinpointing areas where your existing program does not meet the requirements of ISO 7101.

Our auditors are uniquely positioned to help you, thanks to their significant experience and expertise in healthcare quality management. Following your assessment, you'll have information to act upon taking your healthcare QMS maturity to the next level, progressing your organization towards achieving ISO 7101 certification.

Getting the right skills and knowledge embedded in your organization will enhance your healthcare QMS. Explore our courses [here](#).



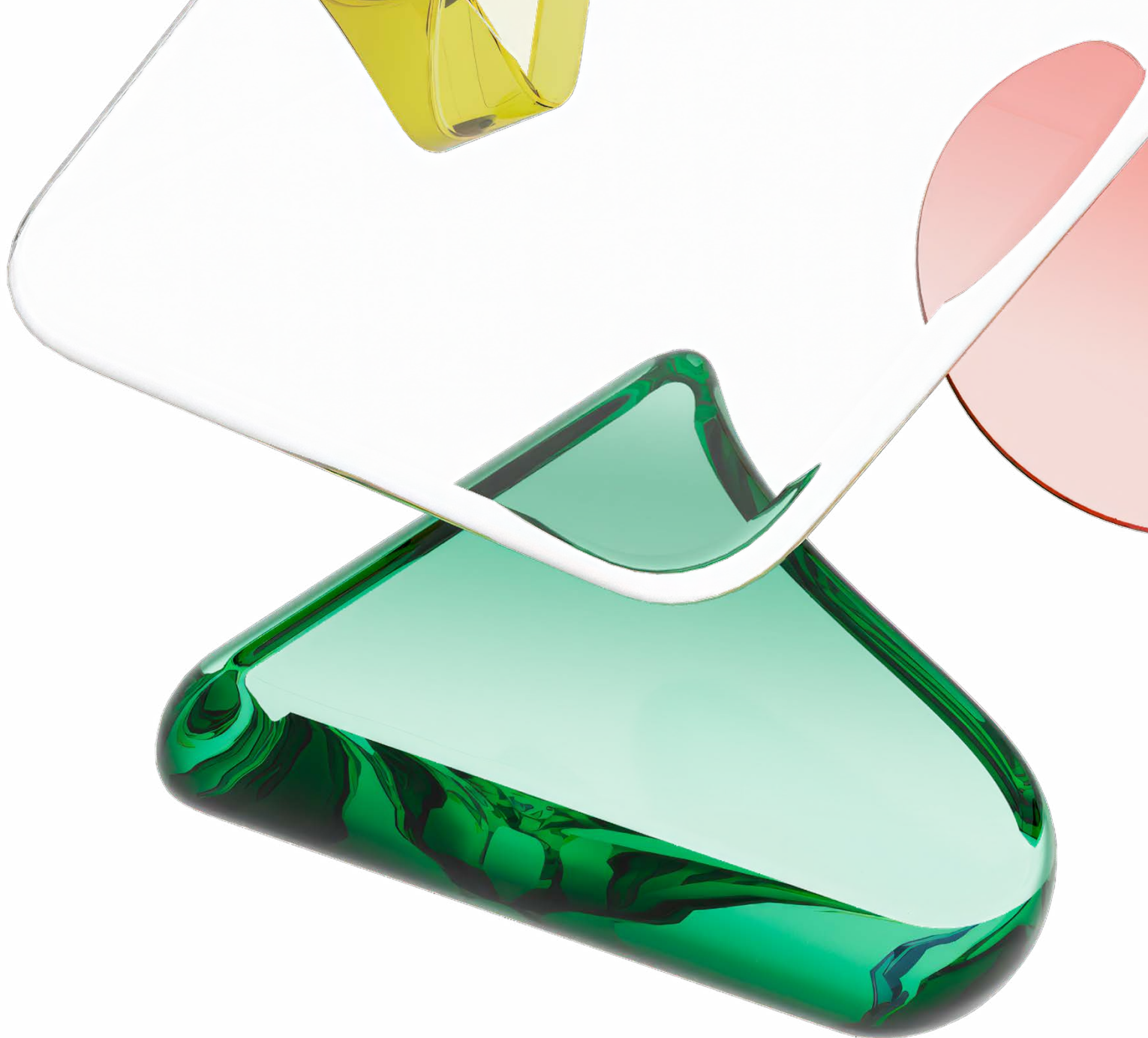
If you scored 21-30 points...

Elevate your healthcare organization QMS with ISO 7101 Certification

Based on your organization's maturity score, you may be ready to achieve ISO 7101 certification.

Certification with BSI comes with the confidence of partnering with an independent, trusted, global organization. Our expert and qualified auditors have a deep knowledge of healthcare quality management, so they understand your needs and challenges.

Once you successfully complete the certification audit, BSI awards you with an accredited and internationally recognized certificate. This acknowledges your organization's commitment to driving growth, risk management, regulatory compliance and continual improvement inspiring confidence and trust in your organization from employees and external parties.



Your partner
in progress