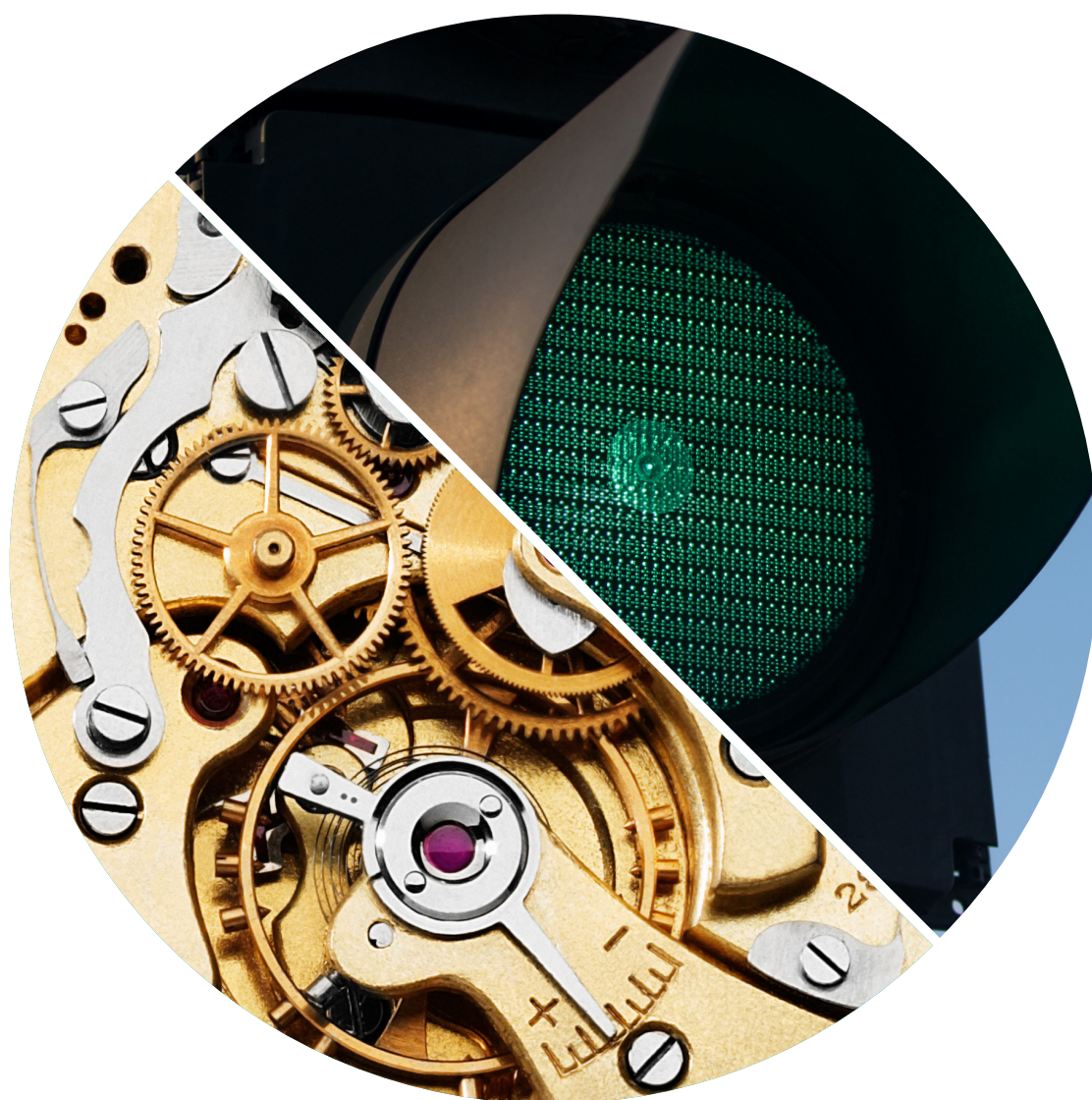


ISO 9001:2015

Your implementation guide



bsi.

...making excellence a habit.™

ISO 9001 is the world's most popular management system standard

Updated in 2015 to make sure it reflects the needs of modern-day business, **ISO 9001** is the world's most popular quality management standard. It's an excellent framework to help manage your business effectively so that you can be operationally resilient, build long-term success, and ensure customer satisfaction. It's suitable for businesses of all sizes – from manufacturing to service providers – and it's designed to be really flexible so you can make it work for the needs of your business and continually improve.

At BSI we have the experience to help make sure that you get the most from **ISO 9001**, in fact it was our experts who helped shape the standard in the first place.

This guide shows you how to implement **ISO 9001** in your business and get the most out of it for the long term. We also showcase our additional support services, which help you not only achieve certification, but unlock further business improvements after certification.

“The new version of the standard has been incredibly useful to us.”

Mark Kennedy, Programme Director, Salus

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- Benefits
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- Top tips from our clients
- Your ISO 9001 journey
- BSI Training Academy
- BSI Business Improvement Software

How **ISO 9001** works and what it delivers for you and your company

ISO 9001:2015 is the new business improvement tool that helps drive continual improvement and deliver results in your organization. It helps your business stand out, gain a competitive edge, and grow.

It's more than a quality management system, it's a complete operational tool designed to improve performance. It uses a process approach to ensure customer satisfaction and places quality right at the heart of your organization, complementing business strategy and helping enhance performance over time. This has been designed with the needs of modern businesses in mind. It provides a framework which helps you to focus on ensuring you anticipate your business environment and customer needs. It's flexible and agile so you can make it work for your business. That's how ISO 9001 really adds value.

Benefits of ISO 9001*

Better products and services

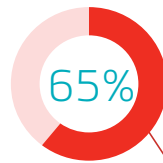


66%
Improving your products and services

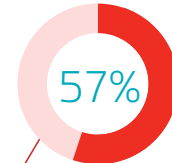


60%
Reducing the likelihood of mistakes

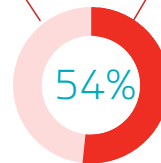
Better for business



Inspiring trust in your business



Attracting new customers



Increases your competitive edge

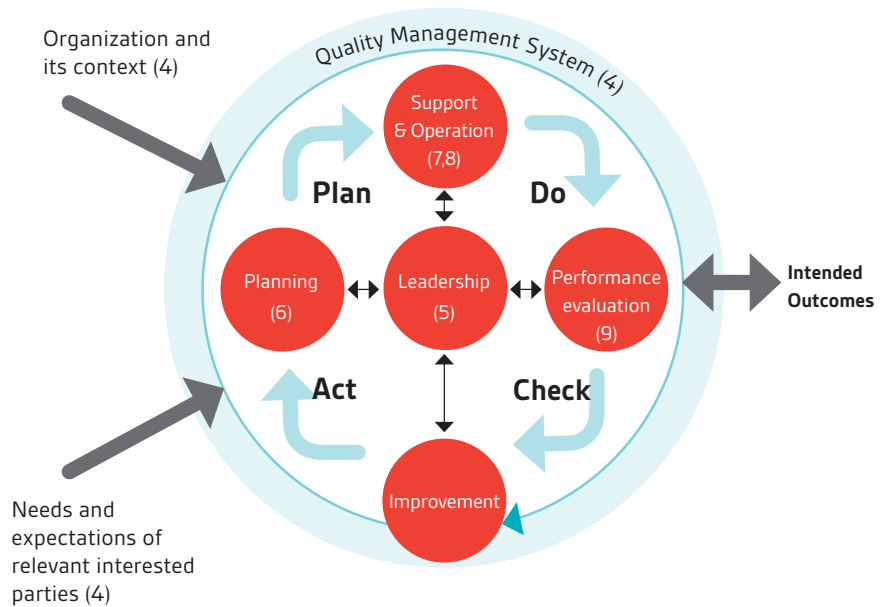


*Source: BSI Benefits survey - BSI clients were asked which benefits they obtained from ISO 9001:2008

How ISO 9001 works

ISO 9001 was revised in 2015 to bring it up to date with the needs of modern businesses and to add even more value. It's based on the high level structure (Annex SL) which is a common framework for all new management system standards. This helps keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards. It makes it easier for organizations to incorporate their quality management system, into core business processes, make efficiencies, and get more involvement from senior management.

Plan-Do-Check-Act (PDCA) is the operating principle of ISO 9001. It's applied to all processes and the QMS as a whole. This diagram shows how Clauses 4 to 10 of ISO 9001 can be grouped in relation to PDCA.



Some of the core concepts of ISO 9001:2015 are:

Concept	Comment
Context of the organization	Consider the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services, investments and interested parties.
Issues	Issues can be internal or external, positive or negative and include conditions that either affect or are affected by the organization.
Interested parties	A person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Examples include suppliers, customers or competitors. You may refer to them as stakeholders.
Leadership	Requirements specific to top management who are defined as a person or group of people who directs and controls an organization at the highest level.
Risk associated with threats and opportunities	Refined planning process replaces preventive action and is defined as the 'effect of uncertainty on an expected result'.
Communication	The standard contains explicit and detailed requirements for both internal and external communications.
Documented information	The meaningful data or information you control or maintain to support your QMS.
Performance evaluation	The measurement of quality performance and the effectiveness of the QMS, covering the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results.
Nonconformity and corrective action	Evaluation of nonconformities and correct actions.
Management review	Will need to be carried out, with requirements relating to inputs and outputs of the review.

Los requisitos clave de la norma ISO 9001:2015

Cláusula 1: Alcance

La primera cláusula detalla el alcance de la norma.

Cláusula 2: Referencias normativas

ISO 9000, Sistema de Gestión de la Calidad - Se hace referencia a los fundamentos y al vocabulario y, proporciona una valiosa orientación

Cláusula 3: Términos y definiciones

Todos los términos y definiciones están contenidos en ISO 9001:2015 – Gestión de la Calidad – Fundamentos y vocabulario.

Cláusula 4: Contexto de la organización

Establece el contexto del SGC y cómo ésta es apoyada por la estrategia de negocio. Esta cláusula es la base del resto de la norma. Proporciona a una empresa la oportunidad de identificar y comprender los factores y partes de su entorno que apoyan el SGC.

El punto de partida es identificar todos los problemas internos y externos que sean relevantes a su SGC. A continuación se deberán establecer todas las "partes interesadas" de qué formas son pertinentes a su SGC. También deberá decidir el alcance de su SGC, pudiendo ser la totalidad de su organización o funciones específicas.

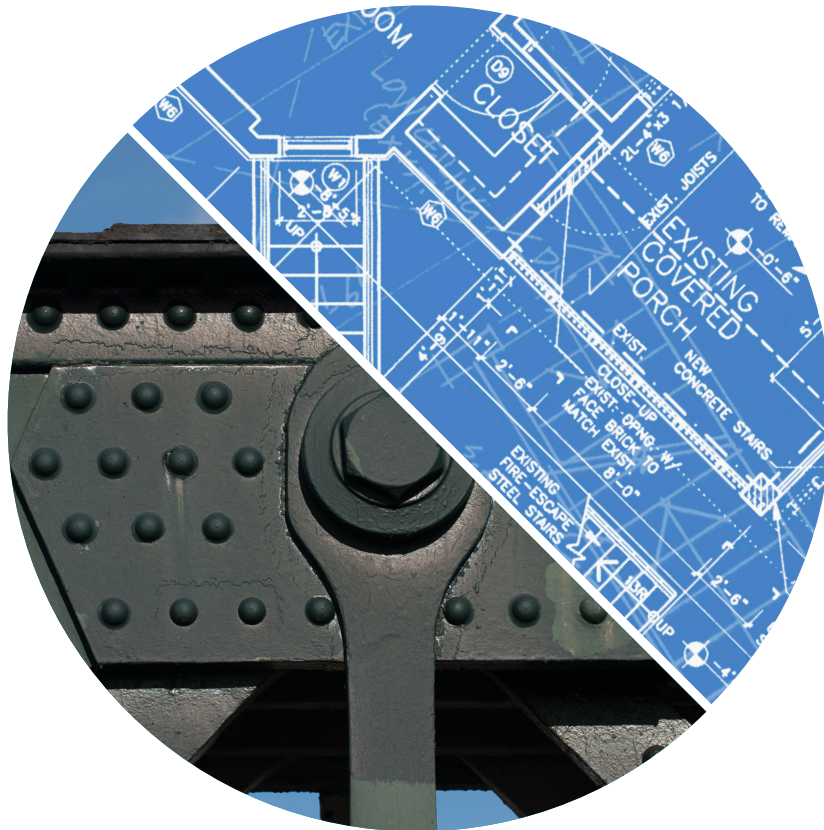
Por último, mediante la utilización del enfoque basado en procesos, necesitará mostrar cómo establecer, implementar, mantener y mejorar continuamente el SGC en relación con la norma.

Cláusula 5: Liderazgo

Esta cláusula consiste en el "papel de la alta dirección", que es el grupo de personas que dirigen y controlan su empresa al más alto nivel.

Deben asegurarse de que el SGC y sus requisitos están integrados en los procesos de la organización y de que la política y los objetivos están alineados con la dirección estratégica de la misma. A su vez tienen que asegurarse de que el SGC es accesible, comunicado, mantenido y comprendido por todas las partes.

Debido a la orientación de esta cláusula en la satisfacción del cliente, la alta dirección ha de mostrar cómo ésta es reforzada. También tendrá que indicar cuáles son las debilidades y fortalezas internas y qué impacto podrían tener en los productos y servicios. Necesitan entender cuáles son los riesgos clave asociados a cada proceso y el enfoque a adoptar para gestionar, reducir o transferir dichos riesgos. La alta dirección puede asignar responsabilidades y personas responsables para el SGC, pero serán los que en última instancia tendrán toda la responsabilidad.



Cláusula 6: Planificación

This clause focuses on how an organization plans actions to address both risks and opportunities. Consideration of risks needs to be proportionate to the potential impact they may have, and opportunities could include new product launches or geographical expansion for example.

Actions to address risks and opportunities must be monitored, managed, and communicated across the organization.

Another key area of this clause is the need to establish measurable quality objectives.

Finally this clause covers what is referred to as “planning of changes”. This has to be done in a systematic manner. For example organizations should consider who is involved, when changes are to take place, and the potential consequences of change.

Cláusula 7: Apoyo

This section of ISO 9001 is all about getting the right resources, the right people, and the right infrastructure in place to meet the organizational goals. Organizations should make sure that resources are made available to do this. It could include making training and personnel available, for example.

Organizational knowledge relating to the QMS is also covered in this clause. Personnel must not only be aware of the quality policy, but they must also understand how they contribute to it and what the implications of not conforming are.

This is where the term “documented information” is referred to. Previous versions of ISO 9001 required a quality manual, the standard no longer stipulates this. It does, however, require organizations to determine the level of documented information that’s necessary to control the QMS. There’s also an emphasis on controlling access to documented information which reflects the importance of information security.



Cláusula 8: Operación

Trata de la ejecución de los planes y procesos que permiten a una organización satisfacer las necesidades del cliente. Reconoce el aumento del uso de las funciones externalizadas y subcontratadas y contiene un requisito de establecer criterios para monitorear el desempeño de estas partes, además de mantener los registros utilizados para establecer los criterios de selección.

Esta cláusula también cubre "los requisitos para los productos y servicios". Hay un requisito para la comunicación con clientes potenciales que podría ser útil en el desarrollo de nuevas soluciones para el mercado.

Por último, hay una sección que cubre las actividades posteriores a la entrega, que podrían incluir el mantenimiento o reparación. Las empresas deben considerar los riesgos asociados a un producto o servicio, los requisitos del cliente, el feedback del cliente, y todos los requisitos legales.

Cláusula 9: Evaluación del desempeño

Consiste en medir y evaluar su SGC para asegurar que éste es efectivo y que le ayuda a mejorar de manera continua.

Será necesario considerar lo que se debe medir, los métodos empleados, y cuándo los datos deben ser analizados y reportados.

Las organizaciones han de buscar activamente información sobre la percepción de sus clientes sobre sus productos o servicios, como por ejemplo, a través de cuestionarios de satisfacción. Tendrán que llevarse a cabo auditorías internas y, hay ciertos "criterios de auditoría" definidos para garantizar que los resultados de estas auditorías se reportan a la dirección correspondiente. En último lugar tendrán que llevarse a cabo las revisiones por la dirección y se guardará como evidencia "información documentada".

Cláusula 10: Mejora

Esta cláusula requiere que las organizaciones determinen e identifiquen las oportunidades para mejorar continuamente el SGC. Uno de los requisitos consiste en buscar de manera activa oportunidades para mejorar los procesos, productos o servicios, con el cliente siempre en mente.

There are some actions that are required that cover the handling of corrective actions. Firstly organizations need to react to the nonconformities and take action. Secondly they need to identify whether similar nonconformities exist or could potentially occur.

Top tips on making **ISO 9001** effective for you

Every year we help tens of thousands of clients. Here are their top tips.

Top management commitment is key to making this a success.



“The earlier that organizations talk to senior managers, the better it will go for them so have those discussions early”.

John Scott, Overbury, leading UK fit-out and refurbishment business

Keep staff informed of what's going on, create a team or assign a champion, as this will increase motivation. This could include a well communicated plan of activities and timescales.



“When we decided to implement the new standard, we assigned an internal champion of the standard inside the organization”.

Ronald Tse, Ribose, Hong Kong cloud service provider

Think about how different departments work together to avoid silos. **Make sure the organization works as a team** for the benefit of customers and the organization.



“It's helped us mobilize all of our employees and all of our employees now understand the key metrics and the success factors. So it's helped us out in a business way and in an operational way”. Maxime Clerik, Vortex Conseils, Canadian consultancy business

Review systems, policies, procedures and processes you have in place – you may already do much of what's in the standard, and make it work for your business.



“Don't try and change your business to fit the standard. Think about how you do things and how that standard reflects on how you do it, rather than the other way around”.

Paul Brazier, Overbury, leading UK fit-out and refurbishment business

Speak to your customers and suppliers. They may be able to suggest improvements and give feedback on your service.



“It results in a more finely-tuned service to your customer, which is obviously very important to us”. Mark Kennedy, Salus, UK occupational health and return to work services

Train your staff to carry out internal audits. This can help with their understanding, but it could also provide valuable feedback on potential problems or opportunities for improvement.



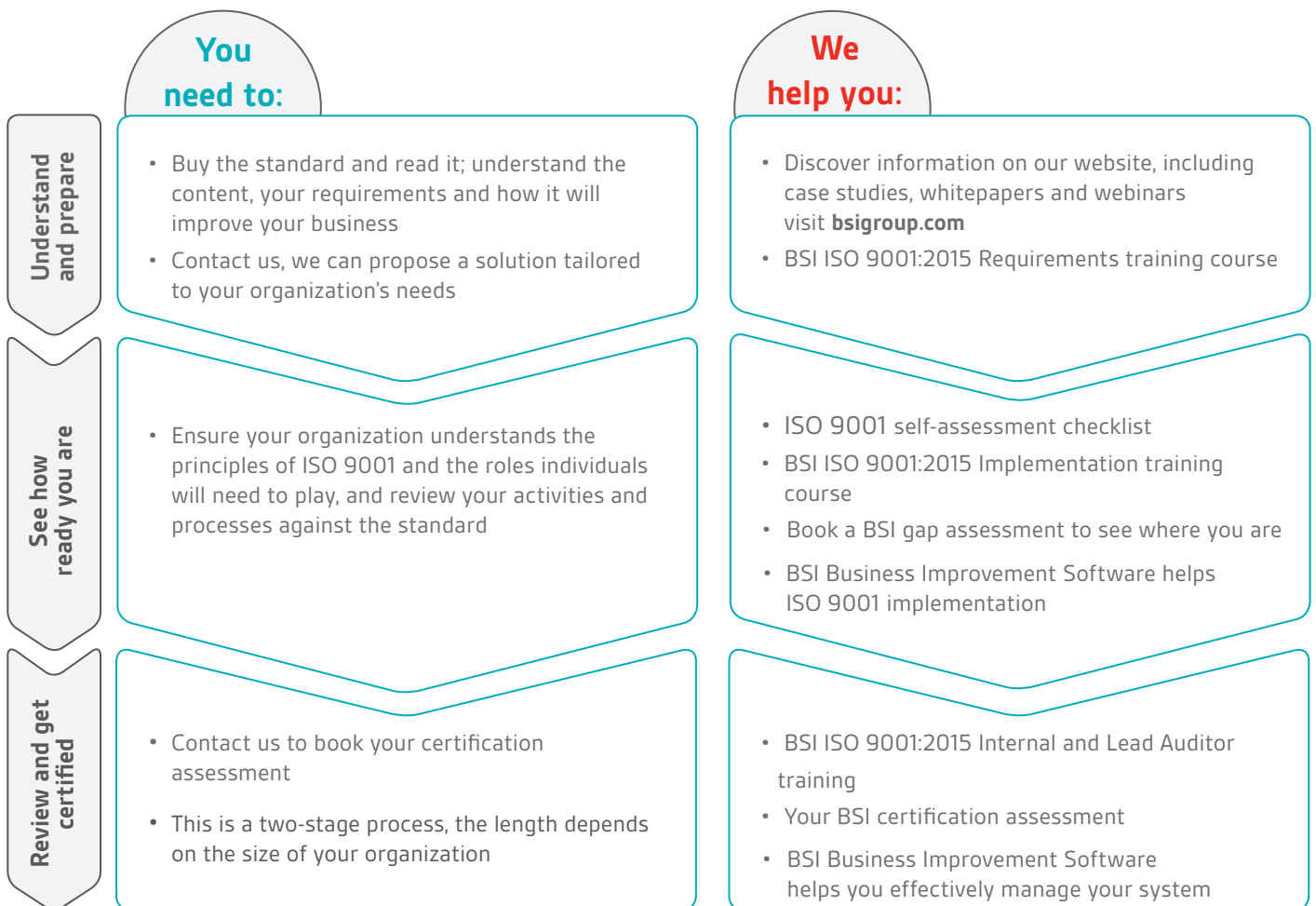
“I have previously attended the internal auditor course and since implemented a QMS for my place of work”. Claire Pressdee-Collins, Ofcom, UK communications regulator

And finally, when you gain certification celebrate your achievement and use the **BSI Assurance Mark** on your literature, website and promotional material.



Your **ISO 9001** Journey

Whether you're new to quality management or looking to enhance your current system, we have the right resources and training courses to help you understand and implement ISO 9001. But our support doesn't stop there. We can help make sure your system keeps on delivering the best for your business.



Continually improve and make excellence a habit

Your journey doesn't stop with certification. We can help you to fine-tune your organization so it performs at its best.

- Celebrate and promote your success – download and use the BSI Assurance Mark to show you are certified.
- Your [BSI Excellerator report](#) will benchmark the performance of your business and highlight where you can improve.
- [Lean Six Sigma training](#) - make your business lean and boost customer satisfaction.
- BSI [Business Improvement Software](#) will help you to manage systems and drive performance.
- Your [BSI Client Manager](#) will visit you regularly to make sure you remain compliant and support your continual improvement.
- Consider [integrating other management system standards](#) to maximize business benefits.

BSI Training Academy

The BSI Training Academy is a world leader in helping clients develop the knowledge and skills they need to embed excellence in their organizations. We offer a range of ISO 9001 training solutions that can be tailored to your needs. Our training courses are developed by experts in their fields who have been directly involved in the development of ISO 9001 so when you train with us you'll benefit from their expertise.

Using the latest research, our accelerated learning approach is proven to fast-track learning and improve knowledge retention. Our experienced tutors can help you get to grips with the matters that concern you and your organization directly, whether delivered in-house or as part of an open course where other delegates can share their experience.

Courses that help you understand ISO 9001 include:

ISO 9001:2015 Senior Management Briefing

- Two-hour face-to-face session
- Understand the purpose of ISO 9001:2015 and the leadership responsibilities outlined in the standard
- Important for top management of organizations implementing to ISO 9001:2015

BSI ISO 9001:2015 Requirements

- One-day classroom-based training course
- Learn about the structure and key requirements of ISO 9001:2015
- Essential for anyone involved in the planning, implementing, maintaining, supervising or auditing of an ISO 9001:2015 QMS

ISO 9001:2015 Implementation

- Two-day classroom-based training course
- Discover how to apply a typical framework for implementing ISO 9001:2015 following the PDCA cycle and using the handy resources contained in the good practice toolkit
- Recommended for anyone involved in the planning, implementing, maintaining, supervising or auditing of an ISO 9001:2015 QMS

ISO 9001:2015 Internal Auditor

- Two-day classroom-based training course
- Learn how to initiate an audit, prepare and conduct audit activities, compile and distribute audit reports and complete follow-up activities
- Ideal for anyone involved in auditing, maintaining or supervising an ISO 9001:2015 QMS

IRCA Certified ISO 9001:2015 Lead Auditor

- Five-day classroom-based training
- Gain the knowledge and skills required to undertake and lead a successful management system audit
- Recommended for anyone involved in auditing, maintaining or supervising an ISO 9001:2015 QMS

ISO 9001:2015 Best Practice Programme

- Six-day in-house programme
- Understand, implement and audit the requirements of the standard with additional gap assessment
- Recommended for any organization wanting a flexible tailored solution to embed ISO 9001, retain knowledge in-house and add real value

BSI Business Improvement Software

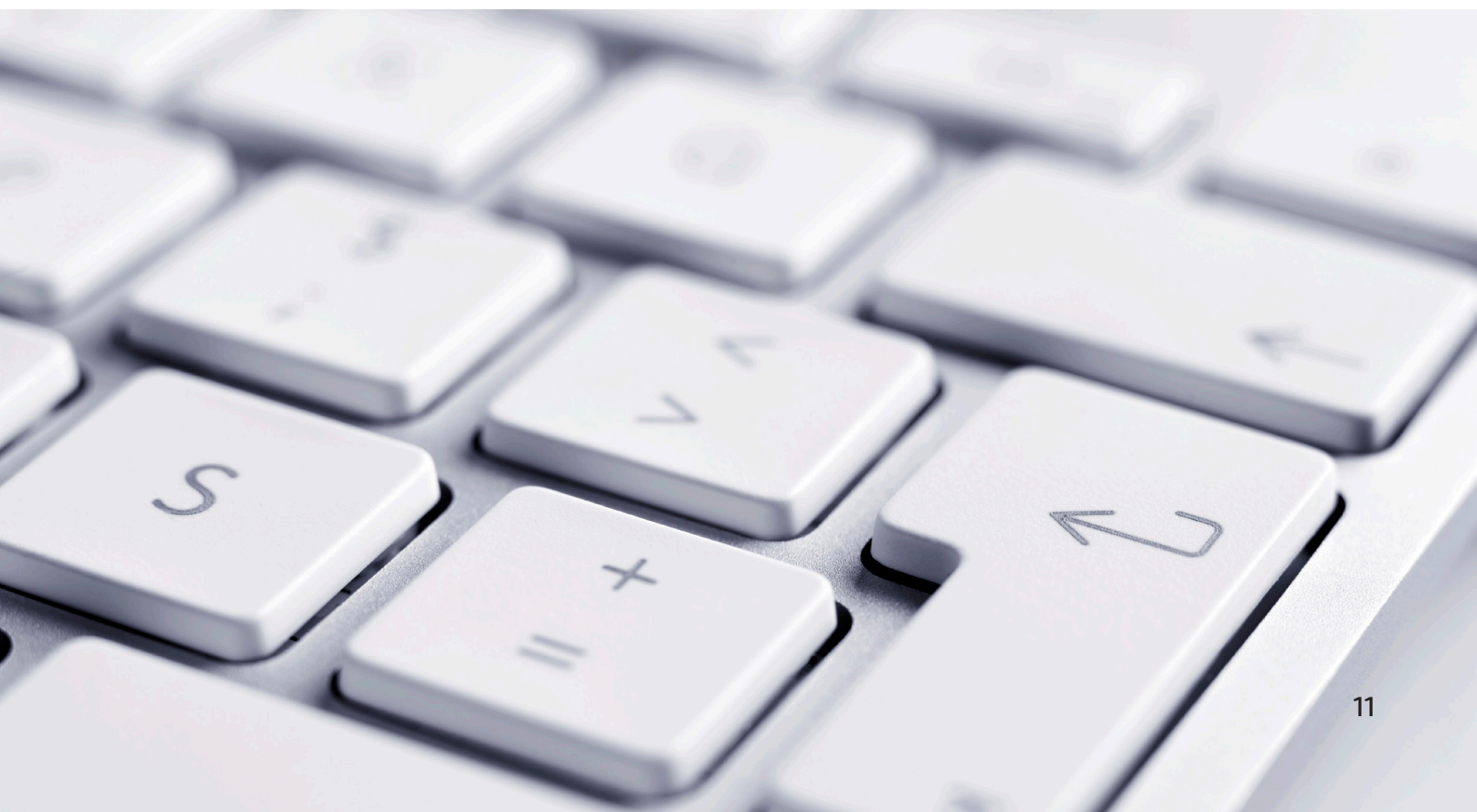
Accelerate implementation time and deliver continual improvements

The decision to implement a new management system standard is a huge opportunity to drive business improvement, but initiating, implementing, and maintaining this can also be a challenge. Ensuring you get the most from your investment is a key driver to your future success. BSI business improvement software provides a solution that can significantly reduce the cost and effort to implement an effective management system such as ISO 9001. It can be configured to the requirements of ISO 9001 and provide your organization with the tools necessary to manage essential elements of ISO 9001 across your organization. The start of your ISO 9001 journey is an ideal time to implement BSI business improvement software to support your QMS.

It can help you to:

- Accelerate implementation time by up to 50%
- Manage your document control effectively
- Provide company-wide visibility on implementation of the standard so you know exactly where you are at any one time
- You can easily and accurately input actions related to audits, incidents/events, risk and performance
- Through its customizable dashboards and reporting tools it gives you early insight into trends that help you make business decisions early on and drive improvement

The savings are the costs you avoid because you could not see what was happening at the facility level.



Why BSI?



BSI has been at the forefront of ISO 9001 since the start. And, it was originally based on BS 5750 which was developed by BSI. Since 1994 we have held the Secretariat of the International Committee developing and evolving ISO 9001 to where it is today. That's why we're best placed to help you understand the standard.

At BSI we create excellence by driving the success of our clients through standards. We help organizations to embed resilience, helping them to grow sustainably, adapt to change, and prosper for the long term. We make excellence a habit.

For over a century our experts have been challenging mediocrity and complacency to help embed excellence into the way people and products work. With 80,000 clients in 182 countries, BSI is an organization whose standards inspire excellence across the globe.



Our products and services

We provide a unique combination of complementary products and services, managed through our three business streams; Knowledge, Assurance and Compliance.

Knowledge

The core of our business centres on the knowledge that we create and impart to our clients. In the standards arena we continue to build our reputation as an expert body, bringing together experts from industry to shape standards at local, regional and international levels. In fact, BSI originally created eight of the world's top 10 management system standards.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We train our clients in world-class implementation and auditing techniques to ensure they maximize the benefits of our standards.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a regulation, market need or standard so that it becomes an embedded habit. We provide consultancy services and differentiated management tools to facilitate this process.



Find out more
Call: +44 (0)345 086 9001
Visit: [bsigroup.com](https://www.bsigroup.com)