



Self-assessment checklist

Use this self-assessment checklist to show how close you are to being ready for an ISO 9001 certification assessment from BSI and which processes you still need to implement in your organization. The checklist is laid out in sections which align with the requirements of the standard.

Mark your answers for **yes** as you work through the checklist to identify which processes are in place or areas which might need

Quality Management System and documentation

Have you identified your core business processes and defined how they are operated and controlled?

Do the core processes have measurements applied to them and are they regularly reviewed?

Where you outsource work that could affect product/service quality, have you defined how this will be controlled?

Do you have a documented quality policy and defined how it is reviewed?

Are the quality objectives defined in a way that can be measured?

Do you have a quality manual that covers the requirements defined in the standard?

Do you have procedures for the control of documents and records?

Management responsibility

Do you have evidence of management commitment to the system and are they actively involved in the management reviews?

At a strategic level, have management defined the activities that are critical to meeting customer requirements?

Have a management representative and deputy been appointed?

Have you defined the frequency and method of carrying out management reviews of the system?

Resource management

Have all staff who can affect quality been trained in their role and do they understand how their roles fit within the quality management system?

Are there appropriate records for training, skills and education?

Is the work infrastructure and work environment suitable for meeting customer and regulatory requirements?

Does the work environment meet all regulations and is it fit for purpose?

Product realization

Is there a defined plan/process for the provision of products and services?



Is the process for receiving and approving supplied goods defined?



Is there a defined method by which customer requirements are agreed?



Do you have a defined method of identification and traceability for products as they go through the realization process?



Are all appropriate regulatory and legal requirements identified as part of the review of customer requirements?



Do you have records of calibration or verification of measuring equipment?



If changes to specification or orders are accepted do you have a method to ensure that these are communicated and controlled?



Measuring, analysis and improvement

Is the process of managing customer complaints and feedback defined?



Do you have a way of monitoring customer satisfaction and perception?



If you carry out product design, are the inputs to the design process defined and documented?



Do you have a defined procedure for performing and analysing internal audits?



Have you defined how you verify that the final design meets the design specification?



Do you have a procedure for identifying potential non-conformities in the system? This may be a 'risk assessment' for instance



Are the design stages defined and reviews carried out with appropriate personnel at all stages?



Do you have a procedure for identifying non-conformities, their cause, and implementing actions to prevent reoccurrence?



Do you have a method to validate that the final product will operate as intended?



Do you have a documented procedure for dealing with non-conforming products which prevent them from being delivered?



Are all changes to the design specification verified and validated and results recorded?



Have you defined how suppliers are selected and their performance reviewed?



To speak to one of our experts and understand how ready you are for certification call **+31 (0)20 346 0780** or visit **bsigroup.nl**

If you need more help, BSI has a range of tools and resources available to assist you.

GAP Analysis

This identifies gaps between your current management systems and the requirements of ISO 9001 – helping you outline the steps you need to take towards certification.

Entropy™ Software

Entropy™ Software has helped BSI clients reduce their management system implementation time on average by 50%. Entropy™ Software provides you with the tools needed to drive business excellence and ensure you get the most from your ISO 9001 investment.

Training

From understanding how a standard can help your business, to implementing, monitoring and auditing your compliance to the standard, we can support you all the way with our extensive range of training courses.

ISO 9001 Toolkits

Wherever you may be on your ISO 9001 journey, BSI have developed a range of Toolkits which group together assessment services, standards, training and online tools to save you both time, and money.

