

This self-assessment questionnaire is designed to assess your readiness for ISO 9001:2015. We hope you find it useful.

PLAN

Context of the Organisation

Have you worked out the external and internal issues relevant to your organisation's purpose, the achievement of customer satisfaction and your organisation's strategic direction?	
Do you have a process in place for reviewing and monitoring these on a regular basis?	
Have you determined the needs and expectations of interested parties that are relevant to your Quality Management System?	
Has the scope of your QMS been determined and has this taken account of the external/internal issues, interested parties and the products and/or services you offer?	
Has your QMS been established including the processes needed and their sequence and interaction?	
Have the criteria for managing these been established, together with responsibilities, methods, requirements and related performance indicators needed to ensure effective operation & control?	

Leadership

Has top management taken accountability for the effectiveness of the QMS?	
Have the policy & objectives compatible with the strategic direction of the organisation been established for the QMS and communicated to the relevant people?	
Have objectives been established at relevant departmental & individual levels within your organisation?	
Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach?	
Have customer requirements and applicable statutory and regulatory requirements been determined, met & communicated throughout the organisation?	
Have risks and opportunities relevant to the QMS been established?	
Have senior management established and communicated the responsibilities and authorities for the effective operation of the QMS?	

Planning

Have you established the risks & opportunities required to give assurance that the QMS can achieve its intended results?	
Has your organisation planned actions to address these risks & opportunities and integrated them into the system processes?	
Is there a defined process to determine the need for changes to the QMS and for managing their implementation?	

Support

Has the organisation determined & provided the resources needed to establish, implement, maintain and continually improve the QMS. This should include people, environmental and infrastructure requirements.	
If you use monitoring and measuring as evidence of conformity for products and services to specified requirements, have the resources needed to ensure valid & reliable monitoring & measurement of results been established?	
Has the organisation determined the knowledge necessary for the operation of its processes and achievement of conformity of products and services and implemented a "lessons learned" process?	
Has the organisation ensured that those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training or experience or taken action to ensure that those people can acquire the necessary competence?	
Has the documented information required by the standard & necessary for the effective implementation and operation of the QMS been established?	

DO

Operation

Is there a clear process for the provision of products & services that meet customer defined requirements?	
Are changes planned and carried out in a controlled way with actions taken to mitigate any adverse effects?	
If you have outsourced processes, are they managed and controlled?	
Is there a defined process for reviewing and communicating with customers with regard to products & services, enquiries, contracts or other relevant requirements?	
Is this review conducted before any commitment is made to supply products &/or services?	
Are the processes for any design and development established and implemented in line with the requirements of the standard?	
Do you also ensure that any externally provided (outsourced) products; processes and services conform to specified requirements?	
Do you have criteria for the evaluation, selection, performance monitoring and re-evaluation of external providers?	
Is the provision of products & services carried out in a controlled manner which includes: <ul style="list-style-type: none"> • The availability of documented information that defines the characteristics of the products & services and the activities to be performed and results achieved. • Monitoring& measurement activities to verify that the criteria for control of processes and process outputs, together with acceptance criteria for control of products & services have been met. • The people carrying out the tasks are competent. 	
Do have effective methods to ensure traceability during the operation process?	
Where property belonging to customers or external providers is used in the provision of the product or service, is this controlled effectively?	
If there is a requirement for post-delivery activities associated with the products/services such as warranty, maintenance, recycling or final disposal. Are these defined and managed?	
Are any nonconforming process outputs managed so as to prevent their unintended use?	

CHECK

Performance Evaluation

Has the organisation determined: <ul style="list-style-type: none"> • What needs to be monitored & measured? • The methods for monitoring, measurement, analysis & evaluation to ensure valid results? 	
Have you established when the results from monitoring and measurement shall be analysed and evaluated?	
Have methods of monitoring customer perceptions of the provision of products and services been established?	
Have you determined the need or opportunities for improvements within the QMS and how these will be fed into the management review process?	
Has a process for internal audit of the QMS been established?	
Has the management review process been established and implemented?	

ACT

Improvement

Has the organisation determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements & enhance customer satisfaction?	
Has the organisation appropriate processes for managing nonconformities and the related corrective actions?	
Has the organisation developed a mechanism for addressing the requirement to continually improve the suitability, adequacy and effectiveness of the QMS?	