Gap Analysis ISO 9001 Checklist

Context of the Organization			
Have all external and internal issues that are relevant to your organization's purpose and the achievement of customer satisfaction and the organization's strategic direction been determined?	Yes	No	N/A
Have the needs and expectations of interested parties that are relevant to the QMS been determined?	Yes	No	N/A
Was the scope of your QMS determined whilst taking into account all the external and internal issues, the needs of interested parties and the scope your products and services?	Yes	No	N/A
Is your QMS established, and does it include a description of the processes required and their sequence and interaction?	Yes	No	N/A
Have the criteria for managing these processes and their interaction been established?	Yes	No	N/A
Have all responsibilities, methods, measurements and related performance indicators, needed to ensure the effective operation and control, been established?	Yes	No	N/A

Leadership			
Has top management taken accountability for the effectiveness of the QMS?	Yes	No	N/A
Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organization, been established and communicated?	Yes	No	N/A
Have the objectives been established at relevant departmental and individual levels with the business?	Yes	No	N/A
Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach?	Yes	No	N/A
Have customer requirements and applicable statutory and regulatory requirements been determined, met and communicated throughout the organization?	Yes	No	N/A
Have the risks and opportunities that are relevant to the QMS been established?	Yes	No	N/A
Has the organization established and communicated the responsibilities and authorities for the effective operation of the QMS?	Yes	No	N/A

Planning			
Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?	Yes	No	N/A
Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?	Yes	No	N/A
Is there a defined process for the determining the need for changes to the QMS and managing their implementation?	Yes	No	N/A

Support			
Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS (including people, environmental and infrastructure requirements)?	Yes	No	N/A
Is monitoring or measuring is used for evidence of conformity of products and services to specified requirements?	Yes	No	N/A
Has the organization determined the knowledge necessary for the operation of its processes and the achievement of conformity of products and services and implemented a lessons learned process?	Yes	No	N/A
Has the organization 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 persons can acquire the necessary competence?	Yes	No	N/A
Has the documented information required by the standard and necessary for the effective implementation and operation of the QMS been established?	Yes	No	N/A

Operation			
Is there a defined process for the provision of products and services that meet the requirements defined by the customer?	Yes	No	N/A
Are there any changes planned?	Yes	No	N/A
Are any outsourced processes managed and controlled?	Yes	No	N/A
Is there a defined process for reviewing and communicating with customers in relation to information relating to products and services, enquiries, contracts or order handling?	Yes	No	N/A
Is this review conducted prior to the organization's commitment to supply products and services?	Yes	No	N/A
Do you design and develop products or services?	Yes	No	N/A
Do you ensure that externally provided processes, products, and services conform to specified requirements?	Yes	No	N/A
Do you have criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	Yes	No	N/A
Is the provision of products and services carried out in controlled conditions which include: • the availability of documented information that denes the characteristics of the products and services? • the availability of documented information that denes the activities to be performed and the results to be achieved? • monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met? • the people carrying out the tasks are competent?	Yes	No	N/A
Do you have effective methods of ensuring traceability during the operation process?	Yes	No	N/A
Is property belonging to customers or external providers used in the provision of the product or service?	Yes	No	N/A
Is there a requirement for post-delivery activities associated with the products and services such as warranty, maintenance services, recycling or final disposal?	Yes	No	N/A
Are any nonconforming process outputs managed so as to prevent their unintended use?	Yes	No	N/A

Performance Evaluation			
Has the organization determined what needs to be monitored and measured and the methods for monitoring, measurement, analysis and evaluation, to ensure valid results?	Yes	No	N/A
Has it established when the results from monitoring and measurement shall be analyzed and evaluated?	Yes	No	N/A
Have methods of monitoring customer perceptions of the provision of products and services been established?	Yes	No	N/A
Has it determined the need or opportunities for improvements within the QMS and how these will be fed into management reviews?	Yes	No	N/A
Has the organization established a process for an internal audit of the QMS?	Yes	No	N/A
Has an approach to perform management reviews been established and implemented?	Yes	No	N/A

Improvement			
Has the organization determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction	Yes	No	N/A
Does the organization operate appropriate processes for managing nonconformities and the related corrective actions?	Yes	No	N/A
Has the organization decided on how it will address the requirement to continually improve the suitability, adequacy, and effectiveness of the QMS?	Yes	No	N/A

Completion

Recommendations:

Inspection Date:

Inspector's Full Name and Signature:

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Please note that this checklist is a hypothetical example and provides basic information only. It is not intended to take the place of, among other things, workplace, health and safety advice; medical advice, diagnosis, or treatment; or other applicable laws. You should also seek your own professional advice to determine if the use of such checklist is permissible in your workplace or jurisdiction.