

PRELIMINARY GAP ANALYSIS FOR QMS

This checklist is a self-assessment tool for organizations to check their internal processes alignment to Quality Management System (ISO 9001).

For Scoring, rate the requirements accordingly.

0	You do not understand what is required or believe it is necessary
1	Your organization does not perform this activity
2	You understand this activity is a good thing to do but do not do it
3	You do this sometimes
4	You do this but not very well
5	You do this quite well.

Quality Management System Preliminary Gap Analysis		Score	Comments
<i>Decide on a number from 0 to 5 for each item below. The scoring criteria are given in a table at the end.</i>		1 to 5	<i>Make notes to explain your score for future reference.</i>
1.	Have you established, documented, implemented and now maintain a Quality Management System (QMS) to any system including ISO 9001, ISO 9002 or ISO 9003?		
2.	Have you identified the processes needed for your QMS and a. the sequence of your production and service delivery processes, b. the criteria and methods needed to ensure the processes are effective, and c. have the resources and the information you need to Support the processes?		
3.	Do you have a. Quality Manual including your Quality Policy and quality objectives, and b. written procedures and work instructions?		
4.	Do your records provide evidence that your business processes are effective?		
5.	Is your Top Management committed to the development and implementation of QMS?		
6.	Has your Top Management communicated the importance of meeting customer and other business requirements to all the employees?		
7.	Has your Top Management made a commitment to ensure your customers' requirements are top priority?		
8.	Do your quality objectives include requirements for production and		

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	delivery?		
9.	Are your quality objectives measurable?		
10.	Have the responsibilities and authorities of managers and employees been defined and communicated to them?		
11.	Does your management have the drive and resources needed a. to implement, and maintain a QMS and continually improve its effectiveness, and b. to enhance customer satisfaction by meeting customer requirements?		
12.	Does your organization have procedures to select competent personnel for work activities?		
13.	Does your organization provide training or take other action to help develop your people?		
14.	Does your organization provide adequate: a. buildings, workspace and utilities, b. process equipment, and c. supporting services such as transport or communication?		
15.	When you receive a customer order do you review it for a. requirements specified by the customer, including the delivery and post-delivery activities, b. requirements not stated by the customer but necessary for specified use or known and intended use, and c. statutory and regulatory requirements related to the product?		
16.	Do you inform your customers concerning a. product information, b. enquiries, contracts or order handling, including changes, and c. channels for customer feedback and complaints?		
17.	Does your organization plan and control product design and development activities?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
18.	Does your organization maintain records of design or development review, verification and validation activities and resulting action?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
19.	Does your organization inspect or otherwise confirm that purchased products, materials, components and services conform to your specified purchase requirements?		
20.	Does your organization select suppliers depending on how important the purchased product is for production?		
21.	Does your organization evaluate suppliers (subcontractors or vendors) based on their ability to satisfy your requirements?		

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22.	Do you ensure production has a. the information that describes the characteristics of the product, b. the necessary work instructions, c. suitable equipment, and d. the monitoring and measuring devices needed?		
23.	Does your organization regularly confirm that your production and service processes are capable of consistently meeting your requirements?		
24.	Are parts, components, subassemblies and products identified throughout production or service delivery?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
25.	Are monitoring and measurement requirements clearly shown with the status of the product?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
26.	Where traceability is a requirement, does production keep records of unique product identification?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
27.	Do you care for and protect customers' property under your control or being used by your people?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
28.	Do you look after your product (including the parts or components) during both production and delivery to the customer, by providing suitable identification, packaging, storage, preservation and handling?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
29.	Do you have instructions needed to identify inspection or monitoring activities to be done during production or service delivery and the devices to be used?		
30.	Is your measuring equipment: a. Calibrated or verified at specified intervals, or prior to use? b. Adjusted or re-adjusted as necessary? c. Identified to enable the calibration status to be determined? d. Safeguarded from adjustments that would invalidate the measurement result? e. Protected from damage and deterioration during handling, maintenance and storage?		<i>If this activity is not applicable to your organization do not put a score in the score column.</i>
31.	Does your organization monitor customer information that shows you have satisfied customer requirements?		
32.	Does your organization conduct internal quality audits at planned intervals?		
33.	Does your organization use suitable methods to monitor and, where practical, measure the performance of your processes?		
34.	Does your organization inspect or measure the characteristics of finished		

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	products and record the results?		
35.	Does your organization identify nonconforming products and review them for disposition?		
36.	Does your organization collect and analyze data to assess the suitability and effectiveness of the QMS?		
37.	Does your organization use data to evaluate or identify where continual improvement of the QMS can be made?		
38.	Does your organization continually improve the effectiveness of the QMS?		
39.	Does your organization take corrective action to eliminate the causes of problems and to prevent their recurrence?		
40.	Does your organization determine and eliminate potential nonconformities in order to prevent their occurrence?		

Add all the points together.

150 - 200	75% - 100%	You are almost ready to complete your ISO 9001 QMS and apply for certification/registration.
100 - 149	50% - 74%	You are ready to implement the QMS. This will likely improve your business results.
0 - 99	0% - 49%	You have a lot to do but should begin. You could consider seeking help from a consultant or specialist.

NOTE - If you excluded some or all of the actions identified above you can deduct the number of exclusions multiplied by five from the total to calculate your position. You will have a general idea of your readiness for seeking ISO 9001 certification/registration.