



# ISO 9001: Are you ready for your audit?

## CHECKLIST

**Use our checklist and find out if you are sufficiently prepared for certification.**

Tick the statements that apply to you or your company to gather a clear overview of the ISO 9001 requirements that you already meet and those that may need further attention.

This checklist is based on the structure of ISO 9001:2015 and focuses on sections four to ten, which contain the requirements for achieving certification to ISO 9001.

### Section 4 - Context of the Organization

☐

You have determined the internal factors that influence performance, strategic direction and the purpose of your company. (e.g. staff, competencies, culture etc.)

☐

You have determined the external factors that influence performance, strategic direction and the purpose of your company. (e.g. legal, competitive or economic factors)

☐

You know what opportunities and risks arise for your company as a result of internal and external factors.

☐

You know the expectations of the internal (e.g. employees, works council) and external (e.g. customers, residents, competitors) interested parties who influence your quality management system (QMS).

☐

You have defined the scope of your quality management system, taking into account all aspects that influence quality (e.g. activities, products/services, interested parties).

☐

You have clearly defined your business processes and know how they influence each other.

☐

You have clearly defined how your business processes are managed and monitor them regularly.

☐

If you have outsourced processes within the defined scope, you can name them and explain the reason for this.

## Section 5 - Leadership

☐

The top management of your company is demonstrably in charge of your QMS and ensures its effectiveness and maintenance (e.g. through regular checks).

☐

The top management of your company has defined, documented and provided the quality policy, taking into account the context and the strategic direction of your company.

☐

The top management of your company ensures that you consistently understand and meet the needs of your customers.

☐

The top management of your company ensures that you consistently understand and comply with legal and regulatory requirements regarding the quality of your products or services.

☐

Roles, responsibilities and authorities within your organization are clearly defined, documented and communicated.

## Section 6 - Planning

☐

You have identified and analyzed opportunities and risks for your company, and you have defined measures for dealing with them.

☐

If you have not defined any measures for certain opportunities and risks, you can explain this clearly and conclusively.

☐

You have defined and documented measurable quality goals for all functions, levels and processes required for the quality management system.

☐

Your quality goals are consistent with your quality policy.

☐

You have defined measures to achieve your quality goals.

☐

Any changes to the QMS are implemented on the basis of systematic planning.

## Section 7 - Support

☐

You have identified the necessary resources to set up, maintain and continuously improve your QMS and are able to provide them.

☐

For the implementation of your QMS, you have determined the necessary people and the necessary infrastructure and can make them available.

☐

You have determined and provided the process environment for the implementation of your QMS, taking into account possible social, psychological and physical influencing factors.

☐

To ensure that your products and services conform to the specified requirements, you have identified and allocated resources to ensure reliable monitoring.

☐

You ensure that the necessary knowledge for process implementation and for achieving product conformity is available and maintained within your organization.

☐

You continuously ensure that the employees in your company have the necessary skills.

☐

You ensure that all persons who carry out tasks under supervision within your company are informed about the quality policy and quality objectives and are aware of the consequences of non-compliance.

☐

You have a defined communication strategy (internal and external).

☐

When dealing with documented information, you proceed strategically and thus ensure that it is always up-to-date, complete and protected in a suitable format.

## Section 8 - Operation

☐

You have precisely determined the requirements for your products or services and follow a defined process to fulfil them.

☐

Your communications with customers related to the provision of products and services are clearly defined.

☐

The handling of customer property is clearly regulated in your company.

☐

You have added "emergency measures" to your customer communication for possible unforeseen events.

☐

Your products or services meet all legal and official requirements.

☐

You are able to control, document and communicate any changes that may be necessary with regard to product and service requirements.

☐

In order to implement and ensure the subsequent production or provision of the services, you have set up a holistic (planning, control, adjustment, handling of results) development process.

☐

You ensure that the development process is checked by suitable personnel.

☐

Possible outsourced processes and services meet your requirements. You have defined the selection process and review of these services.

☐

You check in appropriate phases whether your products or services meet the specified requirements and thus ensure that approval is only given if the implementation is satisfactory.

☐

You have coherent documentation of your approval process.

☐

You control and document non-conforming results according to a defined plan.

## Section 9 – Evaluation of Performance

☐

You have determined what needs to be monitored, measured, analyzed and evaluated when by whom and retain documented information as evidence of the results.

☐

You have identified suitable methods for monitoring customer satisfaction and apply these on an ongoing basis.

☐

You continuously carry out holistically planned internal audits to check the effectiveness and maintenance of your QMS and its consistency with the requirements of the ISO 9001 standard.



## Section 10 - Improvement



You have a defined procedure for handling non-conformities and complaints, which also includes the implementation of corrective measures and documentation.



For the continuous improvement of your QMS, consider the results of your analyses and evaluations and also include the management evaluation.

For more information about ISO 9001 certification, head to our website →

### Why LRQA?

Working with a credible and respected partner to certify your management systems is a uniquely powerful way to show stakeholders that high standards are being set and met. Certification helps ensure that working practices minimise risks in the future while allowing you to enhance your reputation in the present by demonstrating your commitment to safe, sustainable, and ethical ways of working.

#### Strategic vision

Our technical know-how, industry expertise, and innovative, forward-thinking approach will help you meet the challenges of today – and become a safer, cleaner, more resilient, and more ethical organization tomorrow.

#### Technical expertise

Our people are leading experts in their sectors and technologies across certification, inspection services, sustainability, training, and cybersecurity. We work alongside your teams to gain a clear

understanding of risks, challenges, and needs – then share our knowledge to help your business thrive today and tomorrow.

#### Global capability

Operating in more than 160 countries, recognized by over 30 accreditation bodies worldwide, and covering a wide breadth of industries, we can help you manage risk, drive business improvements, build credibility with stakeholders and meet sustainability goals – both within your business and across your supply chain.

#### Effective partnerships

Every business is unique. That's why our experts work with you to fully understand your needs and goals and determine how we can best support them. With our pioneering approach, we have led the way in shaping our industry – and continue to take every opportunity to collaborate with clients and pioneer new ideas, services, and innovations.

### Get in touch

Visit [www.lrqa.com/us](https://www.lrqa.com/us) for more information, email [inquiries-usa@lrqa.com](mailto:inquiries-usa@lrqa.com) or call 866 971 5772

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