

# Part 1

## ISO 9001:2015 for SMEs: sensible, uncomplicated, beneficial!

In the first part of our guide series, you will learn what a quality management system according to ISO 9001 is, what benefits it offers you and what you need to implement it.

According to [statistics](#), there were around 2.12 million small and medium-sized enterprises (SMEs) in Germany in 2021 - a total of over 99 percent of all companies. As with large companies, if not more so, competitiveness is fundamentally important for SMEs. A company can be described as competitive if it can sell its products on the market at prices similar to those of its competitors or compete with other companies in terms of service and product quality. With the introduction of a quality management system (QMS) and a subsequent successful certification according to ISO 9001, SMEs have valid proof that they systematically meet external requirements: a plus with potential clients.

### Quality plus management system equals quality management?

According to the [ISO 9000:2015](#) standard, quality is defined as "a degree to which a set of inherent characteristics of an object meets requirements". In simpler terms, quality is the degree to which a product or service meets existing requirements. This means that quality is not an "end goal", but rather a process subject to constant change.

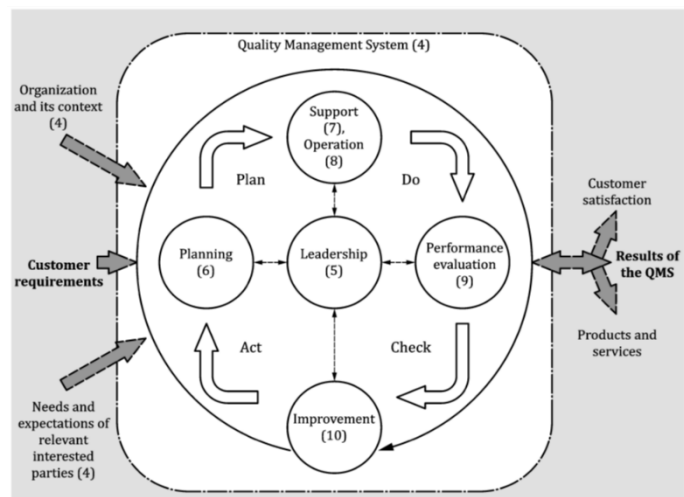
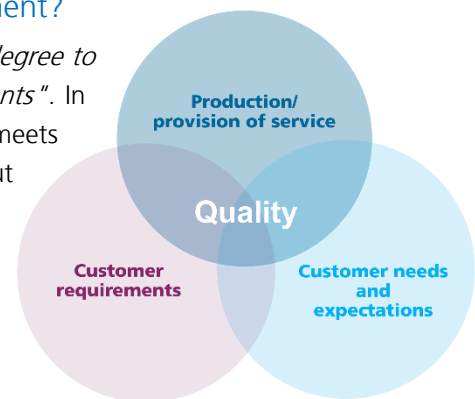
In addition to the applicable legal and regulatory requirements, customer requirements are of particular importance. Quality therefore requires:

- ▶ Identify the customer's requirements and expectations,
- ▶ translate them into requirements for the product and
- ▶ to manufacture and deliver the desired product with the defined specifications

Management system is the "set of interrelated or interacting elements [...] to establish policies, objectives and processes to achieve those objectives". A management system is thus an "operational management system" that enables the systematic implementation of the company's policies and the achievement of its objectives. If one brings both terms together to

To explain a QMS, according to the 2015 revised ISO 9001, it is a systematic approach to: *"the ability to consistently deliver products and services that meet customer requirements and applicable legal and regulatory requirements; opening opportunities to increase customer satisfaction; addressing risks and opportunities in their context and their impact on the company; and objectives; and the ability to demonstrate conformity with specified quality management system requirements..."*.

Since quality is a never-ending process, a systematic approach within the company makes sense: the introduction of a QMS.



Source: ISO 9001:2015, page 13

## What are the advantages of an ISO 9001 QMS for your company?

With the introduction of a QMS according to ISO 9001, you create a system with which the following aspects can be pursued in a line-oriented manner:

- ▶ Rapid adaptation to new market requirements
- ▶ Ensure sustainable business success
- ▶ Ensure and improve product/service quality by constantly reviewing and adapting production/service processes.
- ▶ Improved legal certainty through documented business processes and legally secure records
- ▶ Securing market position and facilitating global trade through image enhancement and improved competitiveness
- ▶ Improved customer communication and interaction with other stakeholders
- ▶ More effective risk and opportunity management
- ▶ Avoiding loss of knowledge through fluctuation in the company
- ▶ Transparency of operational processes
- ▶ Training, qualification and induction of employees with the help of QMS documentation
- ▶ Increase customer satisfaction through systematic handling of errors

Once a QMS is established, it forms the basis for understanding other management systems, e.g. environmental or energy management.

ISO 9001 is applicable to all types and sizes of organisations, easily integrated into existing management systems and of course suitable for self-assessment / self-declaration and certification.

## Quality management principles

The seven principles for quality management serve as a foundation, framework and guide for action for top management and all stakeholders to establish rules for improving quality performance and management systems - even for situations that are not precisely defined. The 7 principles address current trends in society in a special way, namely the striving for sustainable development of an organisation in a constantly changing social environment.

### Principle 1: Customer orientation

The mere fulfilment of defined customer requirements is no longer sufficient to ensure sustainable success. Rather, the aim should be to inspire customers by fulfilling and deliberately exceeding future or implicit expectations.

### Principle 2: Leadership

Supervisors at all levels ensure unity of purpose and direction (unity of vision, practices and ethical values)

### Principle 3: Involvement of people

Competent and committed people are the core of an entire organisation: appreciation and trust are essential for their engagement and creativity.

### Principle 4: Process-oriented approach

Desired results are achieved effectively and efficiently when all activities work as interrelated processes in a connected system (logical structure of the QMS with ability to focus on key processes).

## Principle 5: Improvement

It is essential for the sustainable success of an organisation to consider improving overall performance as a constant goal and to see and use change as an opportunity.

## Principle 6: Fact-based decision-making

Analysing and evaluating data and information with reliable, robust methods is critical to making effective decisions.

## Principle 7: Relationship management

Involving all relevant stakeholders and maintaining good relationships is indispensable for sustainable business success: this can positively influence the organisation's performance.

## Effort for the introduction of a QMS according to ISO 9001

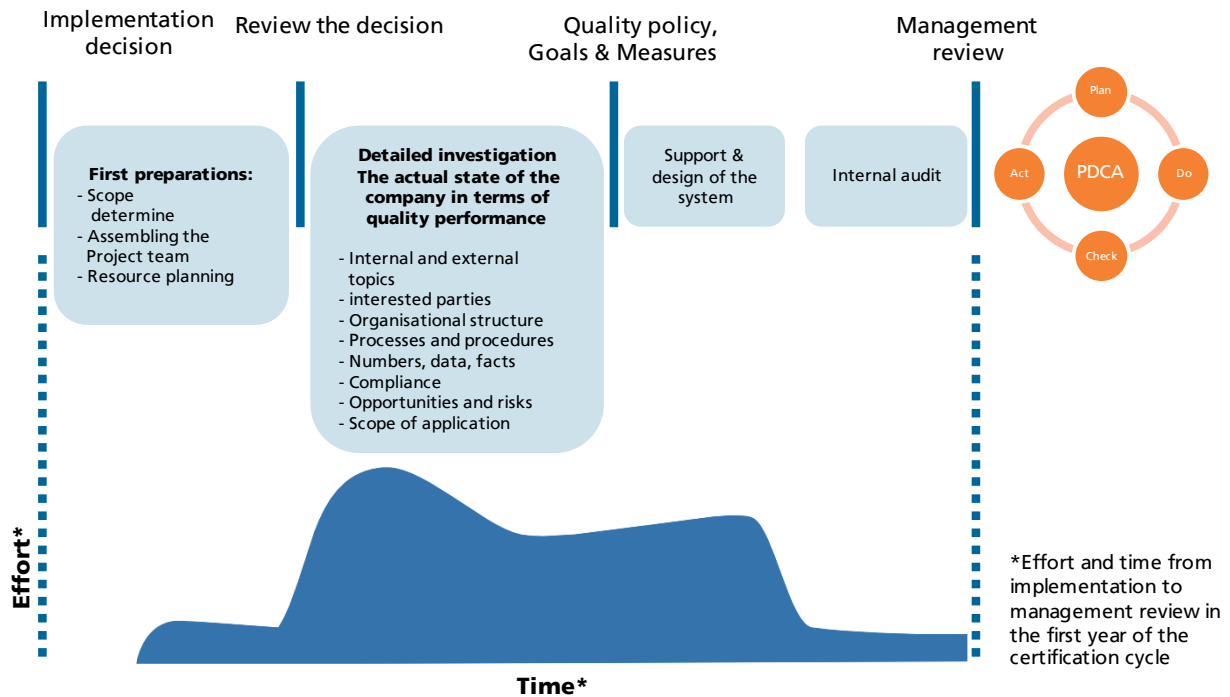
The following figure illustrates the time sequence of the implementation of the QMS in relation to the effort involved. The greatest effort is associated with determining the actual situation of the organisation with regard to its quality performance, existing processes and structures as well as external requirements. After this phase, the essential data basis is created and the effort initially decreases. The QMS now delivers results and can be used. Quality information is continuously updated and serves as a basis for continuous improvement measures. A sensible documentation of processes, procedures, responsibilities and deadlines ensures

**Tip:** Please forget the numerous sample books on how the quality management system should be structured. Develop your own effective management system that is tailored to your company, corresponds to the **lived reality**, keeps the bond to the quality management principles and drives your company forward.

a smooth process.

This reduces the effort over time compared to initial certification. If management systems have already been introduced in an organisation, for example for energy (ISO 50001 / EnMS) or environment (ISO 14001 / EMS), the effort is reduced because the QMS can be easily integrated through the "High Level Structure" (HLS).

# Part 1



Experience shows that the introduction of a QMS can take from 3 months (small companies) to 12 months (medium-sized companies), depending on the size and sector of the company, although there are also examples that fall short of or exceed these times.

The most important prerequisite for this is the intensive and concentrated examination of the standard requirements. The time required for the introduction of the QMS also depends on the complexity of the work processes, the number of employees, the internal capacities and motivation and the scope of documentation.

## QMS according to ISO 9001: Introduction made easy

Those who do not have a clearly defined plan at the beginning or are struggling with questions and ambiguities that keep arising can get support in interpreting the standards and implementing them in practice. Conceivable here is assistance from an external consultant and/or one's own [further training](#).

With the help of this guide series you can get a good overview and become familiar with the standard.

It is possible to receive [funding](#) for quality management consulting. Both young companies that have been on the market for no longer than 2 years and existing companies from the third year after foundation or companies in difficulties can still benefit from the federal SME advisory support programme (initially valid until 31.12.2022).

Explicitly highlighted in the [BAFA leaflet on "Types of advice and topics"](#) is the "Introduction or adaptation of a quality management system in the company". More information on the funding programme is available on the [BAFA](#) website.

## Conclusion Part 1

With more than 1,100,000 certificates worldwide, ISO 9001 remains undisputedly the most important, widely used and internationally recognised management standard. Contrary to popular belief, small and very small companies contribute significantly to this dynamic, as they hold 40% of the certificates!

Every company, whether small, medium or large, lives from satisfied customers and satisfied customers can develop into regular customers. For the competitiveness of a company, not only the quality of its products plays an important role, but also the type of relationship with customers. Introducing a quality management system supports you in meeting the requirements and wishes of your customers and in increasing satisfaction with your performance.

Introducing a management system is challenging and a task that takes some time and energy. But it is easier to successively develop something that is "actually already there" than to start from scratch when a certificate is suddenly needed. Moreover, the primary goal is not the certificate according to ISO 9001, but the establishment of an effective, living quality management system tailored to the company, which brings the company forward in the long term, drives the improvement processes and thus ensures sustainable corporate success.

**In the next part of the publication series, we highlight the importance of the process-oriented approach in quality management and how to best control processes. We also explain the role of process indicators.**

### Your contact



**Miroslava Dubinetska**

+49 30 233 20 21 - 53

[miroslava.dubinetska@gut-cert.de](mailto:miroslava.dubinetska@gut-cert.de)



**Andreas Lemke**

Head of the certification body

+49 30 233 20 21 - 41

[andreas.lemke@gut-cert.de](mailto:andreas.lemke@gut-cert.de)