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Introduction

The industry-independent QM system according to the standard series DIN EN ISO 9000 ff. Is equally well suited for manufacturers, service providers, institutions, software developers and suppliers, but especially for:

- **Suppliers** whose customers demand or will demand a QM system in the near future, such as the automotive industry and public sector clients.
- **Healthcare companies and institutions' (hospitals, nursing homes, etc.) for which a QM scheme is required by law.**
- **Manufacturer of products**, where quality defects can lead to high liability risks (product liability law).
- Companies that manufacture products for which a **CE mark** is required by European directives.
- The following QM specifications are in use for **Automotive Suppliers** beyond ISO 9001: 2008:
 - Germany: VDA 6.1, VDA 6.2, VDA 6.4
 - USA: QS-9000
 - worldwide: ISO/TS 16949 (as overarching worldwide standard)
- A separate QM standard is required for medical device manufacturers: EN ISO 13485:2003.

1.1. Introduction of a QM system

A QM system is introduced according to the following procedure:

1. Beginning of the introduction of the QM system by management decision
2. Name of a QM representative
3. Clarification of the question of whether to engage an external consultant. If so, contact consultants and get information about funding opportunities
4. Creation of a project plan with timelines and steps
5. Early information and involvement of employees
6. Formulating a quality policy with your own quality goals
7. Analysis and definition of [Process descriptions](#)
8. Determining interfaces between the processes
9. Definition of [Role definitions](#)
10. Determining the type of documentation — if necessary, creation of procedural and work instructions
11. Creating a QM manual
12. Introduction and qualification of employees
13. Implementation of internal [Audits](#)
14. Certification
15. Selection of a certifier

1.2. Checklist

The following **checklist** is used to introduce quality management according to the ISO 9001-2015 standard.