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.