Quality Handbook

Approved pages

Approval date	Page	Comment
17 July 2023	Role definitions	
17 July 2023	Process descriptions	
17 July 2023	Work instructions	
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Approval not enabled

Introduction
Quality assurance

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1 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.

2 Quality assurance

Quality assurance or **Quality control** is a collective term for different approaches and measures to ensure defined quality requirements.

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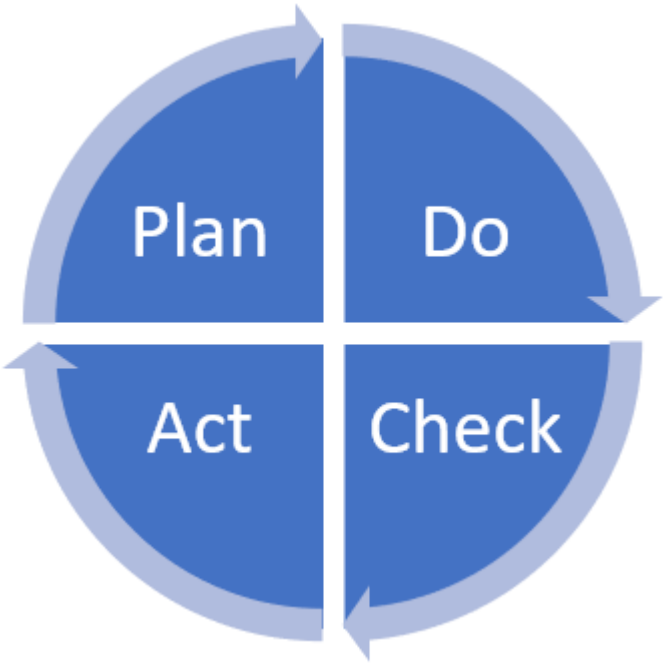
2.1. DIN-Norm

According to DIN EN ISO 9000:2015 3.3.6, quality assurance is the part of quality management that aims to create confidence that quality requirements are met.

Quality assurance existed before the term itself came up. Quality assurance became known in German-speaking countries, as companies began to have their quality management system (QMS) certified according to the ISO 9001 standard series established in 1987.

2.2. Quality assurance process: PDCA



2.3. Application

The PDCA cycle describes the phases in the continuous improvement process (CIP). CIP is the basis of all quality management systems. As a result, the company is constantly improving processes and produres with the goal of improving the efficiency as well as the customer and employee satisfaction of the company.

In industrial enterprises and in the service sector, it is one of the standard procedures. The KVP and PDCA cycles are fundamental components of the DIN EN ISO 9000, ISO 14000, ISO/IEC 20000 and ISO/IEC 27001 "Information Ttchnology - Security techniques - Information security management systems requirements specification" and in the BSI standard 100-1: *Information security management systems (ISMS)*.

After each PDCA cycle, the measures are to be standardized by a *SDCA* cycle. After each introduction of a defined standard (Standardize), this standard is practiced (Do), the procedure checked for correctness and functionality (Check) and changed if necessary (Action). This action is then usually the planning of another PDCA cycle.

2.4. Multimedia

A simple and easy to understand explanation of PDCA.

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3 Role definitions

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Tour 2 Integrated Management system ‹ Meeting minutes next: Process descriptions

Page	Role description	Role owner
Executive Manager	The management represents the company in and out of court.	Janusz Čaplo
Sales Agent	Competent customer advice and sales of the company's products and services.	Irene Parker, Stefan Roth

Tour 2 Integrated Management system ‹ Meeting minutes next: Process descriptions

4 Process descriptions

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Page	Business unit	Process owner	Approval state	Valid until	Status
Procurement of materials	100	Emma Røgeberg	First draft		
Sales process	Sales	Paul Arnoux	Draft	December 31, 2022	◉

Tour 2 Integrated Management system ‹ Role definitions next: Work instructions

5 Work instructions

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Tour 2 Integrated Management system ‹ Process descriptions next: Audit reports

Page	Business unit	Process owner	Approval state	Valid until	Status
Making an offer	Sales	Emma Røgeberg	First draft	December 1, 2023	◉

Tour 2 Integrated Management system ‹ Process descriptions next: Audit reports

6 Audit reports

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Tour 2 Integrated Management system ‹ Process descriptions next: Risk entries

Page	Audit status	Auditor	Audit execution date	Audit planned date	Status
Compliance Check of the Compliance Requirements of the IT Services Department	open	Sandra Meier		August 15, 2024	◉

Tour 2 Integrated Management system ‹ Process descriptions next: Risk entries