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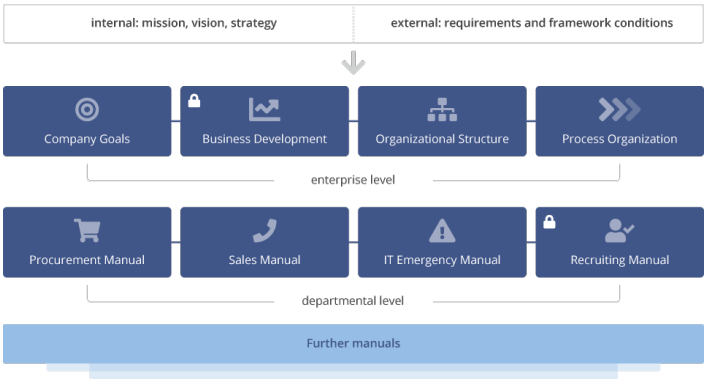
An **Organization Manual** is a structured summary of all regulations of a company. An organization Manual contains, for example, the company history, goals, definitions, organizational instructions and guidelines. If no separate Quality Handbook exists, the Organization Handbook can also contain all processes and work instructions.



Organization Manual in a wiki

A Wiki is the ideal platform to provide and maintain an Organization Manual online:

- **Central point of entry:** The Wiki provides employees and employers with a central point of contact to look up uniform routine processes in their daily work:
  - Employees can use the search function to quickly find all important regulations.
  - The notification system keeps them informed of all new developments.
- **Legal requirements:** Pharmaceutical companies or banks, for example, must ensure that they have "access at all times to the standardized written processes, regulations, rules and organizational structures" of their company.

Example pages

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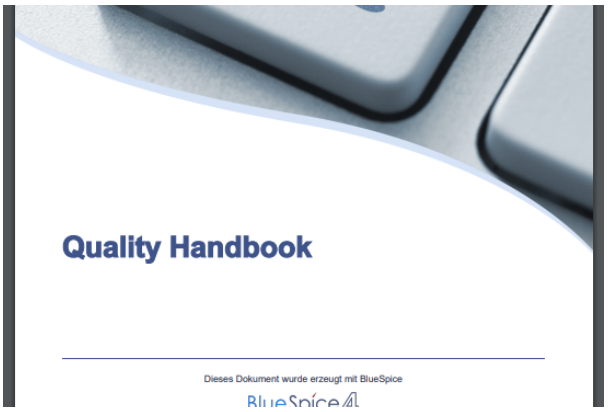

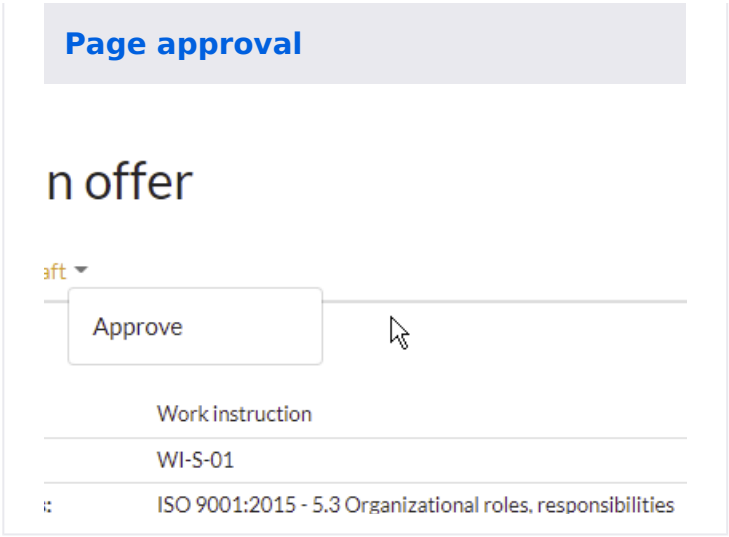

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Approved: ***Not approved*** / Revision: 21:31, 8 May 2024

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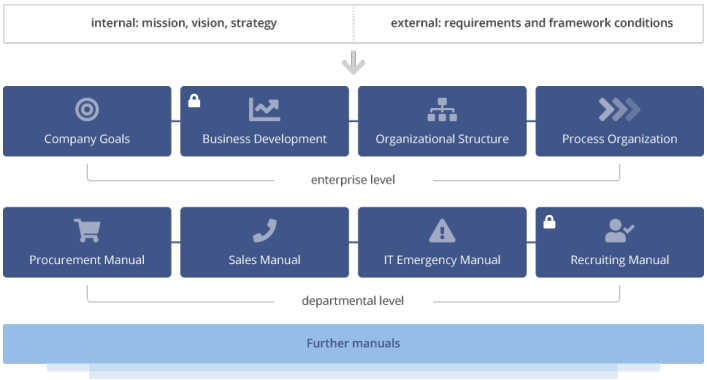

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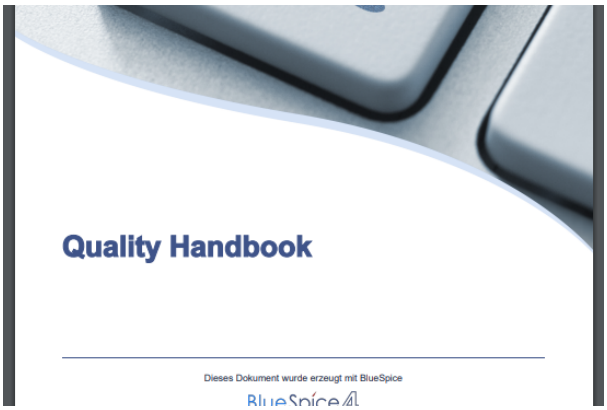

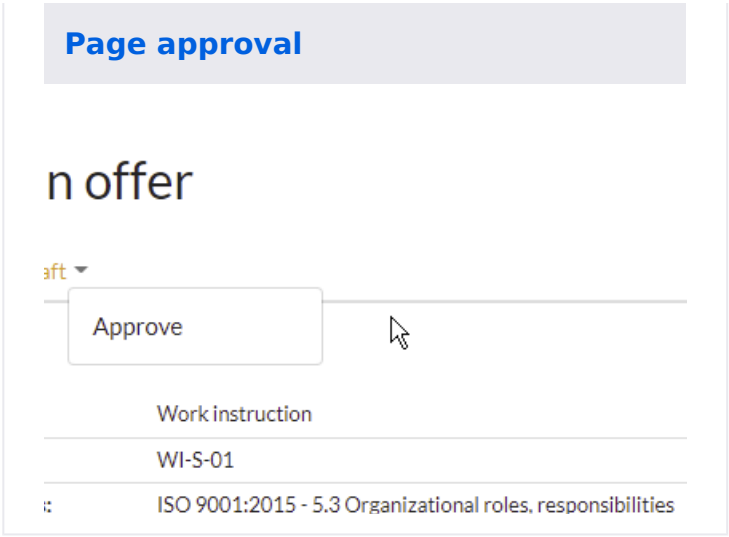

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Introduction

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Contents

1.1. Purpose and goals

The organization handbook (OHB) is used to describe the organizational structure of MyCompany Inc. and the tasks of the positions in the organizational units (divisions, specialist areas).

1.2. Validation

The OHB is valid in the latest version. A new revision status of the manual comes into effect when it is published in the company wiki.

1.3. Release

The OHB is managed or made available digitally in the company wiki. Paper-bound copies are held by the management.

1.4. Review

The OHB is reviewed at least annually. Necessary changes are to be communicated to management. Significant changes require the approval of management.

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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.