QMS ISO 9001 Document Control Plan Template – Example

QMS ISO 9001 Document Control Plan

Company Name		Date

Prepared by	Reviewed by	Approved by

1. Purpose

This section defines the purpose of the Document Control Plan, which is to establish a procedure for the management, control, and revision of all documents relevant to the Quality Management System (QMS) to ensure that they remain current, approved, and properly maintained. The purpose is also to comply with ISO 9001 requirements for document control.

Text

2. Scope

This section outlines the types of documents covered by the Document Control Plan, including policies, procedures, work instructions, forms, manuals, and external documents relevant to the QMS. The scope defines which departments or processes are subject to document control and the applicability of the control system across the organization.

Text

3. Definitions

- **Document:** Any written, electronic, or digital information used within the QMS
- **Revision:** A formal change made to an existing document
- **Obsolete Document:** A document that is no longer valid for use and has been replaced or archived
- **Document Owner:** The individual responsible for ensuring that a document is up-to-date, accurate, and compliant

4. Responsibilities

Defines the key roles in the document control process:

- **Document Owner:** Responsible for drafting, revising, and maintaining the document
- **Document Controller:** Ensures that documents are properly stored, distributed, and updated
- **Approving Authority:** The individual(s) responsible for approving the document before it is released for use
- **Users:** Personnel who must follow the procedures defined in controlled documents

5. Document Control Procedure

5.1 Document Creation and Identification

All documents must be clearly identified with a unique document number, title, version number, issue date, and department or function to which they pertain. Each new document or form must follow a structured naming convention for traceability and control.

5.2 Document Review and Revision

Prior to approval, all documents must undergo a thorough review process. This includes verifying the accuracy, completeness, and relevance of the content, ensuring compliance with applicable standards or regulatory requirements. The document should also be revised periodically to remain current.

5.3 Document Approval

Documents must be formally approved by the relevant authority before being released for use. Each approval must be documented with the name of the approver(s), date of approval, and signature (digital or handwritten). No document may be issued without this approval.

5.4 Document Distribution

Once approved, documents must be distributed to relevant personnel. Distribution methods may include electronic dissemination (e.g., through a document management system) or physical copies. The distribution list must be maintained, ensuring only the latest version of the document is in use.

5.5 Document Revision

Whenever a change is made to a document, a new revision number is assigned. The revision history should clearly state the reason for the revision, date of the change, and the approving authority. All superseded versions must be archived to avoid confusion.

5.6 Document Storage and Accessibility

All controlled documents must be securely stored, whether in a digital or physical format. The document control system must ensure that documents are easily accessible to authorized personnel and protected from damage, loss, or unauthorized changes. Secure backup procedures should be in place for electronic documents.

5.7 Document Retention and Archiving

There must be a defined retention period for each document type based on its relevance, regulatory requirements, or company policy. After this period, documents are archived or disposed of securely. Archived documents must remain accessible for auditing or reference purposes.

5.8 Obsolete Documents

Obsolete or superseded documents must be clearly marked and removed from active use to prevent accidental use. They should be archived or disposed of in accordance with the retention policy. Obsolete documents may only be accessed for historical purposes or audits.

6. Document Control Register

6.1 Register Content

The Document Control Register is a log that tracks all controlled documents, including document number, title, revision number, date of issue, owner, next review date, and status (active or obsolete). It provides a centralized, up-to-date overview of all documents under control.

4.2 Review Schedule

Each document must have a scheduled review date to ensure its continued relevance and accuracy. This schedule should be noted in the register, with reminders set to prompt review before the revision date lapses.

4.3 Revision Status

The revision status of each document (Open, Closed, or Under Review) is tracked in the document control register. This provides transparency on the current state of document updates and any pending revisions.

7. Security and Access Control

7.1 Access Control

Documents should be accessible only to authorized personnel. This section defines security measures, such as password-protected files, restricted access to sensitive documents, and controlled physical storage for paper documents.

7.2 Document Integrity

To prevent unauthorized changes, documents must be protected using digital signatures, encryption, or version control in a document management system. This section also outlines measures to prevent accidental deletion or modification.

8. Training and Awareness

Personnel must be trained on the importance of document control and their role in the system. This section outlines the training requirements for document users, owners, and controllers. Training ensures that all personnel understand how to properly manage and control documents within the QMS.

Text

9. Auditing and Compliance

Periodic internal audits should be conducted to verify that document control procedures are being followed. This section details the audit process, including frequency, audit roles, and corrective actions required when non-compliance is identified.

Text

10. References

Includes references to relevant ISO 9001 clauses, company policies, or other documents that are applicable. This ensures that the document control procedures are aligned with the overall QMS and external documents or regulations.

Text

11. Appendices

Appendices may include sample forms, such as:

- **Document Review Form:** Used to record the review and approval process
- **Revision History Form:** Provides a detailed log of all revisions made to a document
- **Document Control Flowchart:** Visual representation of the document control process

Iso 900document Control

William C. Culley

Iso 900document Control:

    How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements Stephanie L. Skipper,2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system   **Document Control** Denise Robitaille,2011-09 They re supposed to be useful tools but whether they re printouts computer files flowcharts or forms documents can often give more headaches than help And yet without them most organizations couldn t function ISO 9001 and other quality management systems place great emphasis on documents and for good reason Documents aren t individual stand alone elements of the management process They re interrelated formatted in different media and controlled by various and distinct functions Keeping critical information current and in the right hands requires more than just signing off on procedures Document control is essential but where should you begin Inside you ll find clear explanations about the document control process as well as practical solutions for creating organizing and maintaining documents including A discussion of different kinds of documents including electronic media and QMS requirements Identifying and defining responsibility Understanding the relationship between documents and records Tips for document writers Managing and maintaining documents Issues of accessibility Handling revisions and deviations Writing document control procedures   Environmental and Quality Systems Integration William C. Culley,2019-09-17 Global competition corporate downsizing and corporate restructuring have forced many firms to reevaluate their operating methods Today corporations must do more with less while still watching the bottom line and improving profitability ISO 14000 and ISO 9000 because of their similar management system requirements and auditing procedures are g   **Mastering ISO 9001**

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