

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- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.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. The schedule should be noted on the original, with reminders sent to prompt review before the review date expires.

4.3 Revision Status

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

7. Security and Access Control

7.1 Access Control

Documents should be accessible only to authorized personnel. The 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 ensure unaltered integrity, documents must be protected using digital signatures, checksums, or other controls of a document management system. The 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. The section outlines the training requirements for document users, owners, and controllers. Training records must be maintained as part of the QMS.

Text

9. Auditing and Compliance

Regular internal audits should be conducted to verify that document control procedures are being followed. The section details the audit process, including frequency, audit roles, and corrective actions required upon non-compliance.

Text

10. References

Include references to relevant ISO 9001 clauses, company policies, or other documents that are applicable to the document control process. This may include alignment with the product standard and any common standards 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 (provided as detailed log of all revisions made to a document)
- Document Control Register (detailed representation of the document control process)

Iso 9001 Document Control Procedure Example

William C. Culley



Iso 9001 Document Control Procedure Example:

ISO 9001 in Plain English Paton Professional, 2011-05 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

The ISO 9000 Quality System Debby L. Newslow, 2001-02-26 Author is a certified Quality Assurance Lead Auditor who has worked with more than 100 companies seeking ISO 9000 certification One of the only books on ISO 9000 compliance written exclusively for the food industry Examples are based on real world cases although company names and other identifying details are not included to protect privacy These examples can be invaluable to food companies who want to avoid potential pitfalls Relates ISO 9000 to other quality and safety assurance management systems *ISO 9001:2015 for Small Businesses* Ray Tricker, 2016-10-04 Small businesses face many challenges today including the increasing demand by larger companies for ISO 9001 compliance a challenging task for any organisation and in particular for a small business without quality assurance experts on its payroll Ray Tricker has already guided hundreds of businesses through to ISO accreditation and this sixth edition of his life saving ISO guide provides all you need to meet the new 2015 standards ISO 9001 2015 for Small Businesses helps you understand what the new standard is all about and how to achieve compliance in a cost effective way Covering all the major changes to the standards this book provides direct accessible and straightforward guidance This edition includes down to earth explanations to help you determine what you need to enable you to work in compliance with and or achieve certification to ISO 9001 2015 a contextual explanation of ISO 9001 within the structure of ISO 9000 family of standards a detailed description of the structure of ISO 9001 2015 and its compliance with Annex SL coverage of the new requirements for Risk Management and Risk Analysis a guide to the costs involved in implementing ISO 9001 2015 and advice on how to control costs an example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Word Instructions and access to a free software copy of these generic QMS files to give you a starting point from which to develop your own documentation This book is also supported with a complete bibliography containing abbreviations and acronyms as well as a glossary of terms This comprehensive text will provide you and your small business with a complete guide on your way to ISO compliance

Guide to Quality Management Systems for the Food Industry Ralph Early, 2012-12-06 Whenever I step into an aeroplane I cannot avoid considering the risks associated with flying Thoughts of mechanical failure pilot error and terrorist action fill my mind I try to reassure myself with statistics which tell me there is greater chance of injury crossing the road The moment the plane takes off I am resigned to my fate placing faith in pilots who are highly qualified and superbly trained for the task of delivering me safely to my destination To be a passenger in an aeroplane is to express faith in the

systems used by the airline It is to express a faith in the quality of the airline s organisation and the people who work within it The same is true of surgery Thoughts of mortality are difficult to avoid when facing the surgeon s knife However faith in the surgeon s training and skill faith in the anaesthetist and theatre technicians faith in the efficient resources and quality of the hospital all help to convince that there is little need to worry Apart from flying and surgery there are many facets of life which entail risk but knowing the risks we willingly place our confidence in others to deliver us safely In the consumption of food however few of us consider the risks Everyday if we are fortunate we eat food Food sustains and gives us pleasure Food supports our social interactions

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

ISO 9001:2008 for Small Businesses Ray Tricker,2014-01-21 Small businesses face many challenges today including the increasing demand by larger companies for ISO compliance Compliance is a challenging task for any organisation and can often be time consuming and costly particularly for small businesses who are unlikely to have quality assurance experts on the payroll However it is still possible to achieve compliance without the need for expensive consultancy or training that takes you out of the office Ray Tricker has already guided hundreds of businesses through the challenge and this the 5th edition of his life saving ISO guide has been rewritten and refined following 5 years field use of working with the standard The one area that an organisation particularly a small business always wants to know is how much is it going to cost to implement and operate a QMS compliant with ISO 9001 2008 and is it going to be worth the trouble Due to popular demand Edition 5 now includes a brand new chapter on the cost of implementing ISO 9001 2008 This edition provides Relevant examples that put the concepts and requirements of the standard into a real life context Down to earth explanations to help you determine what you need to work in compliance with and or achieve certification to ISO 9001 2008 An example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Work Instructions Access to a free software copy of this generic QMS files available from the author to give you a starting point from which to develop your own documentation ISO 9001 2008 is the

most widely followed quality management standard and the rewards can be great opening up new business opportunities as well as bringing real improvements to your processes and outputs

Industry's Guide to ISO 9000 Adedeji Bodunde Badiru,1995-05-29 Industry's Guide to ISO 9000 offers a complete reference book for industry practitioners It emphasizes technical and managerial processes especially project management techniques to implement changes at the product development level Because personnel play a central role in the ISO 9000 standard Industry's Guide to ISO 9000 focuses on people related issues and shows how with proper management normally arduous procedures can be made easier for all concerned Practitioners in all functional areas of business and industry industrial and systems engineers process engineers designers R D managers plant managers production supervisors manufacturing engineers and quality engineers will find Industry's Guide to ISO 9000 an essential guide to professional success

A Practical Field Guide for AS9100C Erik V. Myhrberg,2010-02-08 The purpose of this field guide is to assist the reader step by step in implementing a Quality Management System QMS in conformance with AS9100C This field guide has been created in order to foster an inner reliance between senior management middle management functional teams and the individual Users of the field guide will find within it practical tools tips and techniques useful for not only implementing a QMS but also for maintaining one What separates this field guide from most other books on AS9100 and its implementation are the flow charts showing the steps to be taken in implementing a QMS to meet a sub clause's requirements You need to turn out aerospace conforming parts on time every time and at a competitive cost as that's exactly what the companies that can compete now and in the future will do A Practical Field Guide for AS9100 will help to get you there

Using ISO 9001 in Healthcare James M. Levett,Robert G. Burney,2010-11-19 Healthcare providers deal with quality concepts and tools on a regular basis but the idea of a quality system or quality management system QMS is not a familiar term Most are familiar with control charts Lean the PDCA cycle Six Sigma and the Baldrige criteria but ISO 9001 is not usually recognized and most have no experience with a systematic program to implement quality objectives within an organization This book explains the overall value of an ISO 9001 based QMS its value in implementing a quality culture within an organization using other quality tools within the ISO framework clinical integration accreditation and performance improvement Several case studies of ISO implementation in healthcare organizations are described including a large multi specialty group a community hospital and hospital system and the State Department Medical Unit in D C

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