

QMS ISO 9001 Document Control Plan Template – Example

QMS ISO 9001 Document Control Plan

Category Name	Date	
Responsible	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, reviewed, 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- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.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.
- User:** Personnel who must follow the procedures defined in controlled documents.

4.1. Review Schedule

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

4.2. Revision Status

The revision status of each document (Draft, Clean, or Under Review) is listed in the document control register. This provides transparency on the current state of document control 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 access-controlled files, restricted access to controlled documents, and controlled physical storage of 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. The section also outlines measures to prevent unauthorized deletion or modification.

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 the 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.

6.2. Review Schedule

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

6.3. Revision Status

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

6.4. Training and Awareness

Training must be applied on the importance of document control and how it fits into the system. This includes the training requirements, the document types, owners, and reviewers. Training records must be maintained and reviewed on a regular basis.

Text

6.5. Auditing and Compliance

Regular internal audits must be conducted to verify that document control processes are being followed. The review period, audit process, including frequency, audit criteria, and corrective action measures must be documented.

Text

10. References

Includes references to relevant ISO 9001 clauses, internal policies, or other documents that are necessary to the document management system. This must ensure alignment with the quality system and relevant regulations.

Text

11. Appendices

- 1. Document Review Form: Used to record the review and approval process.
- 2. Revision History Form: Provides a detailed log of all revisions made to a document.
- 3. Document Control Register: Maintains a log of all documents under control.

Iso 90control Of Documents

**Adalbert Evers, Riitta Haverinen, Kai
Leichsenring, Gerald Wistow**

Iso 90control Of Documents:

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 *Tool and Manufacturing Engineers Handbook: Plastic Part Manufacturing* Philip Mitchell, 1996-12-09 This volume focuses on the practical application of processes for manufacturing plastic products It includes information on design for manufacturability DFM material selection process selection dies molds and tooling extrusion injection molding blow molding thermoforming lamination rotational molding casting foam processing compression and transfer molding fiber reinforced processing assembly and fabrication quality plant engineering and maintenance management **QS-9000 Handbook** Jayanta Bandyopadhyay, 1996-04-01 Here is a survival strategy for suppliers to the automotive industry With QS 9000 serving as the new harmonized quality systems requirement of internal and external suppliers for Chrysler Ford General Motors as well as other automobile and truck manufacturers and assemblers the QS 9000 Handbook is your practical guide for achieving registration Any company that wishes to achieve registration must provide evidence of quality production to third party audits of the registrar The QS 9000 Handbook will do just that as well as show you how to document your quality systems train personnel in quality and improve the effectiveness of any independent quality assurance functions inside your operation

Clinical Engineering Handbook Joseph F. Dyro, 2004-08-27 As the biomedical engineering field expands throughout the world clinical engineers play an ever more important role as the translator between the worlds of the medical engineering and business professionals They influence procedure and policy at research facilities universities and private and

government agencies including the Food and Drug Administration and the World Health Organization Clinical engineers were key players in calming the hysteria over electrical safety in the 1970s and Y2K at the turn of the century and continue to work for medical safety This title brings together all the important aspects of Clinical Engineering It provides the reader with prospects for the future of clinical engineering as well as guidelines and standards for best practice around the world

Developing Quality in Personal Social Services Adalbert Evers,Riitta Haverinen,Kai Leichsenring,Gerald Wistow,2019-05-23 First published in 1997 this volume is about the challenge of introducing business originated concepts of quality assurance personal social services are currently confronted with all over Europe Undoubtedly the new orientation towards a more business like approach in social welfare settings will raise professionalism client orientation and controlling instead of mere inspection There is evidence however that the specificities of personal social services are not always taken into account if it comes to introducing market values and mechanisms Due to this development it becomes essential to promote more adequate criteria for quality standards in the very field of personal social services The challenge is to maintain a certain standard of service provision while at the same time reconsidering the preconditions for defining quality This will imply the search for a consensus between allegedly diverging approaches i e between their different basic concepts aims and standards Given the social and economic context within which these developments are taking place the focus of the contributions is on their critical assessment in different European countries An overview is given about national developments in the areas of care for older persons and other social services The contributors from Austria Belgium Denmark Finland Germany Italy the Netherlands Norway Sweden and the UK look at how and by whom quality is defined and what challenges the actors of the traditionally mixed economy of personal social services are meeting Empirical evidence about user involvement and satisfaction is given but also theoretical reasoning about the impact of business approaches on a public good Thus the book tries to fill an important gap in practice research and policy making concerning personal social services and quality issues

U.S. Coast Guard Systems Times ,1999 Preparation for ISO 9000 Certification at Kolar Machines, Inc., Ithaca, NY Wayne Lam,Sten Peeters,1996 *Quality Engineering Handbook* Thomas Pyzdek,Paul A. Keller,2003-04-09 Written by one of the foremost authorities on the subject the Second Edition is completely revised to reflect the latest changes to the ASQ Body of Knowledge for the Certified Quality Engineer CQE This handbook covers every essential topic required by the quality engineer for day to day practices in planning testing finance and management and thoroughly examines and defines the principles and benefits of Six Sigma management and organization The Quality Engineering Handbook provides new and expanded sections on management systems leadership and facilitation principles and techniques training customer relations documentation systems domestic and international standards and more *ISO 9000 Implementation and Assessment: A Guide to Developing and Evaluating Quality Management Systems ,1996 THE VALUE OF MANAGEMENT CONTROL SYSTEMS: EVIDENCE ON THE MARKET REACTION TO 150 9000 QUALITY*

ASSURANCE CERTIFICATION SHANNON W. ANDERSON, J. DANIEL DALY AND MARILY F. JOHNSON,1995 **Export Quality Management** International Trade Centre UNCTAD/WTO.,2001 The Uruguay Round of multilateral trade negotiations significantly reduced tariff barriers to trade However exporters continue to face non tariff barriers in the form of standards technical regulations sanitary and phytosanitary measures and conformity assessment procedures To meet the requirements these impose and demonstrate compliance with them is a difficult and costly process for exporters in developing countries and transition economies Many of these countries have not yet been able to take full advantage of the WTO Agreements largely because of a lack of resources Given this the International Trade Center has produced this guide providing SME managers in developing countries and transition economies with answers in simple language to their most frequently asked questions on standards and conformity assessment The questions address issues such as technical regulations and standards product certification testing metrology quality management ISO 9000 other management systems accreditation and the Agreements on TBT and SPS **Software Engineering** Roger S. Pressman,2005 For more than 20 years this has been the best selling guide to software engineering for students and industry professionals alike This edition has been completely updated and contains hundreds of new references to software tools **InfoWorld** ,1996-07-29 InfoWorld is targeted to Senior IT professionals Content is segmented into Channels and Topic Centers InfoWorld also celebrates people companies and projects **Document Imaging Report** ,1994 **Integrating QS-9000 with Your Automotive Quality System** Dean H. Stamatis,1996 An overview and critical interpretation of the ISO 9000 series standards and the QS 9000 requirements for those who are new to the topic Coverage includes creation of an implementation strategy using a project management approach developing a training curriculum for ISO 9000 and QS 900 and speci **Impact of the Application of ISO 9000 and ISO 14000 on Selected Industrial Sectors** United Nations. Economic and Social Commission for Western Asia,2001 The aims of this study are to facilitate international and regional trade for industries in the ESCWA region by encouraging manufacturing companies to certify to ISO 9000 2000 and ISO 14000 and to be compatible with international requirements clarifying the issues surrounding the acceptability and adoption of the ISO quality and environment standards and the recognition of certificates issued by national bodies and promoting at reasonable cost the development of those aspects of infrastructure concerned with certification and accreditation including the training of qualified consultants Publisher s description **Texas Instruments Technical Journal** ,1992 **Nonwovens Markets and Fiber Structures Report** ,1993 **Financial Justification of Nondestructive Testing** Emmanuel P. Papadakis,2007 Publisher Description **Nuts & Volts** ,2005

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