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- **Obsolete Document**: A document that is no longer valid for use and has been replaced or archived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 training requirements for document care, access, and control. Training records must be maintained as part of 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 section supports consistency. This helps ensure alignment with the overall QMS and external 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**: Provides a detailed log of all revisions made to a document
- **Document Control Flowchart**: Visual representation of the document control process

Iso 9001 Document Control Procedure Sample

Roy M. Chiulli

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  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 *Implement ISO9001:2008 Quality Management System* DIVYA SINGHAL,K. R. SINGHAL,2012-04-02 ISO 9000 series standards have changed the whole concept of quality management methods ISO 9001 2008 QMS standard has been implemented and ISO 9000 series standards have been adopted as national standards or endorsed for use in 178 countries and economies ISO 9001 2008 Quality Management System QMS is based on eight quality management principles and there are various internal and external benefits of implementing this standard whether or not an organization goes for certification This book provides the readers with an accessible and up to date introduction to the essentials of a quality management system discusses what is in the ISO 9001 2008 QMS and shows how the organizations can implement this system With the authors extensive experience in QMS audit training and advisory services the book incorporates basic information on understanding and implementing ISO 9001 2008 QMS and highlights its importance towards making quality the fundamental business principle The text contains plenty of practical tips and guidance on how to implement ISO 9001 2008 QMS in the real world It discusses sample QMS procedures emphasizes the importance of maintaining a value added internal audit system and highlights the necessity of developing the QMS documentation procedures Apart from the regular BBA MBA and diploma courses in Total Quality Management this book is also suitable for Management Development Programmes in Quality Management and ISO 9001 offered to professionals by many of the B schools   The ASQ Certified Reliability Engineer Handbook Karen Hulting,Mary McShane-Vaughn,2025-11-12 This updated handbook is ideal for working professionals who specialize in improving the reliability maintainability and safety of products systems and processes Organized according to the 2025 ASQ Certified Reliability Engineer CRE Body of Knowledge BoK the fourth edition of The ASQ Certified Reliability Engineer Handbook has been expanded to include new information tools and techniques Inside you ll find a comprehensive view of the role of a reliability engineer with a focus on the basics as well as the latest technology and applications used today Revised sections are also designed to expand the knowledge base of current CREs candidates preparing for the ASQ CRE certification exam and engineering students   **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

SHE Management Systems for Small to Medium-sized Enterprises Anders Jacobsson,2000 The production and use of chemicals frequently involves the handling of hazardous materials Experience built up by chemical manufacturers and users over many years has established methods of working which when correctly applied reduce the risks involved to acceptable levels Major companies in the process industries have found that the safety health and environmental aspects of their operations can be further improved if the individual procedures are integrated into a management system

Textbook of Assisted Reproductive Techniques Fourth Edition David. K Gardner,Ariel Weissman,Colin M. Howles,Zeev Shoham,2012-06-27 Textbook of Assisted Reproductive Techniques has become a classic comprehensive reference for the whole team at the IVF clinic The fourth edition comes more conveniently as a set of two separate volumes one for laboratory aspects and the other for clinical applications The text has been extensively revised with the addition of several important new contributions on laboratory aspects including developing techniques such as PICSI IMSI and time lapse imaging The second volume focuses on clinical applications and includes new chapters on lifestyle factors tailored ovarian stimulation frozen thawed embryo transfer viral disease and religious perspectives As before methods protocols and techniques of choice are presented by eminent international experts The two volume set includes Volume One Laboratory Perspectives Volume Two Clinical Perspectives **Tietz Textbook of Clinical Chemistry and Molecular Diagnostics - E-Book** Carl A. Burtis,Edward R. Ashwood,David E. Bruns,2011-12-16 As the definitive reference for clinical chemistry Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 5th Edition offers the most current and authoritative guidance on selecting performing and evaluating results of new and established laboratory tests Up to date encyclopedic coverage details everything you need to know including analytical criteria for the medical usefulness of laboratory procedures new approaches for establishing reference ranges variables that affect tests and results the impact of modern analytical tools on lab management and costs and applications of statistical methods In addition to updated content throughout this two color

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Complete Guide to ISO 14000 Richard Barrett Clements,1996 This guide offers an overview of ISO 14000 a newly developed set of international standards for environmental management Their benefits and effects on a wide variety of companies are discussed *ISO 9000* Roy M. Chiulli,2001 If you are switching from using MIL Q 9858 to ISO 9000 and don t want to become an ISO 9000 expert this book is for you Easily read in an hour or two the book provides managers and engineers with a quick basic understanding of these important international standards The Certified Quality Manager Handbook Duke Okes,Russ Westcott,2001 Designed as a study aid for those preparing to take the Certified Quality Manager Examination administered by the American Society for Quality ASQ this book provides a thorough understanding of the principles terms and concepts of quality management The new second edition contains practical examples from many different industries and organizations including manufacturing health care government education and the service industries

The Memory Jogger 9000/2000 Robert W. Peach,Bill Peach,Diane S. Ritter,2000 Guide your organization quickly easily and effectively through the ISO 9001 2000 registration process This convenient reference guide is designed to help your organization follow its course toward ISO registration from preparation to implementation and maintenance with additional discussion about further improvement choices Because the registration process will affect everyone in your organization The Memory Jogger 9000 2000 is designed for use by every member of your company not just the few people responsible for guiding the implementation process Each clause is separated into sections describing what the clause is why it should be done how it should be done and what is new in ISO 9001 2000 Examples of quality documents and quality records are included to illustrate ways to comply with ISO requirements **The ISO 9000 Quality Manual Developer** Janet L. Novack,1995 A practical tool to aid in developing basic ISO 9000 quality policies and write a Quality Manual this book disk set includes detailed worksheets designed to be used as a working plan for meetings and discussions towards the development and writing of the quality policies Disk contains templates for converting the step by step plans developed through the worksheets into the required documentation **Integrated Circuit Metrology, Inspection, and Process**

Control ,1994   **Total Quality Management in the Chemical Industry** G. R. Turner,R. P. Hadfield,Society of Chemical Industry (Great Britain),1994 Total Quality in the Chemical Industry relates first hand experiences of both successes and the difficulties encountered in following the Total Quality philosophy It is complementary to existing how to guides illustrating the way this philosophy works in actual practice The book begins with a brief introduction to the subject and goes on to describe real examples of the implementation of total quality management in industry in both manufacturing and research The bulk of the papers cover developments in the chemical industry but other industries are represented as well and the companies featured in the examples are widely recognized as being leaders in Total Quality Management TQM TQM is currently under criticism as being another management philosophy which fails to deliver yet this book shows that success can be gained and that the potential rewards are well worth the effort Total Quality Management in the Chemical Industry is essential reading for managers section leaders and safety professionals in the chemical industry and in most manufacturing industries as well   *Understanding and Implementing ISO 9000:2000* David L. Goetsch,Stanley Davis,2002 As organizations that compete in the global marketplace seek to achieve peak performance worldclass quality and personnel improvement interest in ISO 9000 certification has gained worldwide momentum This practical resource and guide uses a step by step model to understanding the ISO 9000 2000 series of standards and explains how to use them in an organization Provides a detailed summary of similarities and differences between the earlier version and ISO 9000 2000 Features ISO INFO boxes throughout that show how material being discussed applies to an actual work setting Offers a Serialized Case Study after every chapter that applies the information from a given chapter to how it was used in a real setting in which ISO 9000 registration was pursued the story unfolds with each new chapter showing the problems strategies mistakes and achievements of a company going through the registration process Ideal as a step by step how to guide for use in organizations that are interested in ISO 9000 registration   ISO 9000 Quality Management System Design Jay J. Schlickman,1998   **The ISO 9000 Documentation Toolkit** Janet L. Novack,1994 Enlarged revised and completely updated to include the new 1994 Revised ISO Standard this innovative book disk set is a practical toolkit designed to evoke discussion at planning meetings to be annotated and written in and to be employed in the writing of procedures Disk contains documentation templates in Microsoft Word for the PC and Mac and in WordPerfect for DOS   **Quality Manager's Complete Guide to ISO 9000** Richard B. Clements,1999   *Practical Support for ISO 9001 Software Project Documentation* Susan K. Land,John W. Walz,2006-10-13 This book addresses how to meet the specific documentation requirements in support of the ISO 9001 software process definition documentation and improvement which is an integral part of every software engineering effort Provides a set of templates that support the documentation required for basic software project control and management The book provides specific support for organizations that are pursuing software process improvement efforts   **Integrating ISO 14001 Into a Quality Management System** Marilyn R. Block,I. Robert

Marash,2002 This book encourages critical thinking about the similarities between ISO 14001 and the ISO 9001 QS 9000 quality standards and shares approaches used by various organizations through examples of documentation that have withstood the scrutiny of registrars

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