



Document Control Procedure Template

1. Purpose:

The purpose of this document control procedure is to ensure the effective management of documented information within [Organization Name], in accordance with ISO 9001:2015 requirements. This procedure establishes the processes for creating, reviewing, approving, distributing, and revising documents to maintain accuracy, consistency, and compliance with quality management standards.

2. Scope:

This procedure applies to all documented information generated, utilized, or maintained by [Organization Name] as part of its Quality Management System (QMS).

3. Responsibilities:

- **Quality Manager:** The Quality Manager is responsible for overseeing the implementation of this document control procedure and ensuring compliance with ISO 9001 requirements. Responsibilities include:
 - Establishing document control processes and procedures.
 - Providing training and guidance on document control requirements.
 - Monitoring the effectiveness of document control activities and initiating improvements as necessary.
- **Document Owners:** Document Owners are responsible for creating, updating, and maintaining documents within their area of expertise. Responsibilities include:
 - Ensuring that documents are accurate, up-to-date, and aligned with relevant standards and procedures.
 - Reviewing and approving documents before distribution.
 - Notifying the Quality Manager of any changes or updates to documents.
- **Document Controllers:** Document Controllers are responsible for managing the day-to-day activities related to document control. Responsibilities include:
 - Maintaining a central repository of all documents and records.
 - Ensuring that document numbering, naming, and version control are maintained consistently.

Sample Document Control Procedures

Yi-Tong Ma



Sample Document Control Procedures:

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 *Annual Book of ASTM Standards* ASTM International, American Society for Testing and Materials, 2004 **"Code of Massachusetts regulations, 2016"**, 2016 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **The Massachusetts register**, 1991-09-13 **"Code of Massachusetts regulations, 2011"**, 2011 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2008"**, 2008 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2012"**, 2012 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2013"**, 2013 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2010"**, 2010 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2014"**, 2014 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 **"Code of Massachusetts regulations, 2007"**, 2007 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of

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