



## 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

**Michal Rosen-Zvi**



## **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

**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 EPA-600/4 ,1983

**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 given in *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

*Essentials of Blood Transfusion Science* Dr. Erhabor, Dr. Adias, 2013-03-19 Blood transfusion is a field where there have been and continues to be significant advances in science technology and most particularly governance This book aims to provide you with a comprehensive overview of both the scientific and managerial aspects of blood transfusion medicine The book is intended to equip biomedical clinical and allied medical professionals with practical tools to allow for an informed practice in the field of blood transfusion science Dr Erhabor Osaro 2013 [Wiley Practitioner's Guide to GAAS 2011](#) Steven M. Bragg, 2010-12-01 The clearest easiest to use guide to understanding GAAS 2011 on the market fully updated This latest resource to understanding GAAS addresses the toughest part of the job identifying interpreting and applying the many audit attest review and compilation standards relevant to a particular engagement A brief identification of each SAS SSAE and SSARS with its effective date and tips on when to apply it A convenient and comprehensive glossary of official definitions which are usually scattered throughout a standard Behind the scenes explanations of the reasons for each pronouncement and brief explanations of the basic ideas of the section Concise listing and descriptions of each standard s specific mandate Easy to read capsule summary of interpretations plus selected AICPA practice alerts and advisories Helpful techniques for remaining compliant with each standard Examples and illustrations for testing internal controls The only GAAS reference organized according to practitioners actual use of the Statements on Auditing Standards SASs Wiley Practitioner s Guide to GAAS 2011 presents each statement individually explaining how the standards are related and offering guidance on the entire engagement process in the form of practice notes checklists questionnaires and real world examples that illustrate how the fundamental requirements of each section are applied [Wiley Practitioner's Guide to GAAS 2012](#) Steven M. Bragg, 2011-10-19 The clearest easiest to use guide to understanding GAAS 2012 on the market fully updated This latest resource to understanding GAAS addresses the toughest part of the job identifying interpreting and applying the many audit attest review and compilation standards relevant to a particular engagement The only GAAS reference organized according to practitioners actual use of the Statements on Auditing Standards SASs inside you ll find examples and illustrations for testing internal controls techniques for remaining compliant with each standard and explanations of the reasons for each pronouncement A brief identification of each SAS SSAE and SSARS with its effective date and tips on when to apply it A convenient and comprehensive glossary of official definitions which are usually scattered throughout a standard Behind the scenes explanations of the reasons for each pronouncement and brief explanations of the basic ideas of the section Concise

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*Managing Web Projects* Edward B. Farkas, 2009-10-27 Getting Web projects done right and delivered on time is all about efficiency Putting the information you need and tools you can rely on at your ready disposal *Managing Web Projects* is a complete guide for project managers in the Internet networking industry Whether you are a Web developer or an Internet Service Provider whether your project is a qu

Integrating Business Management Processes Titus De Silva, 2020-08-18 Integrating Business Management Processes Volume 3 Harmonising Quality Food Safety and Environmental Processes 978 0 367 48547 4 Shelving Guide Business Management The backbone of any organisation is its management system It must reflect the needs of the organisation and the requirements of its customers Compliance with legal requirements and ethical environmental practices contributes towards the sustainability of the management system Whatever the state of maturity of the management this book one of three provides useful guidance to design implement maintain and improve its effectiveness and is intended to provide readers with practical how to methods for integrating quality safety and environmental management processes This volume sets out procedures and flowcharts to show how the integration of these processes can be achieved Separated into management procedures core procedures support procedures and assurance procedures and complemented by practical examples this book is an invaluable resource for complete systems development and integration This book along with its two companion volumes is a practical guide for real managers designed to help them manage their business more effectively and gain competitive advantage Titus De Silva is a consultant in management skills development pharmacy practice quality management and food safety and an advisor to the newly established National Medicines Regulatory Authority NMRA in Sri Lanka

**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 Green Profits Nicholas P Cheremisinoff, Avrom Bendavid-Val, 2001-05-17 Green Profits covers two tightly connected topics environmental management systems EMS and pollution prevention P2 in a single volume Authored by an environmental engineer and an economist planner Green Profits shows how to implement an EMS especially ISO 14001 so that it leads to profitable pollution prevention innovations and how to identify and implement pollution prevention measures in a sound strategic business framework Green Profits provides the knowledge and tools for enterprise managers to achieve the benefits of both EMS and P2 and to do so in ways that fit in with existing management systems in their enterprises Environmental management systems are planned and organized ways for an enterprise to manage its interactions with the environment in particular those interactions that consume resources degrade the environment and create human health risk Part I of Green Profits provides a thorough and practical understanding of the elements of EMSs in general and ISO 14001 in particular tools and techniques for implementing an EMS and achieving ISO 14001 certification and help with getting the implementation process started Pollution prevention involves replacing process technologies that generate pollution with those that do not or that do so much less It focuses on improving production processes to minimize waste rather than treating effluents or emissions which add to costs Part II of Green Profits provides tools such as step by step guides to conducting a P2 audit and energy and material balances for identifying P2 opportunities in an enterprise examples of P2 practices in specific industry sectors and a set of tools for assessing potential P2 investments from a bottom line point of view With this New Handbook Bring your facility into compliance Improve your corporate image Reduce your company s environmental liabilities Identify and save millions of dollars from pollution prevention projects This New Handbook Includes A step by step approach to implementing ISO 14001 A step by step approach to implementing Pollution Prevention Contains nearly 100 useful charts and tables used by the experts in establishing environmental action plans gap analyses establishing an Environmental Management System Contains dozens of useful charts and calculation methods with examples for evaluating the costs and savings to your company in implementing Pollution Prevention Dozens of industry specific case studies that you can learn and profit from Shows you in stepwise fashion how project financing principles and environmental cost accounting methods when coupled with EMS can save your company money This New Handbook is unique because unlike other volumes that separately

cover Environmental Management Systems and Pollution Prevention you have it all in one single volume written by Experts that are Practitioners Lead-based Paint, 1990 *The Process Approach Audit Checklist for Manufacturing* Karen Welch, 2004-12-31 Finally a comprehensive process audit checklist has been developed to be used with ISO 9001 2000 This manual was developed to assist anyone involved with conducting or planning quality system audits including quality auditors quality managers quality system coordinators management representatives and quality engineers In addition potential auditees in any function or position should find the questions useful in preparing for an audit Although the checklist could be amended to work for a service company the manual was created with a focus on the manufacturing sector to cover common processes such as production management customer related design and development training purchasing etc The manual includes a brief overview of the process approach discussion of problem areas often found by third party auditors the process audit checklist and forms to be used in conjunction with the process audit checklist to increase audit effectiveness Class A ERP Implementation Donald H. Sheldon, 2005-05-15 Class A ERP is often misunderstood and confused with software tools and implementations but is actually a management system for continuous improvement This book will resolve these myths by thoroughly describing the definition of Class A ERP and giving specifics for achieving Class A performance in a reasonable timeframe Examples from successes will be referenced to and the author will build a case for breaking the journey to world class performance into bite sized doable focus areas Class A ERP Implementation will help organizations set the stage for maximum effectiveness of both Lean strategies and Six Sigma and establish ERP disciplines as the prerequisite to success

**Annual Department of Defense Bibliography of Logistics Studies and Related Documents** United States. Defense Logistics Studies Information Exchange, 1993 **Project Execution of Mega-Projects for the Oil and Gas Industries** Soosaiya Anthreas, 2021-03-24 This book covers execution of mega industrial projects especially in oil and gas industries covering engineering procurement construction commissioning and performance testing It enumerates various tasks and deliverables under each discipline and sub disciplines to define the detailed scope of work supplies and services as per level III of Prima Vera Schedule developed from the contract based schedule It gives an overall idea of how a project rolls out from commencement date to initial acceptance and executed practically with total contractor s scope of work broken down into tasks activities at level III platform while highlighting that support for fool proof project execution Quality Assurance for Environmental Measurements John Keenan Taylor, Thomas W. Stanley, 1985 *Implementing Quality in Laboratory Policies and Processes* Donnell R. Christian Jr., Stephanie Drilling, 2009-11-24 In order to gain accreditation every laboratory must have a superior quality assurance program The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components Written by experts with global experience in setting up laboratories *Implementing Quality in Labora* **Developing a Successful Clinical Research Program** Cara East, 2018-08-08 This unique book is designed to help a medical team become a clinical research team It includes practical

information and tips for the initial stages of clinical research building a team negotiating a contract developing a budget and writing and improving a patient consent Chapters describing the nuts and bolts of how to actually perform the study follow including patient recruiting and retention screening follow ups and handling monitor visits Finally there is discussion of the yearly reviews and disclosures and not just surviving but acing the all important Food and Drug Administration audit Clinical research moves medicine forward and is a necessary part of bringing any new therapy device or procedure into routine medical care However it can be costly and convoluted and the methodologies of clinical research are not widely standardized Decreasing some of the chaos present in American clinical research is the primary goal of this book The second goal is to improve the understanding and education of those who enter clinical research whether in the frontline work of the clinical research site in the middleman companies who have a high turnover rate at a research hospital or institution or at medical corporations that depend on good clinical research to bring their products to market The third reason is to standardize American clinical research and to remove some of the vagaries and inconsistencies in the field Practical and user friendly Developing a Successful Clinical Research Program fills a need for a clear guide to developing and improving a first class research program in any clinical setting



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