

	<b>ISO 9001-2008 PROCEDURE</b>	<b>PROCESS OWNER</b> Information Technology Management			
<b>PROCEDURE TITLE:</b> Control of Documents	<b>DOCUMENT NUMBER:</b> ISO_4-23	<b>REVISION LEVEL:</b> Final Draft	<b>REVISION DATE:</b> 01/23/09	<b>Approval:</b> Managing Director	

### **Purpose / Scope:**

**Purpose:** The purpose of this procedure is to define the requirements for document control to assure that quality-related documents affecting work activities show evidence of review and approval by authorized personnel prior to issuing new or revised documentation.

**Scope:** The quality requirements in this section apply to the control of distribution, copies, and locations of documents and forms managed by WCRC.

Documents - Refers to policies, procedures, standards and regulations, or work instructions identified to meet ISO compliance related to our business system. Documents may be in paper or electronic form.

Forms (Records) – Refers to pre-defined documents used for recording information or data from production and other transactions related to the support of our business system. Completed forms may become records.

This procedure does not apply to Federal or State statutes, administrative rules or work instructions and departmental directives which define specific departmental tasks.

### **Responsibility:**

The Information Technology managing staff is responsible for assuring the control of our business system documentation including establishing document controls for specific projects when applicable.

All personnel are responsible for adhering to this procedure to assure that controlled documents are appropriately used, updated, and distributed in accordance to this procedure.

# Sample Work Instruction Document

**Marcel A. Müller**



## **Sample Work Instruction Document:**

**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 **Instruction Manual** ,1985 **ISO 9001:2000 Quality Management System Design** Jay J. Schlickman, 2003 Provides a set of design rules for creating a quality management system that will naturally translate into successful ISO 9001 2000 certification The book identifies the key documentation components and supplies guidelines for outlining and writing the quality manual standard operating procedures work instructions forms and records Two case studies illustrate the upgrade and recertification of a corporation from ISO 9001 1994 to ISO 9001 2000 and the creation of a company s first quality management system The author is an auditor certified by the ASQ ANSI registrar accreditation board Annotation copyrighted by Book News Inc Portland OR *Written Documents in the Workplace* Denis Alamargot, Patrice Terrier, Jean-Marie Cellier, 2008-01-09 Divided into three parts the first of which provides a linguistic definition of professional documents describing their different types and genres This definition necessarily takes into account both the formal characteristics of these types of document e g nature of linguistic units involved and their functional goals the way these linguistic units are used to fulfill the text s communicative aim The second part focuses on the mental mechanisms involved in written production in the workplace One of the aims of a professional writer is to compose a text which can be understood Text composition involves specific processes and strategies that can be enhanced One way of doing this is to give the writer suitable instructions while another is to provide him her with a suitable writing environment This last aspect leads us to

devote the third and final section to the comprehension of written documents in the workplace Awareness of the strategies implemented by different readers with more or less domain expertise in order to understand technical and professional documents can enhance the latter's readability Contributions from linguists psychologists and ergonomists from various countries ensure international scope and comprehensiveness Bridges the gap between fundamental research into writing and reading and the issue of the efficiency of written communication in the workplace Enables better content creation for professional writers

**Total Quality Management**, 1991 The ASQ Certified Six Sigma Black Belt Handbook Mary McShane-Vaughn, 2023-01-11 Fully updated to reflect the 2022 ASQ Certified Six Sigma Black Belt CSSBB Body of Knowledge BoK The ASQ Certified Six Sigma Black Belt Handbook Fourth Edition is ideal for candidates studying for the CSSBB examination This comprehensive reference focuses on the core areas of organization wide planning and deployment team management and each of the DMAIC project phases The fourth edition of this handbook offers thorough explanations of statistical concepts in a straightforward way It also reflects the latest technology and applications of Six Sigma and lean tools Updates you will find in the fourth edition include New topics and tools such as return on investment calculations the roles of coaching and finance in projects process decision program charts interrelationship digraphs A3 analysis maturity models key behavior indicators and audit MSA A new chapter on risk analysis and management Revamped statistics sections New tables figures and examples to help illustrate key points The ASQ Certified Six Sigma Black Belt Handbook Fourth Edition is also a valuable addition to any quality practitioner's library

*Quality Management System Handbook for Product Development Companies* Vivek Nanda, 2005-01-27 Quality Management System Handbook for Product Development Companies describes a systematic approach for quality management and continuous improvement via a formal management system The approach centers on a high level process for defining a QMS from essential prerequisites to improvement mechanisms The book outlines the five major QMS

Laboratory Quality/Management Kenneth N. Parson, 2012-12-29 This book should be of interest to the management of all types of laboratories supporting all types of scientific disciplines Even though the scientific processes may be different the overall approach to management is very similar including how technical processes should be managed and controlled The book addresses principal elements of laboratory management technical and support operations and offers several detailed how to procedures designed to help laboratory management to establish and maintain control through a continuous low level internal audit self assessment process This activity enables management to take prompt corrective action maintain control and provides the ability to measure improvement over time toward achieving a higher more efficient cost effective level of quality services to its assigned customers The objective of this book is to expand on the knowledge and understanding of laboratory quality management system process

**The ASQ Certified Six Sigma Yellow Belt Handbook** Govindarajan Ramu, 2022-06-30 This handbook is a helpful guide to Six Sigma process improvement and variation reduction Individuals studying to pass the ASQ Certified Six Sigma Yellow Belt CSSYB exam will find this

comprehensive text invaluable for preparation and it is also a handy reference for those already working in the field The handbook offers a comprehensive understanding of the Body of Knowledge BoK which will allow readers to support real Six Sigma projects in their current or future roles This handbook updated to reflect the 2022 BoK includes A detailed explanation of each section of the CSSYB BoK Essay type questions in each chapter to test reading comprehension Numerous appendices a comprehensive list of abbreviations and a glossary of useful terms Online contents including practice exam questions

Source lists which include webinars tools and templates and helpful publications **ISO 9000 Intranets Using**

**Microsoft® FrontPage® , The Quality System** Frank Caplan,2024-12-20 In its second edition the purpose of this handbook is to assist remediation site managers and their operating contractors in ensuring that each remediation system is effectively making progress toward site cleanup objectives and remains protective of human health and the environment

Writing and Managing SOPs for GCP Susanne Prokscha,2015-07-29 This book discusses managing SOPs for GCP from conception to retirement It recommends approaches that have a direct impact on improving SOP and regulatory compliance Throughout the text the book provides a user s point of view to keep topics focused on the practical aspects of SOPs and SOP management **Integrated Management System: Combining other standards with ISO 9001** Frede

Jensen,2016-10-07 The book is for the manager tackling the integration of multiple management standards such as for quality environment energy reduction occupational health safety finances and other requirements that we often end up bolting together with resulting inefficiencies due to conflicting approaches and duplication of efforts A well integrated management system will simultaneously provide people with a guide to prevent doing wrong and a platform to doing right from A bad system will put them in a straightjacket and prevent them from doing right The book is divided into bite sized sections overall introducing a management system framework that is compatible with and combines various management systems standards published by the International Standards Organization The framework is suitable for the integrated implementation of ISO 9001 2015 ISO14001 ISO 50001 EN 16001 OHSAS 18001 and most other recognised industry specific management standards **ETV Program Metal Finishing Technologies Quality Management Plan , 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      **Resources in Education** ,2001      *Strategies and Technologies for Developing Online Computer Labs for Technology-Based Courses* Chao, Lee,2007-10-31 For technology based online courses computer labs are necessary to support hands on practice for IT products The implementation of an online computer teaching lab is a challenging task Strategies Technologies for Developing Online Computer Labs for Technology Based Courses discusses design strategies implementation difficulties and the effectiveness of online labs This book provides scholars researchers and practitioners support for lab based e learning gives guidance on the selection of technologies for various projects and illustrates Web based teaching with case studies      **Certification Guide** ,      *ISO 13485:2016* Itay Abuhav,2018-05-11 Summary This book provides valuable effective guidance for understanding interpreting and implementing ISO 13485 2016 standard requirements Despite its more than 800 page length the author has specifically designed its contents to maximize usability for the reader with a table of contents identical to that of the ISO standard itself which enables easy navigation and orientation Pragmatic in style and down to earth in tone this book draws real life examples and case studies from the author s many years of experience in consulting to illustrate even the most complex of ISO 13485 2016 standard requirements and their implementation Identifying relevant requirements and how they harmonize with quality management systems developing processes for design and development as well as product realization and validation are just a few of the issues covered in depth by this publication In addition the author constantly reviews the distinctive characteristics and aspects of the medical device manufacturing industry so that the reader can also appreciate the subject of this book in an everyday context Features A pragmatic and down to earth approach towards the reader s understanding of ISO 13485 2016 standard requirements implementation Uses examples and cases from real life based on the author s many years of experience in quality management A table of contents structured identically to that of ISO 13485 2016 itself allowing easier navigation and orientation for the reader Emphasises guidance for ISO 13495 2016 standard requirements which are difficult to interpret and implement Constantly reviews the aspect of medical device industry characteristics and distinctive so the reader can reflect the content with its daily work      *Building an Effective Information Security Policy Architecture* Sandy Bacik,2008-05-20 Information security teams are charged with developing and maintaining a set of documents that will protect the assets of an enterprise from constant threats and risks In order for these safeguards and controls to be effective they must suit the particular business needs of the enterprise A guide for security professionals Building an Eff

## **Sample Work Instruction Document** Book Review: Unveiling the Power of Words

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