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

Susanne Prokscha

A red circular graphic with a gradient, appearing as a partial circle or a thick arc, located to the right of the author's name.

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 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 Instruction Manual ,1984

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 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 **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 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

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

Fundamentals of Manufacturing, Third Edition Philip D. Rufe, 2013 Fundamentals of Manufacturing Third Edition provides a structured review of the fundamentals of manufacturing for individuals planning to take SME S Certified Manufacturing Technologist CMfgT or Certified Manufacturing Engineer CMfgE certification exams This book has been updated according to the most recent Body of Knowledge published by the Certification Oversight and Appeals Committee of the Society of Manufacturing Engineers While the objective of this book is to prepare for the certification process it is a primary source of information for individuals interested in learning fundamental manufacturing concepts and practices This book is a valuable resource for anyone with limited manufacturing experience or training Instructor slides and the Fundamentals of Manufacturing Workbook are available to complement course instruction and exam preparation

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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 *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

Total Quality Management Mr. Rohit Manglik,2024-07-28 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels *ISO 9000 Intranets Using Microsoft® FrontPage®* , **Total Quality Management, (Revised Edition)** ,2011 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

ETV Program Metal Finishing Technologies Quality Management Plan , 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 *Mastering and Managing the FDA Maze* Gordon Harnack, 2014-07-18 The number of FDA regulations and the agency's increased expectations is staggering and their content tedious, creating a regulated industry need for compliance insight and appropriate detail. This book is the reference needed to successfully navigate through the FDA maze. The target audiences for this desk reference include Regulatory professionals who know their responsibility to keep their firm's employees trained and competent on FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance. Neophytes who know nothing about FDA but need a resource that provides both broad and specific information in sufficient detail to be useful. Beginners who know a little about FDA need to know more and need a reference tool to help them be more effective and productive on the job. Intermediates who know enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail. Busy managers who need to know regulatory requirements and FDA expectations in order to manage compliance in their specific activity. Busy executives, CEOs, COOs, and operations managers whom FDA holds responsible for all regulatory compliance who also need a desk reference with specific information to quickly assess regulatory compliance, identify potential noncompliance, and review corrective, preventive, and compliance actions.

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