



Standard Operating Procedure Document Control

Page 1 of 18
ECN #:
Effective:

SOP 4-002

Revision: 1

1.0 Purpose

- 1.1 The purpose of this procedure is to provide a system for editing, issuing, and controlling documents deemed as necessary by GMP requirements and company management.

2.0 Scope

- 2.1 Company documents are maintained under document control as described by this procedure.
- 2.2 This procedure will also apply to business procedures and other documents not required by GMP's but deemed necessary by the company management. All documents that are required by GMP and management are to be maintained under formal document control.

3.0 Applicable Documents

- 3.1 SOP 4-001 Engineering Change Notice
- 3.2 SOP 4-003 Records Retention Procedure
- 3.3 SOP 4-006 Specification Format Procedure
- 3.4 QMSM Quality Management System Manual
- 3.5 Attachment A: Engineering Change Notice Checklist
- 3.6 Attachment B: Notification and Receipt Sheet
- 3.7 Attachment C: Document Distribution Sheet

4.0 Definitions

- 4.1 Approval Cycle: That period in the life of an ECN from the time that it is placed into the review process to the time that the last required approval signature has been obtained.
- 4.2 Device Master Record (DMR): A compilation of records containing, but not limited to, the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, packaging requirements and labeling of a finished device.
- 4.3 Document Control System: The Document Control System deployed at the company is a paper-based system, which utilizes some on-line tools found on the company's intranet. Examples of these tools are email and shared folders with varied security features.
- 4.4 Document: Any manual or electronic record of a text or graphics image that represents a drawing, parts list, Bill of Material, purchasing specification, process specification, assembly procedure, test or inspection procedure, business procedure, etc., relating to products processed or administrated under the control of the company's Document Control Department.

Examples Of Document Control Procedure

Joanne M. Flood



Examples Of Document Control Procedure:

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

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

Implementing ISO/IEC 17025:2017 Bhavan (Bob) Mehta, 2019-02-21 The focus of this book is to demystify the requirements delineated within ISO IEC 17025 2017 while providing a road map for organizations wishing to receive accreditation for their laboratories AS9100 ISO 9001 2015 and ISO 13485 2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints

for the establishment of a quality management system QMS for many diverse industries Similar to these recognized QMS standards ISO IEC 17025 2017 for laboratory accreditation serves a unique purpose It is not unusual for laboratories to retain dual certification in ISO 9001 2015 and ISO IEC 17025 2017 However ISO IEC 17025 2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001 2015 This book highlights those differences between ISO 9001 2015 and ISO IEC 17025 2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO IEC 17025 2017 For those currently or formerly accredited to the 2005 version of ISO IEC 17025 an appendix outlines the changes between the 2005 and 2017 versions of the standard

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

Implementing ISO/IEC 17025:2017, Second Edition Bob Mehta, 2019-02-21 The focus of this book is to demystify the requirements delineated within ISO IEC 17025 2017 while providing a road map for organizations wishing to receive accreditation for their laboratories AS9100 ISO 9001 2015 and ISO 13485 2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for many diverse industries Similar to these recognized QMS standards ISO IEC 17025 2017 for laboratory accreditation serves a unique purpose It is not unusual for laboratories to retain dual certification in ISO 9001 2015 and ISO IEC 17025 2017 However ISO IEC 17025 2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001 2015 This book highlights those differences between ISO 9001 2015 and ISO IEC 17025 2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO IEC 17025 2017 For those currently or formerly accredited to the 2005 version of ISO IEC 17025 an appendix outlines the changes between the 2005 and 2017 versions of the standard

ISO 14001 Step by Step Naeem Sadiq, Asif Hayat Khan, 2019-01-22 This book provides practical advice on how to achieve compliance with ISO 14001 2015 the international standard for an EMS environmental management system With an EMS certified to ISO 14001 you can improve the efficiency of your business operations and fulfil compliance obligations while reassuring your employees clients and other stakeholders that you are monitoring your environmental impact This easy to follow guide takes a step by step approach and provides many sample documents to help you understand how to record and monitor your organisation s EMS processes Ideal for compliance managers IT and general managers environmental officers auditors and trainers this book will provide you with The confidence to plan and design an EMS Detailed descriptions of the ISO 14001 2015 requirements will give you a clear understanding of the standard even if you lack specialist knowledge or previous experience Guidance to build stakeholder

support for your EMS Information on why it is important for an organisation to have an environmental policy and a sample communications procedure will help you to raise awareness of the benefits of implementing an EMS and Advice on how to become an ISO 14001 certified organisation The book takes a step by step approach to implementing an ISO 14001 compliant EMS Key features A concise summary of the ISO 14001 2015 requirements and how you can meet them An overview of the documentation needed to achieve ISO 14001 2015 accreditation Sample documents to help you understand how to record and monitor your organisation s environmental management processes New for the second edition Updated for ISO 14001 2015 including terms definitions and references Revised approach to take into account requirements to address risks and opportunities Your practical guide to implementing an EMS that complies with ISO 14001 2015 buy this book today to get the help and guidance you need

The ISO 14000 EMS Audit Handbook Greg Johnson,2020-04-28 The ISO 14000 EMS Audit Handbook is an innovative and cost effective approach for the Environmental Management System EMS audit to ISO 14001 The Handbook presents comprehensive strategies for conducting all phases of the EMS audit including effective assessment processes for determining improved environmental performance [Guidelines for Risk Based Process Safety](#)

CCPS (Center for Chemical Process Safety),2011-11-30 Guidelines for Risk Based Process Safety provides guidelines for industries that manufacture consume or handle chemicals by focusing on new ways to design correct or improve process safety management practices This new framework for thinking about process safety builds upon the original process safety management ideas published in the early 1990s integrates industry lessons learned over the intervening years utilizes applicable total quality principles i e plan do check act and organizes it in a way that will be useful to all organizations even those with relatively lower hazard activities throughout the life cycle of a company **Guide to Quality Management**

Systems for the Food Industry Ralph Early,2012-12-06 Whenever I step into an aeroplane I cannot avoid considering the risks associated with flying Thoughts of mechanical failure pilot error and terrorist action fill my mind I try to reassure myself with statistics which tell me there is greater chance of injury crossing the road The moment the plane takes off I am resigned to my fate placing faith in pilots who are highly qualified and superbly trained for the task of delivering me safely to my destination To be a passenger in an aeroplane is to express faith in the systems used by the airline It is to express a faith in the quality of the airline s organisation and the people who work within it The same is true of surgery Thoughts of mortality are difficult to avoid when facing the surgeon s knife However faith in the surgeon s training and skill faith in the anaesthetist and theatre technicians faith in the efficient resources and quality of the hospital all help to convince that there is little need to worry Apart from flying and surgery there are many facets of life which entail risk but knowing the risks we willingly place our confidence in others to deliver us safely In the consumption of food however few of us consider the risks Everyday if we are fortunate we eat food Food sustains and gives us pleasure Food supports our social interactions

Software Metrics & Quality Assurance Mr. Rohit Manglik,2023-05-23 This book offers a detailed exploration of

software metrics quality assurance focusing on key concepts methodologies and practical implementations relevant to modern engineering and technology practices **ISO 9001:2015 in Plain English** Craig Cochran,2015-11-16 Just as he did with the bestselling ISO 9001 in Plain English Cochran has written a comprehensive yet easily understandable guide to ISO 9001 2015 ISO 9001 2015 in Plain English was written so that anyone at any level of the organization can get to the heart of the standard s requirements and how they apply to the organization quickly and simply This straightforward book is ideal for people who are new to ISO 9001 2015 experienced ISO coordinators who want to get more out of an established system as they transition to the new standard and for employees who just need a basic understanding of what ISO 9001 2015 is and how it applies to them Cochran explains each of ISO 9001 2015 s sections and clauses using real world examples and frequently asked questions *Accounting Policies and Procedures Manual* Steven M. Bragg,2012-06-19 Now in a fifth edition *Accounting Policies and Procedures Manual A Blueprint for Running an Effective and Efficient Department* is a how to guide on creating an effective and efficient accounting department policies and procedures manual Written by Steven Bragg the foremost authority in accounting and controllership issues the new edition includes A new complimentary Web site providing readers with the foundation for creating or enhancing their accounting department policies and procedures manual More coverage of accounting procedures including inventory billing cash receipts pricing order entry credit collections sales returns capital budgeting cash forecasting payroll and closing the books *Accounting Policies and Procedures Manual* is the tool every accounting department needs to regularize and systematize its procedures to match the best in the industry

Implementing ISO/IEC 17025:2005 Bhavan "Bob" Mehta,2013-04-16 The purpose of this book is to demystify the requirements delineated within ISO IEC 17025 2005 while providing a road map for organizations that wish to receive maintain accreditation for their laboratories AS9100 ISO 9001 and ISO 13485 are standards that support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for diverse industries Although similar to these recognized QMS standards ISO IEC 17025 serves a unique purpose laboratory accreditation It is not unusual for laboratories to retain dual certification to ISO 9001 and ISO IEC 17025 Strategic Management in Cement Industry Md Shafi Ahmed,2024-08-08 In the rapidly evolving landscape of the cement industry strategic management has become crucial for organizations seeking to maintain a competitive edge and drive sustainable growth This book is designed to serve as a comprehensive guide for professionals in middle management and above who are tasked with steering their organizations through the complexities of modern business environments Unlike introductory texts that focus on basic terminology and concepts this book assumes a foundational understanding of strategic management principles Instead it delves deeply into the specific challenges examples case studies and opportunities unique to the cement industry Aim is to provide actionable insights and practical frameworks that can be directly applied to real world scenarios The structure of this book is thoughtfully organized to cover all critical aspects of

strategic management from initial planning to implementation and ongoing monitoring We explore the nuances of strategic decision making within the context of the cement industry offering a blend of theoretical perspectives and empirical evidence to support effective management practices

Achieving Inventory Accuracy Donald H. Sheldon, 2004-07-15 This book is a step by step guide to achieving inventory record accuracy in a manufacturing retail or distribution facility Starting at day one the author outlines the necessary elements of procedure and discipline necessary for good sustainable process The result is 95 % perfect inventory balances with minimal cycle counting required for on going maintenance The book includes special aids such as Gantt charts cycle count process parameters and process celebration points Donald H Sheldon is certified at the Fellow level by APICS as CFPIM and as CIRM

Guidance Manual for Collection of Samples During RCRA Inspections Laura L. Gentile, 1995

Wiley Practitioner's Guide to GAAS 2019 Joanne M. Flood, 2019-07-30 The definitive reference for clarified standards application and compliance fully updated for 2019 The Wiley Practitioner's Guide to GAAS 2019 is the comprehensive and user friendly guide to Generally Accepted Auditing Standards Fully updated to reflect all new standards practices and statements including Statements on Standards for Accounting and Review Services SSARS and Statements on Standards for Attestation Engagements SSAE this essential resource offers practitioners a clear and complete reference in a single volume This book provides complete coverage of relevant areas including audit planning and documentation audit evaluation and evidence examination and review engagements and more to help auditors interpret and apply current auditing standards while maintaining full compliance with GAAS General auditing standards are subject to frequent updates and divergent interpretations yet practitioners need to keep pace with the latest changes if compliance is to be maintained Employing a logical organizational structure this guide defines and interprets each clarified standard and explains its relation to the engagement process Practice notes checklists questionnaires and relevant real world examples demonstrate how each section is applied This indispensable resource provides in depth guidance on GAAS interpretation application and compliance to help you Identify and apply each auditing SSAE and SSARS section Understand new requirements in clarified attestation standards Access technical alerts interpretation summaries and individual section descriptions and definitions Employ techniques to maintain compliance with each standard The Wiley Practitioner's Guide to GAAS 2019 provides auditing professionals with the expert guidance and up to date information necessary to save you time streamline your workload and maximize your job performance

Wiley Practitioner's Guide to GAAS 2017 Joanne M. Flood, 2017-02-15 The clearest easiest to use guide to understanding all the clarified standards including the new attestation standards fully updated This comprehensive guide to understanding Generally Accepted Auditing Standards GAAS is not just about auditing It addresses the toughest part of an accountant's job identifying interpreting and applying the many audit attest review compilation and preparation standards relevant to a particular engagement Wiley Practitioner's Guide to GAAS 2017 offers a clear and accessible distillation of the official language of GAAS Statements on Standards for Attestation Engagements SSAEs and

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Wiley Practitioner's Guide to GAAS 2017 is completely updated to reflect all the clarified standards and provide valuable implementation information.

Wiley Practitioner's Guide to GAAS 2010 Steven M. Bragg, 2009-10-22 Your clearest, easiest to use guide to understanding GAAS 2010 on the market, fully updated. This latest resource to understanding GAAS addresses the toughest part of your job: identifying, interpreting, and applying the many audit attest, review, and compilation standards relevant to a particular engagement. Wiley Practitioner's Guide to GAAS 2010 offers you:

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Wiley Practitioner's Guide to GAAS 2015 Joanne M. Flood, 2015-02-26 The all in one guide to the latest auditing standards with clear explanations and more. Wiley Practitioner's Guide to GAAS 2015 offers the most comprehensive coverage of auditing standards, practices, and procedures, clarifying complex guidelines in clear, easy to understand language. Each statement is presented individually with explanations and practice notes that highlight main ideas and mandates, giving practitioners a clearer understanding of SAS standards and how they're used. Practical illustrations, checklists, and

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Table of Contents Examples Of Document Control Procedure

1. Understanding the eBook Examples Of Document Control Procedure
 - The Rise of Digital Reading Examples Of Document Control Procedure
 - Advantages of eBooks Over Traditional Books
2. Identifying Examples Of Document Control Procedure
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Examples Of Document Control Procedure
 - User-Friendly Interface
4. Exploring eBook Recommendations from Examples Of Document Control Procedure
 - Personalized Recommendations
 - Examples Of Document Control Procedure User Reviews and Ratings
 - Examples Of Document Control Procedure and Bestseller Lists
5. Accessing Examples Of Document Control Procedure Free and Paid eBooks
 - Examples Of Document Control Procedure Public Domain eBooks
 - Examples Of Document Control Procedure eBook Subscription Services
 - Examples Of Document Control Procedure Budget-Friendly Options
6. Navigating Examples Of Document Control Procedure eBook Formats

- ePub, PDF, MOBI, and More
- Examples Of Document Control Procedure Compatibility with Devices
- Examples Of Document Control Procedure Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Examples Of Document Control Procedure
 - Highlighting and Note-Taking Examples Of Document Control Procedure
 - Interactive Elements Examples Of Document Control Procedure
- 8. Staying Engaged with Examples Of Document Control Procedure
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Examples Of Document Control Procedure
- 9. Balancing eBooks and Physical Books Examples Of Document Control Procedure
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Examples Of Document Control Procedure
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Examples Of Document Control Procedure
 - Setting Reading Goals Examples Of Document Control Procedure
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Examples Of Document Control Procedure
 - Fact-Checking eBook Content of Examples Of Document Control Procedure
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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