

Document Control Standard Operating Procedure (SOP) Template

Document Control SOP

Procedure Name

SOP Number	Author	Date

Purpose
Briefly describe why the SOP exists and how it supports the goal of maintaining controlled documents effectively.

Scope
Define which documents are controlled under this SOP and to which departments or processes it applies.

Responsibility
Identify who is responsible for document control tasks, such as creation, approval, and distribution.

Materials
List the specific tools, software, or resources required for document control (e.g., management systems, templates).

Procedure
Provide a step-by-step outline for creating, reviewing, approving, revising, and distributing documents.

Verification / Documentation
Explain how to verify documents for accuracy and how to track changes and approvals.

Archiving Conventions
Detail how and where documents are archived, including retention periods and access controls.

Definitions
Define key terms used in this SOP to clarify document control processes (e.g., "revision," "owner").

Term	Definition

Systems
Describe the systems used to store and manage controlled documents.

References
List relevant standards, guidelines, or documents that support this SOP.

Document Control Sop Example

Adrian Gee



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Clinical Laboratory Management Shakti Kumar Yadav, Ruchika Gupta, Sompal Singh, 2024-02-26 Medical laboratories not only assist the physicians in diagnosis and management of a disease but also play a role in community health. Apart from the analytical aspects of various investigations, the larger areas of human resource management, inventory management, and the like have been gaining importance as a part of laboratory management. There is a felt need for an understanding of the managerial aspects of a clinical laboratory especially in an institutional setting. Although this knowledge can be acquired from books on general management, subject there is a paucity of books dedicated to clinical laboratory management. Hence is a need for a simple and concise text for management in the clinical laboratory practice. This first of its kind book contains 50 chapters and is divided into ten sections. It is intended to provide an all encompassing overview of management in a clinical laboratory and is written in a way that makes the content easy to comprehend especially for those who have not been trained in the core management concepts. The book begins with an introduction to Laboratory Management and makes the reader familiar with the general aspect of management. Each section that follows focuses on an important aspect of laboratory management including but not limited to human resource management, accounting and finance, quality control, laboratory hazards and safety, and more. Clinical Laboratory Management shall be a valuable resource for clinical laboratorians, students of medical laboratory technology, laboratory managers, and hospital managers. It aims to help readers understand the managerial aspects of a clinical laboratory and serve as more efficient clinical laboratory managers.

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.

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 *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 Good Manufacturing Practices for Pharmaceuticals Joseph D. Nally,2016-04-19 With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change Offering a wide assortment of policy and guidance document references and interpretations this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide An essential companion for every pharmaceutical professional this guide is updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings **The Profitable Corrugated Box Code** Gaurav Malhotra and Vishal Malhotra,2021-08-26 In this book we have squeezed our 37 years of learning and provided the information in a nutshell If you can implement the suggestions made through the book you can tremendously improve the quality of your products and grow at a phenomenal pace You can leave your competition far far behind The book will certainly help corrugated box manufacturers like you break the quality myths make more money increase profits build reputation and avoid common mistakes in selecting the instruments and partnering with the right vendors Process Validation & cGMP (Part - 2) Mr. Rohit Manglik,2024-03-24 Advances knowledge of continuous process monitoring quality by design and advanced regulatory compliance in manufacturing **Quality in Healthcare** Corinne M. Karuppan,Nancy E. Dunlap,Robert Cavagnol,2025-05-15 Master Lean Six Sigma Skills to Improve Quality Across Healthcare Settings Through a fully integrated Lean Six Sigma project approach students build confidence using quality tools dashboards and data analysis to lead

measurable change A continuous case study reinforces concepts through practical A3 reporting while Excel tutorials career tips and video recorded interviews with healthcare professionals make learning dynamic relevant and applied to real settings With a focus on patient safety ethics and leadership this resource examines quality improvement challenges for today and tomorrow s healthcare leaders Key Features Builds a quality mindset around the DMAIC framework with tools dashboards A3 reporting and a Lean Six Sigma Toolkit Prepares students to lead quality improvement efforts across healthcare settings and pursue Lean Six Sigma certification for career advancement Features Excel tutorials FAQs numerous end of chapter problems learning activities and a continuous case study to reinforce hands on learning Written by healthcare and operations experts with deep academic clinical and leadership experience across diverse settings Instructor Resources include an Instructor s Manual PowerPoint slides a Test Bank and more

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition Graham P. Bunn, 2019-02-04 This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task oriented procedure based cultures to truly integrated quality business systems that are self detecting and correcting Chapter flow has been changed to adopt a quality systems organization approach and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends

Cell Therapy Adrian Gee, 2009-09-18 Cell Therapy cGMP Facilities and Manufacturing is the source for a complete discussion of facility design and operation with practical approaches to a variety of day to day activities such as staff training and competency cleaning procedures and environmental monitoring This in depth book also includes detailed reviews of quality the framework of regulations and professional standards It meets a previously unmet need for a thorough facility focused resource Cell Therapy cGMP Facilities and Manufacturing will be an important addition to the cell therapy professional s library Additional topics in Cell Therapy cGMP Facilities and Manufacturing Standard operating procedures Supply management Facility equipment Product manufacturing review release and administration Facility master file

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

Safe Blood and Blood Products: Introductory module: Guidelines and principles for safe blood transfusion practice, 2002

Safe blood and blood products is a series of interactive learning materials developed by the team responsible for Blood Transfusion Safety in the World Health Organization with the aim of assisting national blood programs in providing training

Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry Stephen Robert Goldman, 2003 This handbook details methods for sustainable compliance with GxPs and 21 CFR Part 11 validation requirements regarding computerized systems in the pharmaceutical biotechnology and medical device industry The handbook follows FDA guidelines and best industry practices in defining roles responsib

Complete Guide to ISO 14000

Richard Barrett Clements, 1996 This guide offers an overview of ISO 14000 a newly developed set of international standards for environmental management Their benefits and effects on a wide variety of companies are discussed Vaccine Manual

Noel Mowat, Mark M. Rweyemamu, Food and Agriculture Organization of the United Nations, 1997 This manual represents a response to a recommendation arising from an expert consultation on vaccine production and quality control held in 1991 It attempts to bring together information on the state of the art in veterinary vaccine development *Communicable Disease and Public Health*, 2004

A Laboratory Quality Handbook of Best Practices Donald C. Singer, 2001 **Handbook of Environmental Analysis** Roy Keith Smith, 1999 **Process Industry Procedures and Training Manual** James R.

Sawyers, Margaret M. R. Eastman, 1996 Covers techniques to document training procedures and testing of operator and maintenance personnel to meet regulatory requirements This manual arms you with the information and strategies you need to comply with regulatory standards from training to procedures and reference documentation to testing operations and maintenance personnel ASQC ... Annual Quality Congress Proceedings, 1994

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