

SOP Number: SOP -001		Page 1 of 5
DOCUMENT CONTROL		Revision Number: 1 Effective Date: Supersedes Revision: N/A
Author: Marian Boardley Date: 4/18/2013	Dept. Approval Signature: Date:	QA Approval Signature: Date:

I. PURPOSE

This SOP describes policies, procedures, and record keeping requirements for all documents subject to change control.

II. SCOPE

All SOP's and forms required for compliance with 21 CFR 111, the cGMP's for Dietary Supplements, including:

Subpart	Required Written Procedures
B	Fulfilling the requirements for personnel (21 CFR 111.8)
C	Cleaning the physical plant and pest control (21 CFR 111.16)
D	Fulfilling the requirements for equipment and utensils, including calibrating instruments and controls used in manufacturing or testing a component or dietary supplement; calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements (21 CFR 111.25)
F	The responsibilities of quality control personnel, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing (21 CFR 111.103)
G	Fulfilling the requirements for components, packaging, and labels and for product received for packaging or labeling as a dietary supplement (21 CFR 111.153)
J	Laboratory operations, including written procedures for the tests and examinations conducted to determine whether specifications are met (21 CFR 111.303)
K	Manufacturing operations (21 CFR 111.353)
L	Packaging and labeling operations (21 CFR 111.403)
M	Holding and distributing operations (21 CFR 111.453)
N	Fulfilling the requirements for returned dietary supplements (21 CFR 111.503)
O	Fulfilling the requirements for product complaints (21 CFR 111.553)

Document Control Sop Example

**Noel Mowat, Mark M.
Rweyemamu, Food and Agriculture
Organization of the United Nations**

Document Control Sop Example:

How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements Stephanie L. Skipper, 2015-10-12 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 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 **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, 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

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[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

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 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

A Laboratory Quality Handbook of Best Practices Donald C. Singer,2001

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

Communicable Disease and Public Health ,2004

Site Licensing Canada. Natural Health Products Directorate,2004

Handbook of Environmental Analysis Roy Keith Smith,1999

Process Industry Procedures and Training Manual James R. Sawers,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

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 birng together information on the state of the art in veterinary vaccine development

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