**ATTACHMENT 3 - Standard Operating Procedure Template**

## Standard Operating Procedure
## &lt;Name of Document &gt;

SOP 2017/##
Version No. 0.1

## 1 PURPOSE

*State the purpose of the method.*

## 2 SCOPE

*If appropriate, state any limitations as regards concentration range, matrix, interferences, sources of variability, cross reactions etc.*

*Also state who is to use this document.*

## 3 PRINCIPLE

*Include reactions, where applicable.*

## 4 DEFINITIONS

*Explain a word or action not generally understood, or which may have a specific interpretation in the procedure. If there are no definitions, insert "Nil" under this heading.*

## 5 REQUIREMENTS

*Where possible, list in order of use. Specify grade. Provide brief safety warnings if desired. Include calibrators and internal QC. Give brief details of standardisation of special reagents, where applicable, including in-house IVD classification.*

# Standard Operating Procedure Word Templates

**Jennifer Fulton**

**Standard Operating Procedure Word Templates:**

**Laboratory Control System Operations in a GMP Environment** David M. Bliesner,2020-06-03 Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System LCS operations In Laboratory Control System Operations in a GMP Environment readers are given the guidance they need to implement a CGMP compliant Laboratory Control System LCS that fits within Global Regulatory guidelines Using the Quality Systems Approach regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS In this guide readers learn the fundamental rules for operating a CGMP compliant Laboratory Control System Designed to help leaders meet regulatory standards and operate more efficiently the text includes chapters that cover Laboratory Equipment Qualification and Calibration Laboratory Facilities Method Validation and Method Transfer Laboratory Computer Systems Laboratory Investigations as well as Data Governance and Data Integrity The text also includes chapters related to Laboratory Managerial and Administrative Systems Laboratory Documentation Practices and Standard Operating Procedures and General Laboratory Compliance Practices Additionally a chapter outlining Stability Program operations is included in the text In addition to these topics it includes LCS information and tools such as End of chapter templates checklists and LCS guidance to help you follow the required standards Electronic versions of each tool so users can use them outside of the text An In depth understanding of what is required by the FDA and other globally significant regulatory authorities for GMP compliant systems For quality assurance professionals working within the pharmaceutical or biopharma industries this text provides the insight and tools necessary to implement government defined regulations **Data Integrity and Data Governance** Robert D McDowall,2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry Global regulatory agencies have issued guidance after guidance after guidance in the past few years most of which does not offer practical advice on how to implement policies procedures and processes to ensure integrity These guidances state what but not how Additionally key stages of analysis that impact data integrity are omitted entirely The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry It provides clarification of the regulatory issues and trends and gives practical methods for meeting regulatory requirements and guidance Using a data integrity model as a basis the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs This book is a useful reference for analytical chemists and scientists management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions Consultants will also benefit from the practical guidance provided **Planning Quality**

**Project Management of (EMR/EHR) Software Products** Richard Chamberlain,2017-11-10 When hospitals began implementing their electronic medical records electronic health records systems EMR HER the pharmaceutical companies that were conducting clinical trials at those hospitals wanted to sue the date from those systems instead of having the hospitals enter the data in their EHR systems and also in the study data entry system However the FDA regulations would require that the hospital systems be validated The hospitals and the companies developing the systems argued that was over regulation HIMSS published their Developer Code of Conduct where they said instead they would use Quality Management techniques This book covers how to use Quality Management ISO 9001 to develop computer systems specifically EMR systems It gives a basic introduction to how to implement computer systems It also covers the topic of compliance because the hospitals are required to comply with regulations other than FDS regulations The book also discusses the topics of risk management and conducting audits both of which are part of ISO 9001 quality management of computer systems The book is designed to give the reader an introduction to the things you have to do when implementing a computer system that has to satisfy some standards and where the accuracy of the information could impact the accuracy of a person s medical treatment

   **Business Report Guides** Dorinda Clippinger,2019-01-16 This book includes reports that managers originate often reports they may create occasionally organizational policies procedures and work instructions Inside the reader will discover guides for creating over 20 diverse reports designing report forms planning writing and formatting narrative reports producing digital and print employee manuals and locating the service providers and software that can improve your reports cost effectiveness A crisp writing style bullet points and many authentic examples and visuals convey essential information quickly Each chapter summary includes checklists Business Report Guides gives ample information to apply instantly It also works as a handy reference for use throughout your career     Clever Girl Finance: The Side Hustle Guide Bola Sokunbi,2021-06-29 Get the straight goods on how to build a thriving side hustle from someone who s been there before In Clever Girl Finance The Side Hustle Guide celebrated finance expert influencer CEO and author Bola Sokunbi delivers your own personal key to unlocking more money more freedom and more security in your life You ll find out how to achieve financial prosperity by leveraging a side hustle business to increase your income and build wealth You ll discover how to Build your confidence eliminate your fears and strengthen your focus Establish a strong foundation for your new business even without prior experience Create a solid plan to brand market and grow a business your customers won t be able to get enough of Write a realistic financial plan for your side hustle and to create long term wealth Perfect for those with a side hustle dream and some energy to spare Clever Girl Finance The Side Hustle Guide will also earn a place in the libraries of anyone who s ever thought about building a successful and profitable side hustle from the ground up but didn t know where to start     *Computer Psychotherapy Systems* Morton Wagman,2018-05-15 Originally published in 1988 this was the first book to examine the development application and evaluation of computer counselling and psychotherapy Integrating

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