

STANDARD OPERATING PROCEDURES	Center Name:
	SOP No.:
	Effective Date:
	Page No.: # of #
Approval:	
PRH Reference: #	
Title: Over-the-Counter (OTC) Medications	

This SOP is just an example. Each center must create its own policy to meet its students' needs that complies with applicable state and federal laws.

A. PURPOSE

To provide guidance on how to safely provide over-the-counter (OTC) medications to students for self-management of minor illnesses and conditions.

B. POLICY

OTC medications are drugs that have been found to be safe and appropriate for use without the supervision of a health care professional, such as a physician, and can be purchased without a prescription. OTC medications contain ingredients that may be used to treat certain diseases or conditions with the appropriate dose and instructions for use on the container.

Students periodically develop minor symptoms that are easily managed with OTC medications. These symptoms may develop during the training day or when the Health and Wellness Center (HWC) is closed. Unlicensed (non-health) staff members are trained in the use of Symptomatic Management Guidelines and should have OTC medications available for student use when following these Guidelines.

The health and wellness manager (HWM), in conjunction with the center physician or other dispensing practitioner, must determine which, where, and how OTC medications will be made available to students outside of the HWC.

C. PROCEDURES

- OTC medications provided by non-health staff must be individually packaged for single doses in a properly sealed and properly labeled container.
- OTC medications must be safely secured by staff members who are trained and authorized to hold OTC medications for student use. This will vary by state law.
- If a non-health staff member who is responsible for the OTC medications suspects that there might be inappropriate use by a student, he/she must report this to the HWC staff as soon as possible.
- An OTC medication sign-out sheet must be kept with the OTC medication box. The sign-out sheet should include: the student's name, the medication taken, the signature of the student, and signature of the observing staff member (see OTC Sign-Out Sheet Template).

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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 Validation Standard Operating Procedures Syed Imtiaz Haider, 2006-05-30 Spanning every critical element of validation for any pharmaceutical diagnostic medical device or equipment and biotech product this Second Edition guides readers through each step in the correct execution of validating processes required for non aseptic and aseptic pharmaceutical production With 14 exclusive environmental performance evaluation *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 **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

RibbonX Robert Martin, Ken Puls, Teresa Hennig, 2008-02-13 As the most radical change to the Office interface in its history the Ribbon replaces the traditional menu bar and toolbars and requires a new set of skills for customizing Instructions and examples demonstrate how to customize the Ribbon using VBA XML Access Excel and Word Covers the relevant aspects of security such as trust centers and digital certificates Packed with real world code examples that readers can immediately apply Features helpful references

Technical Writing Process Kieran Morgan, Alison Pickering, Amanda Butler, Caity Cronkhite, Felicity Brand, John New, Steve Moss, Swapnil Ogale, 2024-02-29 From the basics to advanced skills the Technical Writing Process is your comprehensive guide to the art and science of crafting technical documentation With eight core steps Plan Design Write Edit Review Translate Publish and Manage this guide integrates both classical writing principles and the transformative potential of modern tools like AI This book is more than a guide it s an invitation to embrace the art of writing instructions with the mentorship of our experienced technical writers Whether you re a novice writer or an industry stalwart aiming to refine your technical communication skills this book offers a blend of tried and true methods with the power of new age tools AI as a significant element of the modern toolkit receives special attention helping readers stay ahead of the curve Features Insights from industry experts around the world Real world case studies and examples Comprehensive chapters on techniques and concepts Downloadable templates to support each step in the process For exclusive discounts on our premium content use the coupon code in this book About the Authors Our writing team composed of top notch technical writers translation experts and technical documentation managers from around the world has pooled their experience and insights to help you succeed in your technical writing career Praise for the First Edition Every aspiring author tech writer in college should have this book Steve Ballard Manager Enterprise Content Solutions This is exactly the sort of guide I wish I had when I first started tech writing Sharon Witheriff Technical Writer The Technical Writing Process is a practical toolkit that demystifies the art of technical writing with useful templates to help you succeed quickly and smartly Richard Kidd General Manager Aspiring writers throughout the enterprise

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Plunkett's Procedures for the Medical Administrative Assistant Heather D Ramsay, Marie Rutherford, 2019-12-11. NEW. Four Colour design with new art programme better illustrates current concepts and improves readability and visual appeal. UPDATED. Expanded coverage of healthcare plans across Canada. NEW. Coverage of Electronic Medical Records (EMR). NEW. Evolve site including chapter review questions, review questions, videos, forms and templates, audio glossary and more. UPDATED. Reflects contemporary standards, technological tools and terminology used in day to day modern health care practice. NEW. New and revised learning tools including learning objectives, key terms, assignment boxes, tips, critical thinking boxes and Did You Know boxes. UPDATED. Reflects current privacy legislation (PIPEDA) and changes to provincial and territorial Freedom of Information acts. NEW. Chapter order and comprehensive Table of Contents.

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 data 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

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 concepts of artificial intelligence and psychotherapy this book provided extensive research data that compared the human therapist to the computer therapist at the time This title was intended for researchers professionals and students of psychotherapy and artificial intelligence By exploring the automation of therapy and the design of empathetic software this book challenges counsellors and computer scientists to look at what may have been the most fascinating topic to arise in their fields for years to come

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Construction Congress V Stuart D. Anderson, 1997 This collection contains more than 130 papers presented at the Fifth Construction Congress held in Minneapolis Minnesota October 5-7 1997

U.S. Coast Guard Systems Times, 2002

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and desk instructions to Baldrige and the ISO 9000 requirements it applies a customer and quality based systems approach to streamlining and managing your documentation system This second edition is an organized toolbox of powerful methodology and metrics that shows companies how to steer clear of cumbersome and obsolete documentation and gives numerous examples of the tremendous opportunities and pitfalls presented by technology such as the Internet and web based documentation management software The Society for Technical Communication STC awarded this book the Touchstone 2001 award

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