

## Document Change Control Process

An effective systems development and design process is far easier to explain than it is to implement. A framework is needed that organizes the life cycle activities that form the process. This framework is Configuration Management (CM). Software Configuration Management discusses the framework from a standards viewpoint, using the original

The first comprehensive guide to the integration of Design for Six Sigma principles in the medical devices development cycle Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness presents the complete body of knowledge for Design for Six Sigma (DFSS), as outlined by American Society for Quality, and details how to integrate appropriate design methodologies up front in the design process. DFSS helps companies shorten lead times, cut development and manufacturing costs, lower total life-cycle cost, and improve the quality of the medical devices. Comprehensive and complete with real-world examples, this guide: Integrates concept and design methods such as Pugh Controlled Convergence approach, QFD methodology, parameter optimization techniques like Design of Experiment (DOE), Taguchi Robust Design method, Failure Mode and Effects Analysis (FMEA), Design for X, Multi-Level Hierarchical Design methodology, and Response Surface methodology Covers contemporary and emerging design methods, including Axiomatic Design Principles, Theory of Inventive Problem Solving (TRIZ), and Tolerance Design Provides a detailed, step-by-step implementation process for each DFSS tool included Covers the structural, organizational, and technical deployment of DFSS within the medical device industry Includes a DFSS case study describing the development of a new device Presents a global perspective of medical device regulations Providing both a road map and a toolbox, this is a hands-on reference for medical device product development practitioners, product/service development engineers and architects, DFSS and Six Sigma trainees and trainers, middle management, engineering team leaders, quality engineers and quality consultants, and graduate students in biomedical engineering.

Fundamentals of Effective Program Management A Process Approach Based on the Global Standard By Dr. Paul Sanghera, PMP Hardcover, 6x9, 344 Pages ISBN: 978-1-932159-69-1 Publishing November 2008 Retail Price \$59.95 Direct Response Price \$49.95 Notify Me When Book Publishes E-mail this page Print this page About the Item Key Features About the Author(s) Related Titles About the Item: Only a small percentage of projects are run in isolation. The majority of projects are conducted in groups under programs to maximize business and organizational objectives. Due to its proven benefits to organizations of all sizes, program management and the demand for resources on how to do it effectively is growing at a rapid pace. In this new book, best-selling author Paul Sanghera presents a cohesive, concise, yet comprehensive coverage of the fundamentals of program management based on the global standard for program management issued by the Project Management Institute (PMI), and in accordance with generally recognized best practices. This unique guide clearly places program management in the context of project management and project portfolio management and describes processes that can be applied to programs in any field. Because no prior knowledge of program management is assumed, Fundamentals of Effective Program Management is useful for both those new to program/project management, and to experienced practitioners whose daily tasks and responsibilities extend beyond project management and have a direct impact on accomplishing organizational objectives.

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.

The only book of forms that exactly follows the content of the PMBOK Guide, A Project Manager's Book of Forms provides a "road map" approach so readers know exactly where they are and what forms precede and follow their current position on a project. This Second Edition aligns with the release of the Fifth Edition of the PMBOK Guide. Hard copies of the forms may be taken and reproduced directly from the book, and completely editable electronic versions of all the blank forms, in Microsoft Office-compatible format, are available on an accompanying website. You may use them as is or tailor them to your own needs.

SCM practices are recognised as core functional areas in assisting a project team to identify, control, audit, and report on all configuration items of a project. Consequently they are then better able to control changes to the working environment. Moreira presents a totally unique book, offering a "how-to" guide for SCM implementation for commercial and technology fields. A thoroughly practical approach; this guide includes examples and instruction of SCM tasks. This book has an easy to follow set of tasks that can be customized to assist a SCM professional in implementing SCM in a more efficient and expedient manner while also imparting SCM knowledge. Provides a customisable step-by-step process in implementing SCM Discusses typical SCM activities at project level and includes source control, change control, problem management, etc. An accompanying website contains templates, procedures and other materials to aid understanding and encourage the practical applications of the material discussed throughout [www.wiley.com/go/moreira\\_software/](http://www.wiley.com/go/moreira_software/) Anyone who has to implement SCM in his/her company at every level will need this book and find its practical approach useful

The Security Risk Assessment Handbook: A Complete Guide for Performing Security Risk Assessments provides detailed insight into precisely how to conduct an information security risk assessment. Designed for security professionals and their customers who want a more in-depth understanding of the risk assessment process, this volume contains real-wor

A fully updated, step-by-step guide for implementing COSO's Enterprise Risk Management COSO Enterprise Risk Management, Second Edition clearly enables organizations of all types and sizes to understand and better manage their risk environments and make better decisions through use of the COSO ERM framework. The Second Edition discusses the latest trends and pronouncements that have affected COSO ERM and explores new topics, including the PCAOB's release of AS5; ISACA's recently revised CobiT; and the recently released IIA Standards. Offers you expert advice on how to carry out internal control responsibilities more efficiently Updates you on the ins and outs of the COSO Report and its emergence as the new platform for understanding all aspects of risk in today's organization Shows you how an effective risk management program, following COSO ERM, can help your organization to better comply with the Sarbanes-Oxley Act Knowledgeably explains how to implement an effective ERM program Preparing professionals develop and follow an effective risk culture, COSO Enterprise Risk Management, Second Edition is the fully revised,

invaluable working resource that will show you how to identify risks, avoid pitfalls within your corporation, and keep it moving ahead of the competition.

Completely updated for the 2011 version of the PMP exam! If you're preparing for the Project Management Professional (PMP) exam, this thorough book is what you need. Not only does it reflect the very latest version of the exam, it is written by popular project management expert Kim Heldman--author of the five previous editions of this top-selling book--and it also includes a CD with practice exams, exam prep software, electronic flashcards, and over two hours of additional audio review. All exam objectives, as well as essential PMP topics, concepts, and key terms are covered. Prepares candidates to take the Project Management Professional (PMP) exam as well as the Certified Associate Project Management (CAPM) exam, both offered by the Project Management Institute (PMI) Covers all exam objectives plus a wide range of Project Management topics, concepts, and key terms Uses real-world scenarios and How This Applies to Your Current Project sidebars to fully illustrate concepts Includes an invaluable CD with testing software, practice exams, electronic flashcards, and over two hours of audio review Serves as a valuable go-to book to keep on hand--even after the exam Project management is a desired skill in today's IT marketplace. PMP: Project Management Professional Exam Study Guide, Sixth Edition can help you prepare. CD-ROM/DVD and other supplementary materials are not included as part of the e-book file, but are available for download after purchase.

Every year, in response to new technologies and new laws in different countries and regions, there are changes to the fundamental knowledge, skills, techniques, and tools required by all IT security professionals. In step with the lightning-quick, increasingly fast pace of change in the technology field, the Information Security Management Handbook, updated yearly, has become the standard on which all IT security programs and certifications are based. It reflects new updates to the Common Body of Knowledge (CBK) that IT security professionals all over the globe need to know. Captures the crucial elements of the CBK Exploring the ten domains of the CBK, the book explores access control, telecommunications and network security, information security and risk management, application security, and cryptography. In addition, the expert contributors address security architecture and design, operations security, business continuity planning and disaster recovery planning. The book also covers legal regulations, compliance, investigation, and physical security. In this anthology of treatises dealing with the management and technical facets of information security, the contributors examine varied topics such as anywhere computing, virtualization, podslurping, quantum computing, mashups, blue snarfing, mobile device theft, social computing, voting machine insecurity, and format string vulnerabilities. Also available on CD-ROM Safeguarding information continues to be a crucial concern of all IT professionals. As new risks threaten the security of our systems, it is imperative that those charged with protecting that information continually update their armor of knowledge to guard against tomorrow's hackers and software vulnerabilities. This comprehensive Handbook, also available in fully searchable CD-ROM format keeps IT professionals abreast of new developments on the security horizon and reinforces timeless concepts, providing them with the best information, guidance, and counsel they can obtain.

Readers discover exciting opportunities and challenges in technology today with Schwalbe's INFORMATION TECHNOLOGY PROJECT MANAGEMENT, 8E. This unique book demonstrates principles distinctive to managing information technology (IT). No book offers more insights and tools for IT project management success, including updates that reflect the latest PMBOK Guide. This edition weaves theory with successful practices for an integrated focus on the concepts, tools, and techniques that are most effective today. This is the only text to apply all 10 project management knowledge areas to IT projects. Readers master skills in project integration, scope, time, cost, quality, human resource, communications, risk, procurement, and stakeholder management as well as all five process groups -- initiating, planning, executing, monitoring and controlling, and closing. Important Notice: Media content referenced within the product description or the product text may not be available in the ebook version.

Sarbanes-Oxley Internal Controls: Effective Auditing with AS5, CobiT, and ITIL is essential reading for professionals facing the obstacle of improving internal controls in their businesses. This timely resource provides at-your-fingertips critical compliance and internal audit best practices for today's world of SOx internal controls. Detailed and practical, this introductory handbook will help you to revitalize your business and drive greater performance.

Each book covers all the necessary information a beginner needs to know about a particular topic, providing an index for easy reference and using the series' signature set of symbols to clue the reader in to key topics, categorized under such titles as Tip, Remember, Warning!, Technical Stuff and True Story.

"This new edition of a unique handbook is fully updated for the latest regulatory and technological developments. Containing the 2005 revisions to BS7799 and ISO17799, it guides business managers through the issues involved in achieving ISO certification in information Security Management and covers all aspects of data security." "Written by business managers for business managers, it is an essential resource to be used in organizations of all shapes and sizes, and particularly those with well-developed internal IT systems and those focussed on e-commerce."--Jacket. The accessible, easy-to-follow guide that demystifies documentation management When it comes to receiving documentation to confirm good science, U.S. and international regulators place high demands on the healthcare industry. As a result, companies developing and manufacturing therapeutic products must implement a strategy that allows them to properly manage their records and documents, since they must comply with rigorous standards and be available for regulatory review or inspection at a moment's notice. Written in a user-friendly Q&A style for quick reference, Managing the Documentation Maze provides answers to 750 questions the authors encounter frequently in their roles as consultants and trainers. In simple terms, this handy guide breaks down the key components that facilitate successful document management, and shows why it needs to be a core discipline in the industry with information on: Compliance with regulations in pharmaceutical, biological, and device record keeping Electronic systems, hybrid systems, and the

entire scope of documentation that companies must manage How to write and edit documents that meet regulatory compliance Making the transition to an electronic system, including how to validate and document the process Anyone responsible for managing documents in the health field will find this book to be a trusted partner in unraveling the bureaucratic web of confusion, while it initiates a plan on how to put an effective, lasting system in place—one that will stand up to any type of scrutiny.

Updated to reflect the Project Management Institute's (PMI's) Project Management Body of Knowledge (PMBOK® Guide), Fifth Edition, the new edition of this bestselling textbook continues to provide a practical and up-to-date overview of project management theory. Project Management Theory and Practice, Second Edition explains project management theory using language that is easy to understand. The book integrates the organizational environment that surrounds a project to supply the well-rounded knowledge of theories, organizational issues, and human behavior needed to manage real-world projects effectively. This edition includes a new chapter on Stakeholder Management, which is a new knowledge area covered in the new PMBOK® Guide. It also provides updated references and a new streamlined organization of chapters. There are several project-related model frameworks sponsored by PMI®, and many of these are covered in this text. Specifically, the book details: Work breakdown structures (WBS) Earned value management (EVM) Enterprise project management (EPMO) Portfolio management (PPM) Professional responsibility and ethics For many of the major sections, the PMI Global Accreditation curriculum learning objectives have been adapted with permission of PMI and used to guide the content. Filled with end-of-chapter questions, scheduling and budgeting problems, and scoping projects, this text is ideal for classroom use and essential reading for anyone seeking project management certification. The book also includes sample empirically oriented worksheets that demonstrate various management decision and analysis-oriented tools.

This book was written for experienced project management professionals and executives who find themselves in front of difficult projects and want to be successful. Managing projects in today's rapidly changing business environment has proven to be more challenging than most project managers and executives would like to admit. This is evidenced by the alarming number of projects that fail to complete within budget, on time, with the right scope, with the right quality, and a highly satisfied customer. The chapters are laid out in a logical sequence and the information is structured in a way that it can be followed like a recipe book. Each chapter includes the following sections: Overview, Why is this important, Who is involved, When should someone use this process, Initial set-up, Execution (how to do it), Summary & Conclusion, More than you wanted to know and Bibliography. This book also provides an extensive companion website. The companion website contains tools, processes, and templates that may be used immediately to complete any size project or program. The objective of this book is to share best practices enabling project and program managers to make better decisions and be more successful. This book contains the most critical aspects of initiating, planning, executing, controlling, and closing out a project.

Software Quality Concepts and Practice John Wiley & Sons

Handbook to aid candidates in preparation for the Certified Associate in Project Management (CAPM) exam.

Sales are to growth as controls are to profitability and success within a business. In Entrepreneurial Controls, author Jack E. Trent guides small-business owners through the complexities of understanding how financial and operational controls protect them from unnecessary risks. Trent shows how controls are the single most important method for preventing fraud within a company. In Entrepreneurial Controls, Trent details the background and definition of controls and the important role they play in driving profitability for a business. The book is a carefully compiled collection of thorough research and Trent's personal experiences as an entrepreneur, small-business owner, financial officer, and accountant. In addition to the breadth of knowledge presented, small vignettes called "reality checks" depict real-life applications of the concepts discussed. A no-nonsense, one-stop source for using control systems within a small-business setting, Entrepreneurial Controls covers the basics of: Project, fraud, risk, and cash management Accounting, inventory, and operational controls Internal auditing Customer service Using instructions, lessons, best practices, and guidelines, Entrepreneurial Controls shows entrepreneurs how to effectively and efficiently set up a new business or how to revise a struggling company's operations. With practical applications and easy-to-understand examples, Trent demonstrates how to bridle a small business and rein in financial success.

Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r Discover exciting behind-the-scenes opportunities and challenges in technology today with Schwalbe's unique INFORMATION TECHNOLOGY PROJECT MANAGEMENT, REVISED 7E. This one-of-a-kind book demonstrates the principles distinctive to managing information technology (IT) projects that extend well beyond standard project management requirements. No book offers more up-to-the minute insights and software tools for IT project management success, including updates that reflect the latest PMBOK Guide, 5th edition, the global standard for managing projects and earning certification. The book weaves today's theory with successful practices for an understandable, integrated presentation that focuses on the concepts, tools, and techniques that are most effective today. INFORMATION TECHNOLOGY PROJECT MANAGEMENT is the only book to apply all ten project management knowledge areas to IT projects. You master skills in project integration, scope, time, cost, quality, human resource, communications, risk, procurement, and stakeholder management as well as all five process groups--initiating, planning, executing, monitoring and controlling, and closing. Intriguing examples from familiar companies featured in today's news, a new Agile case, opportunities with MindView software, and a new chapter on project stakeholder management further ensure you are equipped to manage information technology projects with success. The REVISED Seventh Edition has updated Appendix A for Microsoft Project 2013. Important Notice: Media content referenced within the product description or the product text may not be available in the ebook version.

Essential project management forms aligned to the PMBOK® Guide—Sixth Edition A Project Manager's Book of Forms is an essential companion to the Project Management Institute's A Guide to the Project Management Body of Knowledge. Packed with ready-made forms for

managing every stage in any project, this book offers both new and experienced project managers an invaluable resource for thorough documentation and repeatable processes. Endorsed by PMI and aligned with the PMBOK® Guide, these forms cover all aspects of initiating, planning, executing, monitoring and controlling, and closing; each form can be used as-is directly from the book, or downloaded from the companion website and tailored to your project's unique needs. This new third edition has been updated to align with the newest PMBOK® Guide, and includes forms for agile, the PMI Talent Triangle, technical project management, leadership, strategic and business management, and more. The PMBOK® Guide is the primary reference for project management, and the final authority on best practices—but implementation can quickly become complex for new managers on large projects, or even experienced managers juggling multiple projects with multiple demands. This book helps you stay organized and on-track, helping you ensure thorough documentation throughout the project life cycle. Adopt PMI-endorsed forms for documenting every process group Customize each form to suit each project's specific needs Organize project data and implement a repeatable management process Streamline PMBOK® Guide implementation at any level of project management experience Instead of wasting time interpreting and translating the PMBOK® Guide to real-world application, allow PMI to do the work for you: A Project Manager's Book of Forms provides the PMBOK®-aligned forms you need to quickly and easily implement project management concepts and practices.

Equip yourself with SOFTWARE PROJECT SURVIVAL GUIDE. It's for everyone with a stake in the outcome of a development project--and especially for those without formal software project management training. That includes top managers, executives, clients, investors, end-user representatives, project managers, and technical leads. Here you'll find guidance from the acclaimed author of the classics CODE COMPLETE and RAPID DEVELOPMENT. Steve McConnell draws on solid research and a career's worth of hard-won experience to map the surest path to your goal--what he calls "one specific approach to software development that works pretty well most of the time for most projects." Nineteen chapters in four sections cover the concepts and strategies you need for mastering the development process, including planning, design, management, quality assurance, testing, and archiving. For newcomers and seasoned project managers alike, SOFTWARE PROJECT SURVIVAL GUIDE draws on a vast store of techniques to create an elegantly simplified and reliable framework for project management success. So don't worry about wandering among complex sets of project management techniques that require years to sort out and master. SOFTWARE PROJECT SURVIVAL GUIDE goes straight to the heart of the matter to help your projects succeed. And that makes it a required addition to every professional's bookshelf.

Cytogenetic Laboratory Management: Chromosomal, FISH and Microarray-Based Best Practices and Procedures is a practical guide that describes how to develop and implement best practice processes and procedures in the genetic laboratory setting. The text first describes good laboratory practices, including quality management, design control of tests and FDA guidelines for laboratory developed tests, and pre-clinical validation study designs. The second focus of the book describes best practices for staffing and training, including cost of testing, staffing requirements, process improvement using Six Sigma techniques, training and competency guidelines and complete training programs for cytogenetic and molecular genetic technologists. The third part of the text provides step-wise standard operating procedures for chromosomal, FISH and microarray-based tests, including pre-analytic, analytic and post-analytic steps in testing, and divided into categories by specimen type, and test-type. All three sections of the book include example worksheets, procedures, and other illustrative examples that can be downloaded from the Wiley website to be used directly without having to develop prototypes in your laboratory. Providing both a wealth of information on laboratory management and molecular and cytogenetic testing, Cytogenetic Laboratory Management will be an essential tool for laboratorians world-wide in the field of laboratory testing and genetics testing in particular. This book gives the essentials of: Developing and implementing good quality management programs in laboratories Understanding design control of tests and pre-clinical validations studies and reports FDA guidelines for laboratory developed tests Use of reagents, instruments and equipment Cost of testing assessment and process improvement using Six Sigma methodology Staffing training and competency objectives Complete training programs for molecular and cytogenetic technologists Standard operating procedures for all components of chromosomal analysis, FISH and microarray testing of different specimen types This volume is a companion to Cytogenetic Abnormalities: Chromosomal, FISH and Microarray-Based Clinical Reporting. The combined volumes give an expansive approach to performing, reporting and interpreting cytogenetic laboratory testing and the necessary management practices, staff and testing requirements.

Organizations waste millions of dollars every year on failed projects. Failure is practically guaranteed by poor or incomplete requirements that do not properly define projects in their initial stages. Business analysis is the critical process ensuring projects start on the path toward success. To accurately determine project requirements, busines

The Financial Crimes Enforcement Network (FinCEN) relies extensively on its own computer systems, as well as those at the IRS to administer the Bank Secrecy Act (BSA) and fulfill its mission of safeguarding the U.S. financial system from financial crimes. Effective info. security controls over these systems are essential to ensuring that BSA data, which contains sensitive financial info. used by law enforcement agencies to prosecute financial crime, is protected from inappropriate or deliberate misuse, improper disclosure, or destruction. This report evaluated whether security controls that effectively protect the confidentiality, integrity, and availability of the info. and systems that support FinCEN's mission have been implemented. Illus.

Project Managing E-learning provides an essential framework, based on the globally accepted IPECC model, for planning, designing, delivering, managing and evaluating e-learning projects successfully. It focuses on practical, easy-to-understand methods and offers applications of project management principles in the real world. Illustrated by case studies of projects undertaken in business and academia it provides a step-by-step guide and highlights where projects typically fail. Each chapter begins with a definition and conceptualisation of the process, provides examples of how the process steps may vary dependent on organization or project size and discusses the typical problems organisations face when performing steps in the project management process. Covering all of the essentials as well as cutting-edge technology, it guides designers and managers through all stages of implementing and managing a project. Selected themes include: using focus groups gaining sponsors risk management pedagogical considerations testing quality control how to know when trouble is imminent PM software systems podcasting. The practical framework and sound advice offered in Project Managing E-learning is essential reading for all those who want to successfully implement and manage high quality e-learning in both academic and corporate training settings on time and to budget.

- This is the latest practice test to pass the CAPM PMI Certified Associate in Project Management (PMI-100) Exam. - It contains 1103 Questions and Answers. - All the questions are 100% valid and stable. - You can reply on this practice test to pass the exam with a good mark and in the first attempt.

With the increasing application of software in systems, especially safety- or even life-critical systems, it is no longer sufficient for the software developer to rely solely on testing the code produced. Testing must begin with the specification of requirements, continue on the design and finally on the implemented system. This book gives guidance on how testing can be carried out at each of the stages of software development. It does this by looking at the development process from four viewpoints: that of the intended user of the system, of its designers, of its programmers, and of the manager responsible for development. The product of each stage of development is individually examined to see how it can be checked for correctness and consistency with earlier specifications. References are given to techniques available to the software developer and there are many helpful checklists. The contributors are all members of the British Computer Society's Working Group on Testing, and between them have an impressive breadth of practical experience in the commercial development of small

and large software systems. Their combined experience makes this a most valuable book for the computing professional.

Having a robust and functional Quality Management system is a QSR requirement for all Pharmaceutical, Biomedical, and Medical Device companies. This book does the following for you: 1. It helps Managers in Startup companies design a Quality management system that meets and exceeds QSR requirements. 2. It helps you understand requirements for the design of a Quality Management system for Medical Device, Pharmaceutical, Tissue, and Biomedical industries. 3. It provides the Quality system document structure. 4. It helps you understand Quality system requirements for ISO 13485, and ISO 9001. 5. It provides standard definitions for the Quality management system. 6. It provides examples of Quality system related warning letters written by the FDA during onsite audits. 7. It provides the reader several models of a Quality Management system.

Addressing the unique difficulties involved in day-to-day project management communication, The Project Manager's Communication Toolkit provides proven methods for creating clear and effective communications-including text-based plans, reports, messages, and presentations. It examines the many tools available and goes beyond traditional coverage to

The book presents a comprehensive discussion on software quality issues and software quality assurance (SQA) principles and practices, and lays special emphasis on implementing and managing SQA. Primarily designed to serve three audiences; universities and college students, vocational training participants, and software engineers and software development managers, the book may be applicable to all personnel engaged in a software projects. Features: A broad view of SQA. The book delves into SQA issues, going beyond the classic boundaries of custom-made software development to also cover in-house software development, subcontractors, and readymade software. An up-to-date wide-range coverage of SQA and SQA related topics. Providing comprehensive coverage on multifarious SQA subjects, including topics, hardly explored till in SQA texts. A systematic presentation of the SQA function and its tasks: establishing the SQA processes, planning, coordinating, follow-up, review and evaluation of SQA processes. Focus on SQA implementation issues. Specialized chapter sections, examples, implementation tips, and topics for discussion. Pedagogical support: Each chapter includes a real-life mini case study, examples, a summary, selected bibliography, review questions and topics for discussion. The book is also supported by an Instructor's Guide.

This book contains both the theory and practice of risk management (RM) and provides the background, tools, and application of risk in pharmaceutical and biologics manufacturing and operations. It includes case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding.

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