# Download Ebook Biopharmaceutical Contract Manufacturing Best Practices

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## KEY=MANUFACTURING - CLINTON KASSANDRA

**Biopharmaceutical Contract Manufacturing Best Practices Pricing Study 2013/2014 Biopharmaceutical Contract Manufacturing Best Practices Pricing Study 2006 Current Good Manufacturing Practices Pharmaceutical, Biologics, and Medical Device Regulations and Guidance Documents, Concise Reference, Second Edition PharmaLogika Books** *FDA Regulations and Associated Guidance Documents: - Code of Federal Regulation Title 21 Overview - Part 11 Electronic Records; Electronic Signatures (21CFR§11) and Guidance for Industry - Part 26 Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community (21CFR§26) - Part 200 Drugs: General (21CFR§200) - Part 207 Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and The National Drug Code (21CFR§207) - Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General (21CFR§210) - Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (21CFR§211) - Part 600 Biological Products: General (21CFR§600) - Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21CFR§807) - Part 820 Quality System Regulation (21CFR§820) - Part 11, Electronic Records; Electronic Signatures - Scope and Application - Guidance for Industry and FD A Staff: Current Good Manufacturing Practice Requirements for Combination Products - Guidance for Industry: CGMP for Phase 1 Investigational Drugs - Process Validation: General Principles and Practices - PAT - A Frame work for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance - Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations - Contract Manufacturing Arrangements for Drugs: Quality Agreements -*

*Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP - Formal Dispute Resolution: Sponsor Appeals Above the Division Level Reference Tools: - Glossaries combined in one location - GMP Keyword Index for 21CFR211 - Combined Index for all documents* **Contract Manufacturing of Medicines Kluwer Law International B.V.** *Taking advantage of liberal regulations under the current world trade regime that permit the separation of manufacturing from marketing, many pharmaceutical companies (like other companies) outsource the actual manufacture of their products. However, because the quality of medicines is crucial to public health, the pharmaceutical industry is perhaps the most regulated of all industries. In most countries medicines are controlled prior to their marketing, and their manufacture is carried out under strict supervision. Necessarily, numerous international initiatives have led to elaboration of standards relating to the manufacture and marketing of medicines. These standards impose stringent rules on all parties to pharmaceutical manufacturing contracts. This very useful book provides a comprehensive global guide to the legal issues and procedures involved in outsourcing the manufacture of medicines. It describes the legal requirements relating to the manufacture and distribution of medicines, emphasising the impact of regulatory supervision on the rights and obligations of persons who outsource manufacturing of medicines and on those who provide the manufacturing services. The author provides detailed coverage of such pertinent topics as the following: and definition of and medicineand in different jurisdictions; and categories of medicines; and manufacturing and importation regulation in numerous jurisdictions worldwide; and inspection regimes; and good manufacturing practice (GMP); and marketing authorization; and manufacturing documentation; and complaints and product recall; and liability insurance; and protection of trade secrets; and data exclusivity and data protection; and deficiencies and delays; and and recognition and enforcement of judgements. A significant part of the book is devoted to cross-border problems arising from such matters as conflict of laws or taxation. Indispensable to counsel for pharmaceutical companies of any size, Contract Manufacturing of Medicines will also be of great value to practitioners and academics concerned with international trade for its precise, in-depth delineation of the inner workings of a complex and highly significant trade regime.* **Biopharmaceutical Manufacturing Principles, Processes, and Practices Walter de Gruyter GmbH & Co KG** *Biopharmaceuticals, medicines made by or from living organisms (including cells from living organisms), are extremely effective in treating a broad range of diseases. Their importance to human health has grown significantly over the years as more biopharmaceutical products have entered the market, and now the biggest selling drugs in the world are biopharmaceuticals. Biopharmaceutical Manufacturing: Principles, Processes and Practices provides concise, comprehensive, and up-to-date coverage of biopharmaceutical manufacturing. Written in a clear and informal style, the content has been influenced by the authors' substantial industry experience and teaching expertise. That expertise enables the authors to address the many questions posed over the years both by university students and professionals with experience in the field. Consequently, the book will appeal both to undergraduate or graduate students using it as a textbook and specialized industry practitioners seeking to understand the big picture of biopharmaceutical*

*manufacturing. This book:* **Continuous Biomanufacturing Innovative Technologies and Methods John Wiley & Sons** *This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.* **Validation of Pharmaceutical Processes CRC Press** *Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va* **Global Supply Chains in the Pharmaceutical Industry IGI Global** *In a rapidly growing global economy, where there is a constant emergence of new business models and dynamic changes to the business ecosystem, there is a need for the integration of traditional, new, and hybrid concepts in the complex structure of supply chain management. Within the fast-paced pharmaceutical industry, product strategy, life cycles, and distribution must maintain the highest level of agility. Therefore, organizations need strong supply chain capabilities to profitably compete in the marketplace. Global Supply Chains in the Pharmaceutical Industry provides innovative insights into the efforts needed to build and maintain a strong supply chain network in order to achieve efficient fulfillment of demand, drive outstanding customer value, enhance organizational responsiveness, and build network resiliency. This publication is designed for supply chain managers, policymakers, researchers, academicians, and students, and covers topics centered on economic cycles, sustainable development, and new forces in the global economy.* **Sign Risk-sharing Contract with Contract Manufacturing Organizations in Pharmaceutical Industry** *Outsourcing risks problem for the new ethical drugs manufacturing and commercialization is one of the most challenging problems for the pharmaceutical firms due to the big uncertainty of the FDA testing result, fluctuating market performance, changing government and finance environment. Motivated by the need of the ethical drugs risks sharing in the pharmaceutical industry, we are introducing a finite period analysis based on three different types of contracts which distinguished by the level of risk sharing including price discount, quantity flexibility and forecasting methods. These contracts are short term contract, long term time flexible contract and long term time inflexible contract. In order to analyze the performances of risk sharing of those contracts, we use mathematical functions to express the price discount, quantity flexibility and the demand risk and put them into the model of total extra outsourcing cost. By successfully use the concept of the Leibnitz's Rule and newsvendor model, we successfully simplified the problem and classified the level of risk sharing for each contract, and also realized the complexity for those contracts. At the end of this thesis, we use a numerical analysis to give an introduction of how our model could*

*be used in the contract selection. A quantitative solution is followed after that introduction and will select the best contract strategy under certain circumstance. The purpose of this thesis is to generate cost functions for the contracts, and help the firm to select the best contract strategy under different circumstances.* **The Application of PMBOK® Guide Practices at Your Pharmaceutical Manufacturing Organization Would it Stand Up to an Audit?** *A standard practice when qualifying a pharmaceutical contract manufacturing organization (CMO) to complete work includes conducting an on-site quality audit. In the pharmaceutical manufacturing field, the quality audit is also designed to assure compliance with agencies such as the Federal Drug Administration [i.e. Food and Drug Administration] (FDA) or the European Medicines Agency (EMEA). During a routine quality audit, the core systems used for operation and control are examined to gain assurance that the CMO will successfully complete the contracted work. Although a quality audit may demonstrate that a CMO is compliant with regulatory requirements, the CMO may not be able to successfully meet project goals due to a less than effective project management system. A functional project management office (PMO) is a valuable core system that enables projects to proceed smoothly, offers client liaison, provides a mechanism for collaboration, and promotes mentoring within a facility. A facility audit, which includes an assessment of the PMO, would explore the applications and systems used to facilitate project success. Specific to pharmaceutical manufacturing, this would include an assessment of communications not only within and between project teams, their management, and stakeholders, but also with regulatory agencies. Each part of the multidisciplinary team is required to adhere to guidelines specific to the pharmaceutical industry. As such, an evaluation of the systems that govern the project management responsibilities in the CMO could be considered a necessary part of the audit process. A Guide to the Project Management Body of Knowledge (PMBOK® Guide) offers guidance into the industry's best practices; applying these practices and assembling an appropriate system of project management for a CMO would form a solid foundation and would stand up to such an audit. This paper focuses on the steps a PMO would take to assemble existing systems into an auditable format, which would allow an auditor to determine the PMO was appropriately equipped to deal with the project management demands of a complex pharmaceutical process transfer and other project types handled by the PMO. It begins by discussing the foundation for creating the ideal pharmaceutical PMO. It also covers applying the process groups and creating a system. A discussion on creating the tools and training personnel is also included. The paper provides 13 project management system challenge questions and concludes with a discussion on self-evaluation for continuous improvement.* **Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Best Practices Guide to Electronic Records Compliance CRC Press** *Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a*

*practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.* **A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry CRC Press** *This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation's knowledge assets can provide a path towards business excellence.* **Commercialization Secrets for Scientists and Engineers CRC Press** *Commercializing a knowledge-based product or service requires a realistic, methodical approach combined with a great deal of perseverance. Commercialization Secrets for Scientists and Engineers serves as a high-level guide to answering key questions and critical issues that confront founding entrepreneurs on their quest to commercialize their knowledge-based innovations. It highlights the unique problems shared by all technologists across knowledge-intensive fields and how to overcome the most predictable obstacles faced by technology entrepreneurs. It demystifies the process of commercializing advanced products that require a high degree of specialized knowledge. Typically, these are "disruptive technologies" with the potential to revolutionize whole industries. The book simplifies the launch of high-tech ventures such as pharmaceuticals, genetic and biotechnology products, wireless devices, fuel cells, and minimally invasive medical devices. Additionally, it will help readers bring their disruptive technologies to profitability.* **Pharmaceutical Manufacturing Handbook Production and Processes John Wiley & Sons** *This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.* **Good Design Practices for GMP Pharmaceutical Facilities CRC Press** *This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.* **Contract Research and Manufacturing Services (CRAMS) in India The Business, Legal, Regulatory and Tax Environment in the Pharmaceutical and Biotechnology Sectors Elsevier** *The field of contract research and manufacturing broadly encompasses those services in the pharmaceutical and biotechnology sectors that require extensive research and development and large-scale manufacturing facilities. The field has great potential for growth in the Indian outsourcing industry, which is world-renowned for its provision of cheap and highly-skilled services. Contract research and manufacturing services (CRAMS) in India*

*provides a detailed account of the current scenario in India and the advantages that the Indian outsourcing industry can offer in the field of CRAMS. Following an overview of the services and their emergence in India, chapters in the book begin by discussing the legal and regulatory scenario and major concerns and issues. In the latter part of the book, topics covered include service agreements, dispute resolution and contract negotiations, followed by a discussion of the outlook for CRAMS in India and some concluding remarks. Several appendices are included, offering a list of major players in the field and various forms for use in licence applications. Simple and accessible presentation using tables, charts and diagrams Practical tips from leading practitioners Inclusion of relevant case laws and other legal considerations* **Genetic Engineering News GEN. Strategic Management The Challenge of Creating Value Routledge** *Students trying to navigate the strategy jungle may lose sight of the fact that strategic management is about creating value in an organization. Understanding strategic management is a core part of all business qualifications and this textbook brings a new and easy-to-follow understanding of this vital business function. In addition to walking the student through the basics of the subject, the authors provide an array of analytical tools to help facilitate a thorough understanding of strategic management. The book addresses thoroughly the impact of financial markets on a firm's strategic capabilities, as well as looking at other challenging environmental factors. Aided by an array of student-friendly features, such as: learning objectives, 'strategic management in practice' case studies and review questions in each chapter, Strategic Management will help students to excel in their strategic management classes and better prepare them for the real business world. A comprehensive companion website, containing a wealth of supplementary materials for students and lecturers alike, is available at: http://www.routledge.com/cw/fitzroy.* **Advancing Pharmaceutical Processes and Tools for Improved Health Outcomes IGI Global** *There has been a growing concern for the improvement of pharmaceutical services provided by healthcare institutions. This concern is also shared by other stakeholders including patients, regulatory organizations, pharmaceutical companies, insurance companies, and research institutions. Advancing Pharmaceutical Processes and Tools for Improved Health Outcomes presents research-based perspectives on the pharmaceutical industry in today's digitally-fueled world. Focusing on technological innovations for pharmaceutical applications as well as current trends in the industry, this publication is ideally designed for use by pharmacists, medical professionals, administrators in the medical field, health insurance professionals, researchers, and graduate-level students.* **Single-Use Technology in Biopharmaceutical Manufacture John Wiley & Sons** *Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the*

*lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.*

**Pharmaceutical and Biomedical Project Management in a Changing Global Environment John Wiley & Sons** *Pharmaceutical and Biomedical Portfolio Management in a Changing Global Environment explores some of the critical forces at work today in the complex endeavour of pharmaceutical and medical product development. Written by experienced professionals, and including real-world approaches and best practice examples, this new title addresses three key areas – small molecules, large molecules, and medical devices - and provides hard-to-find, consolidated information relevant to and needed by pharmaceutical, biotech, and medical device company managers.* **Handbook of Stability Testing in Pharmaceutical Development Regulations, Methodologies, and Best Practices Springer Science & Business Media** *This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.* **Leading Pharmaceutical Operational Excellence Outstanding Practices and Cases Springer Science & Business Media** *Achieving operational excellence is a challenge for the pharmaceutical industry, with many companies setting successful examples time and again. This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry. Based on the St.Gallen OPEX Model the authors describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies.*

**Biotechnology Operations Principles and Practices CRC Press** *Because of rapid developments in the biotechnology industry—and the wide range of disciplines that contribute to its collective growth—there is a heightened need to more carefully plan and fully integrate biotech development projects. Despite the wealth of operations experience and associated literature available, no single book has yet offered a comprehensive, practical guide to fundamentals. Filling the void, Biotechnology Operations: Principles and Practices reflects this integrative philosophy, serving as a practical guide for students, professionals, or anyone else*

*with interests in the biotech industry. Although many books emphasize specific technical aspects of biotech, this is perhaps the first to integrate essential concepts of product development and scientific and management skills with the seven functional areas of biotechnology: Biomanufacturing Clinical trials Nonclinical studies Project management Quality assurance Quality control Regulatory affairs A practical roadmap to optimizing biotechnology operations, this reference illustrates how to use specific product planning, design, and project management processes to seamlessly merge plans and efforts in the key functional areas. Applying lessons learned throughout the nascent history of biotech, author Michael Roy highlights developmental principles that could bring future products to market more safely and efficiently. Drawing from his experiences working in industry and teaching a graduate course at the University of Wisconsin, this hotly anticipated book clarifies basic methodologies and practices to help reduce risks and resolve problems as future technological discoveries are developed into tangible products.* **Good Clinical, Laboratory and Manufacturing Practices Techniques for the QA Professional Royal Society of Chemistry** *Quality assurance and good laboratory practices are becoming essential knowledge for professionals in all sorts of industries. This includes internal and external audit procedures for compliance with the requirements of good clinical, laboratory and manufacturing practices. Spanning chemical, cosmetic and manufacturing industries, Good Clinical, Laboratory and Manufacturing Practices: Techniques for the QA professional is aimed at: chemists, clinicians, ecotoxicologists, operation managers, pharmaceutical process managers, quality assurance officers, technicians and toxicologists. In addition sections on harmonisation of quality systems will be of value to safety, health and environment advisors. This comprehensive and high level reference will be an indispensable guide to research laboratories in academia and industry. Additional training material is also included.* **Business Development for the Biotechnology and Pharmaceutical Industry CRC Press** *Business Development in the biotechnology and pharmaceutical industries accounts for over $5 billion in licensing deal value per year and much more than that in the value of mergers and acquisitions. Transactions range from licences to patented academic research, to product developments as licences, joint ventures and acquisition of intellectual property rights, and on to collaborations in development and marketing, locally or across the globe. Asset sales, mergers and corporate takeovers are also a part of the business development remit. The scope of the job can be immense, spanning the life-cycle of products from the earliest levels of research to the disposal of residual marketing rights, involving legal regulatory manufacturing, clinical development, sales and marketing and financial aspects. The knowledge and skills required of practitioners must be similarly broad, yet the availability of information for developing a career in business development is sparse. Martin Austin's highly practical guide spans the complete process and is based on his 30 years of experience in the industry and the well-established training programme that he has developed and delivers to pharmaceutical executives from across the world.* **Handbook of Validation in Pharmaceutical Processes, Fourth Edition CRC Press** *Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and*

*blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture* **Patient-Focused Network Integration in BioPharma Strategic Imperatives for the Years Ahead CRC Press** *The biopharmaceutical industry as we know it today is going through a massive upheaval as a result of the uncertainty of healthcare reform and increasing regulatory pricing pressure. A wake-up call to all sectors of the healthcare value chain, Patient-Focused Network Integration in BioPharma: Strategic Imperatives for the Years Ahead explores patient-focused network integration as quite possibly the only way for organizational evolution to occur. The book discusses how to align enterprises with the patient at the center. It details the historical context of the biopharmaceutical value chain and the current set of challenges facing the industry, and then details the author’s unique and sustainable agenda for change. The book traces the critical but often ignored relationships between hospitals, insurance companies, biopharma manufacturers, government regulators, and clinical scientists. For too long, these parties have been operating in a void, without recognizing the interconnectedness of their objectives, even though these objectives are often competing and misaligned. This book points out the gaps that exist and develops a set of recommendations regarding disease treatments, clinical development of new products, and collaboration between these players that can result in a sustainable solution to the healthcare mess. Each chapter can be viewed as an independent essay, in that it deals with a specific dimension of the healthcare value chain. However, together they provide an integrated discussion on how to begin the task of creating an integrated value chain network for healthcare. The book begins with the patient, and then works its way back down the value chain, all the way to the drug development and clinical trials stage of the value chain. The common thread throughout the chapters is the emphasis on collaboration, strategic alignment, and a focus on delivering value to the end patient. Very simply, all parties in the healthcare value chain network must align their strategic planning to derive innovation solutions. It is only through true collaboration and aligned thinking that the parties in the drug development, distribution, insurance payors, and hospital provider network can deal with the incredible complexity and massive challenges that face the industry. The book provides a compelling maturity model that enables readers to gauge the level of network integration their enterprise is at today, and*

*where they need to move in the future.* **Disruptive Technology: Concepts, Methodologies, Tools, and Applications Concepts, Methodologies, Tools, and Applications IGI Global** *The proliferation of entrepreneurship, technological and business innovations, emerging social trends and lifestyles, employment patterns, and other developments in the global context involve creative destruction that transcends geographic and political boundaries and economic sectors and industries. This creates a need for an interdisciplinary exploration of disruptive technologies, their impacts, and their implications for various stakeholders widely ranging from government agencies to major corporations to consumer groups and individuals. Disruptive Technology: Concepts, Methodologies, Tools, and Applications is a vital reference source that examines innovation, imitation, and creative destruction as critical factors and agents of socio-economic growth and progress in the context of emerging challenges and opportunities for business development and strategic advantage. Highlighting a range of topics such as IT innovation, business strategy, and sustainability, this multi-volume book is ideally designed for entrepreneurs, business executives, business professionals, academicians, and researchers interested in strategic decision making using innovations and competitiveness.* **Biopharmaceutical Processing Development, Design, and Implementation of Manufacturing Processes Elsevier** *Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference* **Pharmaceutical Outsourcing: Discovery and Preclinical Services Lulu.com China Rx Exposing the Risks of America's Dependence on China for Medicine Prometheus Books** *Millions of Americans are taking prescription drugs made in China and don't know it-- and pharmaceutical companies are not eager to tell them. This probing book examines the implications for the quality and availability of vital medicines for consumers. Several decades ago, penicillin, vitamin C, and many other prescription and over-the-counter products were manufactured in the United States. But with the rise of globalization, antibiotics, antidepressants, birth control pills, blood pressure medicines, cancer drugs, among many others are made in China and sold in the United States. China's biggest impact on the US drug supply is making essential ingredients for thousands of medicines found in American homes and used in hospital intensive care units and operating rooms. The authors convincingly argue that there are at least two major problems with this scenario. First, it is inherently*

*risky for the United States to become dependent on any one country as a source for vital medicines, especially given the uncertainties of geopolitics. For example, if an altercation in the South China Sea causes military personnel to be wounded, doctors may rely upon medicines with essential ingredients made by the adversary. Second, lapses in safety standards and quality control in Chinese manufacturing are a risk. Citing the concerns of FDA officials and insiders within the pharmaceutical industry, the authors document incidents of illness and death caused by contaminated medications that prompted reform. This is a disturbing, well-researched book and a wake-up call for improving the current system of drug supply and manufacturing.*

**Theory and Practice of Quality and Reliability Engineering in Asia Industry Springer** *This book discusses the application of quality and reliability engineering in Asian industries, and offers information for multinational companies (MNC) looking to transfer some of their operation and manufacturing capabilities to Asia and at the same time maintain high levels of reliability and quality. It is also provides small and medium enterprises (SME) in Asia with insights into producing high-quality and reliable products. It mainly comprises peer-reviewed papers that were presented at the Asian Network for Quality (ANQ) Congress 2014 held in Singapore (August, 2014), which provides a platform for companies, especially those within Asia where rapid changes and growth in manufacturing are taking place, to present their quality and reliability practices. The book presents practical demonstrations of how quality and reliability methodologies can be modified for the unique Asian market, and as such is a valuable resource for students, academics, professionals and practitioners in the field of quality and reliability.* **The Future of Outsourcing Strategic Outsourcing Controls and the Backsourcing Evolution Springer Nature** *This book provides a new evolutionary perspective on outsourcing. The traditional prioritization of continuous outsourcing has resulted in increased hidden costs that have sabotaged business profits. As a result of undisciplined outsourcing, businesses have lost a defining characteristic of their success: decision control. In contrast, the ability to combine outsourcing with backsourcing is a winning strategy for business leaders across a broad range of industries. In this book, the author traces the essence of the outsourcing industry as it has evolved over the past two centuries. With compelling case studies from the pharmaceutical, aviation, insurance, and cookware industries, this book moves beyond theorizing. It highlights key insights from some of the leading outsourcing pioneers who helped to define the industry. The case studies demonstrate the evolution of outsourcing, from a past marked by a costly outsourcing approach to a future fueled by the diversification of sourcing for optimal business success. Through the provision of decision models and best practices, this book provides academics and practitioners with tangible steps to implement successful outsourcing and backsourcing strategies.* **TechVenture New Rules on Value and Profit from Silicon Valley John Wiley & Sons** *Drawn from the popular TechVenture program at the Kellogg School of Management, this book provides a deep understanding of the key finance and business trends in e-commerce Viewing Silicon Valley as a test lab for e-commerce strategies, this book delivers the latest financial and business models shaping the e-commerce industry. TechVenture focuses on the Silicon Valley phenomenon, the new financial strategies, and evolving e-business models. Each chapter draws from field research and*

*interviews with the top minds in business today, and covers the most recent advances in e-finance, including: technology incubators, start-up funds, measuring intellectual capital, valuation techniques for Internet firms, and emerging technologies. In addition, TechVenture features intriguing and informative case studies and examples of major companies, including Idealab, Merrill Lynch, Pfizer, and Amazon.com. General business and finance readers, as well as those fascinated by the Internet economy, will find TechVenture an invaluable read that is on the cutting edge of e-business. Mohanbir Sawhney (Evanston, IL) is the McCormick Tribune Professor of Electronic Commerce and Technology at the Kellogg Graduate School of Management, Northwestern University. Mr. Sawhney was recently named one of the twenty-five most influential people in e-business by Business Week magazine. Ranjay Gulati (Chicago, IL) is the Associate Professor of Management and Organizations at the Kellogg Graduate School of Management and the Director of the Center for Resource on E-Business Innovation. Anthony Paoni (Chicago, IL) is Associate Professor at the Kellogg Graduate School of Management.* **Formulation tools for Pharmaceutical Development Elsevier** *A range of new and innovative tools used for preformulation and formulation of medicines help optimize pharmaceutical development projects. Such tools also assist with the performance evaluation of the pharmaceutical process, allowing any potential gaps to be identified. These tools can be applied in both basic research and industrial environment. Formulation tools for pharmaceutical development considers these key research and industrial tools. Nine chapters by leading contributors cover: Artificial neural networks technology to model, understand, and optimize drug formulations; ME_expert 2.0: a heuristic decision support system for microemulsions formulation development; Expert system for the development and formulation of push-pull osmotic pump tablets containing poorly water-soluble drugs; SeDeM Diagram: an expert system for preformulation, characterization and optimization of tables obtained by direct compression; New SeDeM-ODT expert system: an expert system for formulation of orodispersible tablets obtained by direct compression; and 3D-cellular automata in computer-aided design of pharmaceutical formulations: mathematical concept and F-CAD software. Coverage of artificial intelligence tools, new expert systems, understanding of pharmaceutical processes, robust development of medicines, and new ways to develop medicines Development of drugs and medicines using mathematical tools Compilation of expert system developed around the world* **Pharmaceutical Manufacturing Handbook Regulations and Quality John Wiley & Sons** *With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.* **From Innovation to Cash Flows Value Creation by Structuring High Technology Alliances John Wiley & Sons** *Praise for From Innovation to Cash Flows "Critically important topics for all entrepreneurs, new and experienced.*

*Collaboration, intellectual property, and funding are described with depth and thoughtfulness. From Innovation to Cash Flows provides both the theoretical structure and the rich examples to serve as a great reference. Not to be missed!" —Cheryl A. Fragiadakis, Head of Technology Transfer and Intellectual Property Management, Lawrence Berkeley National Laboratory "From Innovation to Cash Flows is a unique book that covers many of the essentials to be successful as a biotechnology or high-tech entrepreneur. The combination of theory and practical examples adds direct business value. This comprehensive work will prevent any starting venture from making costly mistakes." —Jeroen Nieuwenhuis, PhD, MBA, Corporate Entrepreneur, Magnotech Venture, Philips Healthcare Incubator "Truly exhaustive in its coverage of all the different aspects of managing high-technology innovations, this book constitutes an invaluable resource for technology entrepreneurs." —Juhana Rauramo, Partner, Bio Fund Management Ltd. "From Innovation to Cash Flows is a wellspring of insights and inspiration for anyone with a desire to start up a high-tech venture. The reader is guided step by step through the twists and turns of strategy, contract law, intellectual property rights management, and strategic partnering. A global team of experts from law, science, and business collaborated to write this book; their pooled know-how and collective experiences shine through. The result is highly recommended. Every aspiring entrepreneur with a scientific bent will want to own this book for his or her own library." —Laura Cha, Deputy Chairman, The Hongkong and Shanghai Banking Corporation Ltd. "Alliances often are a vital component of successful high-tech ventures. Through its unique blend of sound management theory and wise business and legal advice, this book shows high-tech entrepreneurs how to build innovative business models based on strategic collaboration with other firms." —Xavier Mendoza, Deputy Director General, ESADE, Ramon Llull University, and former Dean, ESADE Business School, Spain "This book is distinctive because it tells you how to turn your idea into a profitable business—a combination of savvy business advice and extensive legal documents that is original. This is a book to be read, and then revisited. You will want to come back to it time and again for references, for sample documents, and for sage advice on how to take the next step." —From the Foreword by Henry Chesbrough, Adjunct Professor and Executive Director, Center for Open Innovation, Haas School of Business, UC Berkeley, and Karl S. Pister, Dean and Roy W. Carlson Professor of Engineering Emeritus, UC Berkeley* **Computer-Aided Applications in Pharmaceutical Technology Elsevier** *Research and development in the pharmaceutical industry is a time-consuming and expensive process, making it difficult for newly developed drugs to be formulated into commercially available products. Both formulation and process development can be optimized by means of statistically organized experiments, artificial intelligence and other computational methods. Simultaneous development and investigation of pharmaceutical products and processes enables application of quality by design concept that is being promoted by the regulatory authorities worldwide. Computer-aided applications in pharmaceutical technology covers the fundamentals of experimental design application and interpretation in pharmaceutical technology, chemometric methods with emphasis of their application in process control, neural computing (artificial neural networks, fuzzy logic and decision trees, evolutionary computing and genetic*

*algorithms, self-organizing maps), computer-aided biopharmaceutical characterization as well as application of computational fluid dynamics in pharmaceutical technology. All of these techniques are essential tools for successful building of quality into pharmaceutical products and processes from the early stage of their d*