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Industry Business Intelligence Report Volume 1 Strategic Information, Regulations, Contacts *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals* *Interface between Regulation and Statistics in Drug Development* **Good Drug Regulatory Practices** **Statistical Thinking for Non-Statisticians in Drug Regulation** **Approaching China's Pharmaceutical Market** *New Drug Development* *Federal Regulation of Methadone Treatment* **Drug Regulation in African Countries** The Clinical Research Process in the Pharmaceutical Industry **An Overview of FDA Regulated Products** Improving and Accelerating Therapeutic Development for Nervous System Disorders Fundamentals of US Regulatory Affairs

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In the wake of publicity and congressional attention to drug safety issues, the Food and Drug Administration (FDA) requested the Institute of Medicine assess the drug safety system. The committee reported that a lack of clear regulatory authority, chronic underfunding, organizational problems, and a scarcity of post-approval data about drugs' risks and benefits have hampered the FDA's ability to evaluate and address the safety of prescription drugs after they have reached the market. Noting that resources and therefore efforts to monitor medications' riskâ€"benefit profiles taper off after approval, The Future of Drug Safety offers a broad set of recommendations to ensure that consideration of safety extends from before product approval through the entire time the product is marketed and used. FDLI's popular reference book, A Practical Guide to FDA's Food and Drug Law and Regulation, Seventh Edition, provides an introduction to the laws and regulations governing development, marketing, and sale of FDA-regulated products, including topics on food, drugs, medical devices, biologics, dietary supplements, cosmetics, new animal drugs, cannabis, and tobacco and nicotine products. Structured to serve as a reference and as a teaching tool, the book offers practical legal and regulatory fundamentals, and each chapter builds sequentially from the last to provide an accessible overview of the key topics relevant to practitioners of food and drug law and regulation.

This book is a standard legal text in law schools and graduate regulatory programs and has been cited as a reference in judicial opinions (including the U.S. Supreme Court). This Seventh Edition includes new sections on controlled substances, compounded drugs, and cannabis and cannabis-derived compounds. It also incorporates the latest amendments to the Federal Food, Drug, and Cosmetic Act, as well as FDA regulations and guidances. The past several decades have been a time of rapid globalization in the development, manufacture, marketing, and distribution of medical products and technologies. Increasingly, research on the safety and effectiveness of new drugs is being conducted in countries with little experience in regulation of medical product development. Demand has been increasing for globally harmonized, science-based standards for the development and evaluation of the safety, quality, and efficacy of medical products. Consistency of such standards could improve the efficiency and clarity of the drug development and evaluation process and, ultimately, promote and enhance product quality and the public health. To explore the need and prospects for greater international regulatory harmonization for drug development, the IOM Forum on Drug Discovery, Development, and Translation hosted a workshop on February 13-14, 2013. Discussions at the workshop helped identify principles, potential approaches, and strategies to advance the development or evolution of more harmonized regulatory standards. This document summarizes the workshop. Statistical Thinking for Non-Statisticians in Drug Regulation, Second Edition, is a need-to-know guide to understanding statistical methodology, statistical data and results within drug development and clinical trials. It provides non-statisticians working in the pharmaceutical and medical device industries with an accessible introduction to the knowledge they need when working with statistical information and communicating with statisticians. It covers the statistical aspects of design, conduct, analysis and presentation of data from clinical trials in drug regulation and improves the ability to read, understand

and critically appraise statistical methodology in papers and reports. As such, it is directly concerned with the day-to-day practice and the regulatory requirements of drug development and clinical trials. Fully conversant with current regulatory requirements, this second edition includes five new chapters covering Bayesian statistics, adaptive designs, observational studies, methods for safety analysis and monitoring and statistics for diagnosis. Authored by a respected lecturer and consultant to the pharmaceutical industry, Statistical Thinking for Non-Statisticians in Drug Regulation is an ideal guide for physicians, clinical research scientists, managers and associates, data managers, medical writers, regulatory personnel and for all non-statisticians working and learning within the pharmaceutical industry. This book brings together eleven case studies of inductive risk-the chance that scientific inference is incorrect-that range over a wide variety of scientific contexts and fields. The chapters are designed to illustrate the pervasiveness of inductive risk, assist scientists and policymakers in responding to it, and productively move theoretical discussions of the topic forward. The use of drugs in food animal production has resulted in benefits throughout the food industry; however, their use has also raised public health safety concerns. The Use of Drugs in Food Animals provides an overview of why and how drugs are used in the major food-producing animal industries--poultry, dairy, beef, swine, and aquaculture. The volume discusses the prevalence of human pathogens in foods of animal origin. It also addresses the transfer of resistance in animal microbes to human pathogens and the resulting risk of human disease. The committee offers analysis and insight into these areas Monitoring of drug residues. The book provides a brief overview of how the FDA and USDA monitor drug residues in foods of animal origin and describes quality assurance programs initiated by the poultry, dairy, beef, and swine industries. Antibiotic resistance. The committee reports what is known about this controversial problem and its potential effect on human health. The volume also looks at how drug

use may be minimized with new approaches in genetics, nutrition, and animal management. November Destined to become every regulatory director's essential desktop companion Professionals working to submit major documents to the Food and Drug Administration (FDA) are guaranteed to encounter numerous unexpected and daunting hurdles. Guidebook for Drug Regulatory Submissions offers a readable and clearly written road map for effective submission of documents for required regulatory reviews during drug development. Demystifying this complex, high-stakes process, author and nationally recognized drug regulation expert Sandy Weinberg presents professionals with authoritative tips, tools, and advice including suggestions for preparation, checklists for submission, an FDA evaluation tool for review, and copies of relevant FDA guidelines. As well, vital information is provided on the most common types of submissions, including: Meeting Requests Orphan Drug Applications Investigatory New Drug Applications (INDAs) New Drug Applications (NDAs) 505(b)2 NDAs Abbreviated New Drug Applications (ANDAs) Annual Report This reference also explores the pressures affecting the industry and the general public, as well as how these pressures will change the general nature and specific aspects of the submissions process over the near future. In addition, retired Canadian trade consul and regulatory consultant Carl Rockburne guest-authors a chapter comparing the FDA process to the four other major regulatory environments of Canada, the European Union, Japan, and Australia. Guidebook for Drug Regulatory Submissions is more than a useful guide—it is an essential tool to be kept on the desk of every regulatory director, submissions manager, vice president of Regulatory Affairs, and Food and Drug Administration reviewer responsible for the process of drug regulatory submissions. This book examines the sequence of events and methodology in the industrial clinical research process; a reference for multidisciplinary personnel. It is the conceptual framework involving the philosophical, economic, political, historical, regulatory,

planning, and marketing aspects of the process. The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines. Ensuring the safety of food and the quality and safety of medicines in a country is an important role of government, made more complicated by global manufacturing and international trade. By recent estimates, unsafe food kills over 400,000 people a year, a third of them children under 5, mostly in low- and middle-income countries; every year poor quality medicines cause about 70,000 excess deaths from childhood pneumonia and roughly 8,500 to 20,000 malaria deaths in sub-Saharan Africa alone. The Federal Drug Administration (FDA) Office of Global Policy and Strategy is charged with improving capacity of the agency's foreign counterpart offices and increasing understanding of the importance of regulatory systems for public health, development, and trade. At the request of the FDA, this study sets out a

strategy to support good quality, wholesome food and safe, effective medical products around the world. Its goal is to build on the momentum for strengthening regulatory systems and to set a course for sustainability and continued progress. The 2012 report Ensuring Safe Food and Medical Products Through Stronger Regulatory Systems Abroad outlined strategies to secure international supply chains, emphasized capacity building and support for surveillance in low- and middle-income countries, and explored ways to facilitate work sharing among food and medical product regulatory agencies. This new study assess progress made and the current regulatory landscape. Today's challenge, especially for many newcomers to the regulated industry, is not necessarily to gather regulatory information, but to know how to interpret and apply it. The ability to discern what is important from what is not, and to interpret regulatory documents correctly, provides a valuable competitive advantage to any newcomer or established professional in this field. An Overview of FDA Regulated Products: From Drugs and Medical Devices to Food and Tobacco provides a valuable summary of the key information to unveil the meaning of critical, and often complex, regulatory concepts. Concise and easy to read with practical explanations, key points, summaries and case studies, this book highlights the regulatory processes involved in bringing an FDA regulated product from research and development to approval and market. Although the primary focus will be on the US system, this book also features global perspectives where appropriate. A valuable resource for students, professors and professionals, An Overview of FDA Regulated Products illustrates the most important elements and concepts so that the reader can focus on the critical issues and make the necessary connections to be successful. Provides an overview of key regulatory requirements using a practical approach that features detailed discussions of hypothetical and real-world case studies in order to highlight the concepts and applications of regulations Covers all FDA regulated products, including drugs, biologics, medical

devices, cosmetics, foods, dietary supplements, cosmetics, veterinary products, tobacco and more in one single reference Illustrates complex topics in a clear, succinct and engaging manner by breaking down technical terms and offering straightforward and easy to understand explanations Advocates of rapid access to medicines and critics fearful of inadequate testing both argue that globalization will supersede national medical practices and result in the easy transfer of pharmaceuticals around the world. In Pharmacopolitics, Arthu Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine. We like to imagine that medicine is based on evidence and the results of fair

testing and clinical trials. In reality, those tests and trials are often profoundly flawed. We like to imagine that doctors who write prescriptions for everything from antidepressants to cancer drugs to heart medication are familiar with the research literature about a drug, when in reality much of the research is hidden from them by drug companies. We like to imagine that doctors are impartially educated, when in reality much of their education is funded by the pharmaceutical industry. We like to imagine that regulators have some code of ethics and let only effective drugs onto the market, when in reality they approve useless drugs, with data on side effects casually withheld from doctors and patients. All these problems have been shielded from public scrutiny because they're too complex to capture in a sound bite. But Ben Goldacre shows that the true scale of this murderous disaster fully reveals itself only when the details are untangled. He believes we should all be able to understand precisely how data manipulation works and how research misconduct in the medical industry affects us on a global scale. With Goldacre's characteristic flair and a forensic attention to detail, Bad Pharma reveals a shockingly broken system and calls for regulation. This is the pharmaceutical industry as it has never been seen before. With the critical role of statistics in the design, conduct, analysis and reporting of clinical trials or observational studies intended for regulatory purposes, numerous guidelines have been issued by regulatory authorities around the world focusing on statistical issues related to drug development. However, the available literature on this important topic is sporadic, and often not readily accessible to drug developers or regulatory personnel. This book provides a systematic exposition of the interplay between the two disciplines, including emerging themes pertaining to the acceleration of the development of pharmaceutical medicines to serve patients with unmet needs. Features: Regulatory and statistical interactions throughout the drug development continuum The critical role of the statistician in relation to the changing regulatory and healthcare

landscapes Statistical issues that commonly arise in the course of drug development and regulatory interactions Trending topics in drug development, with emphasis on current regulatory thinking and the associated challenges and opportunities The book is designed to be accessible to readers with an intermediate knowledge of statistics, and can be a useful resource to statisticians, medical researchers, and regulatory personnel in drug development, as well as graduate students in the health sciences. The authors' decades of experience in the pharmaceutical industry and academia, and extensive regulatory experience, comes through in the many examples throughout the book. For nearly three decades, methadone hydrochloride has been the primary means of treating opiate addiction. Today, about 115,000 people receive such treatment, and thousands more have benefited from it in the past. Even though methadone's effectiveness has been well established, its use remains controversial, a fact reflected by the extensive regulation of its manufacturing, labeling, distribution, and use. The Food and Drug Administration regulates the safety and effectiveness of methadone, as it does for all drugs, and the Drug Enforcement Administration regulates it as a controlled substance. However, methadone is also subjected to a unique additional tier of regulation that prescribes how and under what circumstances it may be used to treat opiate addiction. Federal Regulation of Methadone Treatment examines current Department of Health and Human Services standards for narcotic addiction treatment and the regulation of methadone treatment programs pursuant to those standards. The book includes an evaluation of the effect of federal regulations on the provision of methadone treatment services and an exploration of options for modifying the regulations to allow optimal clinical practice. The volume also includes an assessment of alternatives to the existing regulations. Improving and Accelerating Therapeutic Development for Nervous System Disorders is the summary of a workshop convened by the IOM Forum on Neuroscience and Nervous System Disorders to examine opportunities to

accelerate early phases of drug development for nervous system drug discovery. Workshop participants discussed challenges in neuroscience research for enabling faster entry of potential treatments into first-in-human trials, explored how new and emerging tools and technologies may improve the efficiency of research, and considered mechanisms to facilitate a more effective and efficient development pipeline. There are several challenges to the current drug development pipeline for nervous system disorders. The fundamental etiology and pathophysiology of many nervous system disorders are unknown and the brain is inaccessible to study, making it difficult to develop accurate models. Patient heterogeneity is high, disease pathology can occur years to decades before becoming clinically apparent, and diagnostic and treatment biomarkers are lacking. In addition, the lack of validated targets, limitations related to the predictive validity of animal models - the extent to which the model predicts clinical efficacy - and regulatory barriers can also impede translation and drug development for nervous system disorders. Improving and Accelerating Therapeutic Development for Nervous System Disorders identifies avenues for moving directly from cellular models to human trials, minimizing the need for animal models to test efficacy, and discusses the potential benefits and risks of such an approach. This report is a timely discussion of opportunities to improve early drug development with a focus toward preclinical trials. Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters

cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance Globalization is rapidly changing lives and industries around the world. Drug development, authorization, and regulatory supervision have become international endeavors, with most medicines becoming global commodities. Drug companies utilize global supply chains that often include facilities in countries with inconsistent regulations from those of the United States, perform pivotal trials in multiple countries to support registration submissions in various jurisdictions, and subsequently market their medicines throughout most of the world. These companies operate across borders and require individual national regulators to ensure that drugs authorized for use in their countries are safe and effective, and appropriate for their health care system and their population. This process involves significant resources and often duplicative work. It is important to consider how this process can be improved in order to better allocate resources, time, and efforts to improve public health. Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators considers the role of mutual recognition and other reliance activities among regulators in contributing to enhancing public health. This report identifies opportunities for leveraging reliance activities more broadly in order to potentially impact public health globally. Key topics in this report include the job of medicines regulators in today's world, what policy makers need to know about today's regulatory environment, stakeholder views of recognition and reliance, as well as removing

impediments and facilitating action for greater recognition and reliance among regulatory authorities. ?This authoritative volume examines the major laws, regulations and guidelines related to pharmaceutical product development in China. With a focus on patent, clinical and registration strategies, the book helps Western companies introduce their clinical drugs to the Chinese market, determine a strategic path and bridge the gap for regulatory and legal differences between China and the Western world. For a better understanding of the drug registration process, it explores the differences between the China Food and Drug Administration (CFDA)—including its regulations and registration procedures—and those of the Western world. The volume discusses disparities between China's application requirements compared to Western standards to make it easier for companies to prepare their application packages. It also provides detailed commentary on CFDA guidelines in reference to clinical trial (IND) and market application (NDA) requirements. Overall, this book offers guidance for Western companies aspiring to expand into China’s pharmaceutical market in hopes that they may gain a fundamental understanding of its rules and complexities in order to ensure a smooth transition and prevent future issues. FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the

new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that's broadly useful to both business and academia. Most national governments have created agencies with the responsibility for deciding which medicinal drugs should be imported or manufactured and made available through their health systems. Many of these agencies were set up some twenty years ago in the wake of the thalidomide disaster. Since that time they have developed in quite different ways in response to national, cultural and economic influences. Their direct cost is very small in comparison to overall health budgets but their indirect effects, both in terms of health and the economy, can be substantial. In 1980 the World Health Organization (WHO) Regional Office for Europe set up a series of studies of drug evaluation in the European region aimed at determining the effects of the work of regulatory agencies on the availability of drugs, on the pharmaceutical industry, and on the health of individuals in the countries concerned. This book sets that work in a historical context and describes the sources of the data used by the project team and the methods used by WHO and others in assessing the work of these agencies and its repercussions for the community. Finally, it presents an analysis of current knowledge and the plans and prospects for future research. The first draft of this book was presented to a meeting of experts in the field of drug regulation at Oslo in March 1984, and the present text embodies the views and conclusions of that meeting. New edition of

succesful standard reference book for thepharmaceutical industry and pharmaceutical physicians! The Textbook of Pharmaceutical Medicine is the coursebookfor the Diploma in Pharmaceutical Medicine, and is used as astandard reference throughout the pharmaceutical industry. The newedition includes greater coverage of good clinical practice, acompletely revised statistics chapter, and more on safety. Coversthe course information for the Diploma in PharmaceuticalMedicine Fully updated, with new authors Greater coverage of good clinical practice and safety New chapters on regulation of medical devices in Europe andregulation of therapeutic products in Australia Learn how international governments have committed themselves to improving access to quality health care! International Drug Regulatory Mechanisms explores the environment, organization, structure, functioning, and finance of health systems and pharmaceutical markets in 19 countries. Local experts describe each country's experiences with and lessons learned from the regulation of pharmaceutical products. This book will help government officials, pharmacy educators, and pharmaceutical industry leaders from around the globe identify and develop successful methods for controlling pharmaceutical drug prices and utilization. In International Drug Regulatory Mechanisms, you will learn about the health care system of each country and each government's measures to control drug costs. This text shows you what government interventions are feasible as well as effective, and the impact of these measures on consumers, government agencies, and the pharmaceutical companies and distributors. Drug policies, reimbursement concepts, and health insurance companies are all examined to give you a better working knowledge of the methodology and guidelines involving drug control in nations such as: Iceland Canada Israel Malaysia Argentina Taiwan Mexico Italy International Drug Regulatory Mechanisms is an extensive text that shows how pharmaceuticals are regulated throughout the world. This book examines how—despite similar goals—price controls, utilization controls, record keeping,

and quality requirements differ greatly between countries. Using numerous graphs, tables, and figures, this one-of-a-kind resouce provides you with new insight into which strategies are superior and how to implement these strategies in your own country. Good Drug Regulatory Practices offers a series of policies and procedures to assure quality and timely regulatory submissions to national regulatory agencies. This book begins with introductory chapters describing the need for policy documentation, and the philosophy underlying the policies, and presents policies and standards that can be used as presented or adapted to individual situations in your company. Today we witness an eventful time in which the powerful new forces of genomics, information technology and economics are rapidly changing the science and art of medicine. This will require more specialization than ever before. However, there is also an increasing demand for an integrated approach, which is provided by the discipline of Clinical Pharmacology (CP). CP pursues a scientific goal by studying drug action in patients and volunteers, a clinical goal by administering appropriate drug therapy and a regulatory goal by assessing the risk/benefit ratio of drug candidates in drug development and reimbursement. This introduction to current topics of CP covers traditional topics of clinical drug research and trial methodology but also provides insight in current topics like genomics, imaging technology and issues in drug reimbursement. A number of concrete case studies in clinical drug research and development help to give a better understanding of the general principles of CP. 2011 Updated Reprint. Updated Annually. China Pharmaceutical Chemicals Producers Directory Ensuring the safety of food and the quality and safety of medicines in a country is an important role of government, made more complicated by global manufacturing and international trade. By recent estimates, unsafe food kills over 400,000 people a year, a third of them children under 5, mostly in low- and middle-income countries; every year poor quality medicines cause about 70,000 excess deaths from childhood

pneumonia and roughly 8,500 to 20,000 malaria deaths in sub-Saharan Africa alone. The Federal Drug Administration (FDA) Office of Global Policy and Strategy is charged with improving capacity of the agency's foreign counterpart offices and increasing understanding of the importance of regulatory systems for public health, development, and trade. At the request of the FDA, this study sets out a strategy to support good quality, wholesome food and safe, effective medical products around the world. Its goal is to build on the momentum for strengthening regulatory systems and to set a course for sustainability and continued progress. The 2012 report Ensuring Safe Food and Medical Products Through Stronger Regulatory Systems Abroad outlined strategies to secure international supply chains, emphasized capacity building and support for surveillance in low- and middle-income countries, and explored ways to facilitate work sharing among food and medical product regulatory agencies. This new study assess progress made and the current regulatory landscape. Statistical Thinking for Non-Statisticians in Drug Regulation, Second Edition, is a need-to-know guide to understanding statistical methodology, statistical data and results within drug development and clinical trials. It provides non-statisticians working in the pharmaceutical and medical device industries with an accessible introduction to the knowledge they need when working with statistical information and communicating with statisticians. It covers the statistical aspects of design, conduct, analysis and presentation of data from clinical trials in drug regulation and improves the ability to read, understand and critically appraise statistical methodology in papers and reports. As such, it is directly concerned with the day-to-day practice and the regulatory requirements of drug development and clinical trials. Fully conversant with current regulatory requirements, this second edition includes five new chapters covering Bayesian statistics, adaptive designs, observational studies, methods for safety analysis and monitoring and statistics for diagnosis. Authored by a respected lecturer and consultant to the

pharmaceutical industry, Statistical Thinking for Non-Statisticians in Drug Regulation is an ideal guide for physicians, clinical research scientists, managers and associates, data managers, medical writers, regulatory personnel and for all non-statisticians working and learning within the pharmaceutical industry. Drug Drug Interactions is a comprehensive review of the scientific and regulatory perspectives of drug drug interactions from the point-of-view of academia, industry, and government regulatory agencies. This book is intended for professionals in the pharmaceutical industry, health care, and governmental regulatory agencies. Topics of interest include the mechanistic understanding of drug drug interactions, the prediction of drug drug interaction potential of new drugs, and the avoidance of clinically significant drug drug interaction in patients. Provides useful references on the science of drug-drug interactions Describes in a basic and comprehensive manner drug-drug interactions from the mechanistic viewpoint Contains original data from academic and industrial laboratories Presents an overview of regulatory agency positions "The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author!

In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed. Regulatory Affair and its Importance - Drug Discover and Development - Regulatory Strategy - Investigational New Drug Application IND - New Drug Application NDA - Abbreviated New Drug Application ANDA - Drug Master File DMF - Orphan Drug - Biological Licensing Application BLA - Registrationa of Drug Products in Overseas Markets Pharmaceutical export - Regulatory Authorities and Agencies - Overview of Drug and Cosmetic Act - Regulatory Guidelines - Useful Information