Biopharmaceutical Supply Chains: Distribution, Regulatory, Systems And Structural Changes Ahead

In recent years, high prices of pharmaceutical products have posed challenges in high- and low-income countries alike. In many instances, high prices of pharmaceutical products have led to significant financial hardship for individuals and negatively impacted on healthcare systems' ability to provide population-wide access to essential medicines. Pharmaceutical pricing policies need to be carefully planned, carried out, and regularly checked and revised according to changing conditions. Strong, well-thought-out policies can guide well-informed and balanced decisions to achieve affordable access to essential health products. This guideline replaces the 2015 WHO guideline on country pharmaceutical pricing policies, revised to reflect the growing body of literature since the last evidence review in 2010. This update also recognizes country experiences in managing the prices of pharmaceutical products.

The authors identify key emerging trends and drivers in supply chain management, introduce powerful new strategies for redesigning supply chains, and present comprehensive global case studies showing how Nortel and General Motors have transformed their own supply chains to optimize value and drive out costs.

A guide for mining the imagination to find powerful new ways to succeed. We need imagination now more than ever—to find new opportunities, rethink our businesses, and discover paths to growth. Yet too many companies have lost their ability to imagine. What is this mysterious capacity? How does imagination work? And how can organizations keep it alive and harness it in a systematic way? The Imagination Machine answers these questions and more. Drawing on the experience and insights of CEOs across several industries, as well as lessons from neuroscience, computer science, psychology, and philosophy, Martin Reeves of Boston Consulting Group's Henderson Institute and Jack Fuller, an expert in neuroscience, provide a fascinating look into the mechanics of imagination and lay out a process for creating ideas and bringing them to life: The Seduction: How to open yourself up to surprises The Idea: How to generate new ideas The Collision: How to rethink your idea based on real-world feedback The Epidemic: How to spread an evolving idea to others The New Ordinary: How to turn your novel idea into an accepted reality The Encore: How to repeat the process—again and again. Imagination is one of the least understood but most crucial ingredients of success. It's what makes the difference between an incremental change and the kinds of pivots and paradigm shifts that are essential to transformation—especially during a crisis. The Imagination Machine is the guide you need to demystify and operationalize this powerful human capacity, to inject new life into your company, and to head into unknown territory with the right tools at your disposal.

A very high portion of the seafood we eat comes from abroad, mainly from China and Southeast Asia, and most of the active ingredients in medicines we take originate in other countries. Many low- and middle-income countries have lower labor costs and fewer and less stringent environmental regulations than the United States, making them attractive places to produce food and chemical ingredients for export. Safe Foods and Medical Products Through Stronger Regulatory

Systems Abroad explains that the diversity and scale of imports makes it impractical for U.S. Food and Drug Administration (FDA) border inspections to be sufficient to ensure product purity and safety, and incidents such as American deaths due to adulterated heparin imported from China propelled the problem into public awareness. The Institute of Medicine Committee on Strengthening Core Elements of Regulatory Systems in Developing Countries took up the vital task of helping the FDA to cope with the reality that so much of the food, drugs, biologics, and medical products consumed in the United States originate in countries with less-robust regulatory systems. Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad describes the ways the United States can help strengthen regulatory systems in low and middle income countries and promote cross-border partnerships - including government, industry, and academia - to foster regulatory science and build a core of regulatory professionals. This report also emphasizes an array of practical approaches to ensure sound regulatory practices in today's interconnected world.

Proceedings of a Workshop

Countering the Problem of Falsified and Substandard Drugs

Research and Development in the Pharmaceutical Industry (A CBO Study)

Biopharmaceutical Supply Chains

Pharmaceutical Manufacturing Handbook

Bridging Between Theory and Practice

Materials for Advanced Packaging

This book examines issues related to the alignment of business strategies and analytics. Vast amounts of data are being generated, collected, stored, processed, analyzed, distributed and used at an ever-increasing rate by organizations. Simultaneously, managers must rapidly and thoroughly understand the factors driving their business. Business Analytics is an interactive process of analyzing and exploring enterprise data to find valuable insights that can be exploited for competitive advantage. However, to gain this advantage, organizations need to create a sophisticated analytical climate within which strategic decisions are made. As a result, there is a growing awareness that alignment among business strategies, business structures, and analytics are critical to effectively develop and deploy techniques to enhance an organization's decision-making capability. In the past, the relevance and usefulness of academic research in the area of alignment is often questioned by practitioners, but this book seeks to bridge this gap. Aligning Business Strategies and Analytics: Bridging Between Theory and Practice is comprised of twelve chapters, divided into three sections. The book begins by introducing business analytics and the current gap between academic training and the needs within the business community. Chapters 2 - 5 examines how the use of cognitive computing improves financial advice, how technology is accelerating the growth of the financial advising industry, explores the application of advanced analytics to various facets of the industry and provides the context for analytics

in practice. Chapters 6 - 9 offers real-world examples of how project management professionals tackle big-data challenges, explores the application of agile methodologies, discusses the operational benefits that can be gained by implementing real-time, and a case study on human capital analytics. Chapters 10 - 11 reviews the opportunities and potential shortfall and highlights how new media marketing and analytics fostered new insights. Finally the book concludes with a look at how data and analytics are playing a revolutionary role in strategy development in the chemical industry.

The concepts, applications, and practical issues of Quality byDesign Quality by Design (QbD) is a new framework currently beingimplemented by the FDA, as well as EU and Japanese regulatoryagencies, to ensure better understanding of the process so as toyield a consistent and high-quality pharmaceutical product. QbDbreaks from past approaches in assuming that drug quality cannot betested into products; rather, it must be built into every step ofthe product creation process. Quality by Design: Perspectives and Case Studies presentsthe first systematic approach to QbD in the biotech industry. Acomprehensive resource, it combines an in-depth explanation ofbasic concepts with real-life case studies that illustrate thepractical aspects of QbD implementation. In this single source, leading authorities from thebiotechnology industry and the FDA discuss such topics as: The understanding and development of the product's criticalquality attributes (CQA) Development of the design space for a manufacturingprocess How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates toQbD Relevant PAT tools and applications for the pharmaceuticalindustry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) toQbD Filled with vivid case studies that illustrate QbD at work incompanies today, Quality by Design is a core reference forscientists in the biopharmaceutical industry, regulatory agencies,and students.

This study has emerged from an ongoing program of trilateral cooperation between WHO, WTO and WIPO. It responds to an increasing demand, particularly in developing countries, for strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies.

Significant progress has been made in advanced packaging in recent years. Several new packaging techniques have been developed and new packaging materials have been introduced. This book provides a comprehensive overview of the recent developments in this industry, particularly in the areas of microelectronics, optoelectronics, digital health, and bio-medical applications. The book discusses established techniques, as well as emerging technologies, in order

to provide readers with the most up-to-date developments in advanced packaging.
Strategic Imperatives for the Years Ahead
Transforming Supply Chains Into Integrated Value Systems
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Patient-Focused Network Integration in BioPharma
How Individuals Create and Deliver Breakthrough Innovations in Mature Firms
Distribution, Regulatory, Systems and Structural Changes Ahead
IFIP WG 5.7 International Conference, APMS 2021, Nantes, France, September 5–9, 2021, Proceedings, Part III
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. Serial Innovators: How Individuals Create and Deliver Breakthrough Innovations in Mature Firms zeros in on the cutting-edge thinkers who repeatedly create and deliver breakthrough innovations and new products in large, mature organizations. These employees are organizational powerhouses who solve consumer problems and substantially contribute to the financial value to their firms. In this pioneering study, authors Abbie Griffin, Raymond L. Price, and Bruce A. Vojak detail who these serial innovators are and how they develop novel products, ranging from salt-free seasonings to improved electronics in companies such as Alberto Culver, Hewlett-Packard, and Procter & Gamble. Based on interviews with over 50 serial innovators and an even larger pool of their co-workers, managers and human resources teams, the authors reveal key insights about how to better understand, emulate, enable, support, and manage these unique and important individuals for long-term corporate success. Interestingly, the book finds that serial innovators are instrumental both in cases where firms are aware of clear market demands, and in scenarios when companies take risks on new investments, creating a consumer need. For over 25 years, research on innovation has taken the perspective that new product development can be managed like any other (complex)

process of the firm. While a highly structured and closely supervised approach is helpful in creating incremental innovations, this book finds that it is not conducive to creating breakthrough innovations. The text argues that the drive to routinize innovation has gone too far; in fact, so far as to limit many mature firms' ability to create breakthrough innovations. In today's economy, with the future of so many large firms on the line, this book is a clarion call to businesses to rethink how to nurture and thrive on their innovative workforce.

The growing area of peptide and protein therapeutics research is of paramount importance to medical application and advancement. A needed reference for entry level researchers and researchers working in interdisciplinary / collaborative projects, Peptide and Protein Delivery addresses the current and emerging routes for delivery of therapeutics. Covering cerebral delivery, pulmonary delivery, transdermal delivery, intestinal delivery, ocular delivery, parenteral delivery, and nasal delivery, this resource offers an overview of the main routes in therapeutics. Researchers across biochemistry, pharmaceutical, molecular biology, cell biology, immunology, chemistry and biotechnology fields will find this publication invaluable for peptide and protein laboratory research. Discusses the most recent data, ideas and concepts Presents case studies and an industrial perspective Details information from the molecular level to bioprocessing Thought provoking, for the novice to the specialist Timely, for today's biopharmaceuticals market

The latest edition of this highly acclaimed textbook, provides a comprehensive and up-to-date overview of the science and medical applications of biopharmaceutical products. Biopharmaceuticals refers to pharmaceutical substances derived from biological sources, and increasingly, it is synonymous with 'newer' pharmaceutical substances derived from genetic engineering or hybridoma technology. This superbly written review of the important areas of investigation in the field, covers drug production, plus the biochemical and molecular mechanisms of action together with the biotechnology of major biopharmaceutical types on the market or currently under development. There is also additional material reflecting both the technical advances in the area and detailed information on key topics such as the influence of genomics on drug discovery.

Quality by Design for Biopharmaceuticals

Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad
Public Perceptions, Economic Realities, and Empirical Evidence
The Evolving Imperative of Operating in Real Time
Pharmaceutical Price Regulation
The LIVING Supply Chain
Regulations and Quality

Today is a time of unparalleled excitement in the world of biopharmaceuticals. This book is a compendium of a tremendous body of knowledge, distilled into its most essential parts. Not only are there theoretical and conceptual ideas about biopharmaceutical manufacturing, but also content specific to skills and abilities. It serves as a well-paced guide for beginning learners as well as a cogent reference for seasoned biotechnology professionals alike. This book will help a new generation of students to become inspired and familiarize themselves with the theories, principles, and vernacular of biopharmaceutical production and all that it entails. A quick overview of contents include; Operational Excellence, Facilities, Metrology, Validation, Environmental Health & Safety (EHS), Quality Assurance, Microbiological Control, Quality Control Biochemistry, Upstream Processing, Downstream Processing, Process Development, and a Master Glossary.

The five-volume set IFIP AICT 630, 631, 632, 633, and 634 constitutes the refereed proceedings of the International IFIP WG 5.7 Conference on Advances in Production Management Systems, APMS 2021, held in Nantes, France, in September 2021. The 378 papers presented were carefully reviewed and selected from 529 submissions. They discuss artificial intelligence techniques, decision aid and new and renewed paradigms for sustainable and resilient production systems at four-wall factory and value chain levels. The papers are organized in the following topical sections: Part I: artificial intelligence based optimization techniques for demand-driven manufacturing; hybrid approaches for production planning and scheduling; intelligent systems for manufacturing planning and control in the industry 4.0; learning and robust decision support systems for agile manufacturing environments; low-code and model-driven engineering for production system; meta-heuristics and optimization techniques for energy-oriented manufacturing systems; metaheuristics for production systems; modern analytics and new AI-based smart techniques for replenishment and production planning under uncertainty; system identification for manufacturing control applications; and the future of lean thinking and practice Part II: digital transformation of SME manufacturers: the crucial role of standard; digital transformations towards supply chain resiliency; engineering of smart-product-service-systems of the future; lean and Six Sigma in services healthcare; new trends and challenges in reconfigurable, flexible or agile production system; production management in food supply chains; and sustainability in production planning and lot-sizing Part III: autonomous robots in delivery logistics; digital transformation approaches in production management; finance-driven supply chain;*

*gastronomic service system design; modern scheduling and applications in industry 4.0; recent advances in sustainable manufacturing; regular session: green production and circularity concepts; regular session: improvement models and methods for green and innovative systems; regular session: supply chain and routing management; regular session: robotics and human aspects; regular session: classification and data management methods; smart supply chain and production in society 5.0 era; and supply chain risk management under coronavirus Part IV: AI for resilience in global supply chain networks in the context of pandemic disruptions; blockchain in the operations and supply chain management; data-based services as key enablers for smart products, manufacturing and assembly; data-driven methods for supply chain optimization; digital twins based on systems engineering and semantic modeling; digital twins in companies first developments and future challenges; human-centered artificial intelligence in smart manufacturing for the operator 4.0; operations management in engineer-to-order manufacturing; product and asset life cycle management for smart and sustainable manufacturing systems; robotics technologies for control, smart manufacturing and logistics; serious games analytics: improving games and learning support; smart and sustainable production and supply chains; smart methods and techniques for sustainable supply chain management; the new digital lean manufacturing paradigm; and the role of emerging technologies in disaster relief operations: lessons from COVID-19 Part V: data-driven platforms and applications in production and logistics: digital twins and AI for sustainability; regular session: new approaches for routing problem solving; regular session: improvement of design and operation of manufacturing systems; regular session: crossdock and transportation issues; regular session: maintenance improvement and lifecycle management; regular session: additive manufacturing and mass customization; regular session: frameworks and conceptual modelling for systems and services efficiency; regular session: optimization of production and transportation systems; regular session: optimization of supply chain agility and reconfigurability; regular session: advanced modelling approaches; regular session: simulation and optimization of systems performances; regular session: AI-based approaches for quality and performance improvement of production systems; and regular session: risk and performance management of supply chains *The conference was held online.*

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.

This book bridges the gap between practitioners of supply-chain management and pharmaceutical industry experts. It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply-chains within the globally important pharmaceutical sector. Scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until a drug has been registered, but should start as early as possible in the development process and before registration or clinical trials. The author suggests that CMC (chemistry manufacturing controls) drug development must reset the line of sight – from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.

Peptide and Protein Delivery

Aligning Business Strategies and Analytics

Pain Management and the Opioid Epidemic

International Regulatory Harmonization Amid Globalization of Drug Development

Serial Innovators

Delivering Patient Value for Pharmaceuticals and Biologics

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017

A comprehensive exploration of the massive changes in the biopharmaceutical supply chain that have occurred during the past 10 years, and predicted future trends, Biopharmaceutical Supply Chains: Distribution, Regulatory, Systems and Structural Changes Ahead documents the specific impacts of these changes for key players in the supply chain. Based

This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as

follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

Creates a managerial compass for entering into the LIVING (Live, Intelligent, Velocity, Interactive, Networked, and Good) era of supply chain management and defines the imperative for creating Velocity and Visibility as the focal point for exploiting new digital, mobile, and cloud-based technologies Written by well-known researchers in the field, this book addresses the changes that have occurred and are still unfolding at various organizations that are involved in building real-time supply chains. The authors draw on their experiences with multiple companies, along with references to the natural evolution of ecosystems throughout to help identify the “new rules of supply chain management." The LIVING principles associated with the rapid digitization and technology changes occurring in the global economy are discussed, along with the push to become more sustainable and responsive to customer needs. “ Handfield and Linton reveal the “secret ingredient” to leveraging the power of a well managed supply chain....will revolutionize the way companies approach supply chain management.” Frank Crespo, Vice President, Global Supply Network Division (CPO/Logistics/IoT Analytics), Caterpillar Inc. “ The LIVING supply chain is a wake up call to any enterprise that depends on suppliers and contractors. Be fast, be nimble and make supply chain transparency the nucleus of your operations or become endangered.” Paul Massih, Vice President, BP PSCM “ ...a fascinating journey through the future of supply chain management ... a must read for every supplychain professional.” Yossi Sheffi, Professor, MIT Center for Transportation and Logistics “ ... a great “living” reading on how to bring supply chains to a powerful living state. The idea of Live-Interactive-Velocity-Intelligent-Networked-Good is the foundation of how supply chains can be agile, adaptive and aligned. ...of value to every supply chain executive and practitioner.” Hau Lee, Professor, Stanford University “ Successful businesses are those that support the success of their customers. This book captures the essence of our volatile, uncertain world and the opportunities that exist for the commercially astute, organizationally integrated business. More important, it offers insight to the recipe for 21st century operations and the management of complex supply ecosystems.” Tim

Cummins, CEO, International Association of Commercial and Contract Management " A LIVING supply chain requires a living company. The authors make a great case for how Flex is creating a living company to thrive in the living supply chain." Tom Choi, Harold E. Fear on Eminent Scholar Chair of Purchasing Management, Arizona State University, Executive Director, CAPS Research " To survive we need to have an adaptive supply chain and capability to both optimize and adapt simultaneously. This book begins to describe the ability to shift from functional silos to E2E Frictionless flow with the maturity to make E2E tradeoff decisions as a key enabler for success." Wayne Rothman, Vice President, Enterprise Supply Chain Planning, Johnson & Johnson "A fantastic read and excellent stories from Dr. Handfield and Tom." Joanne E. Wright, Vice President, IBM Supply Chain ROBERT HANDFIELD, PhD, is Bank of America University Distinguished Professor of Supply Chain Management and Director of the Supply Chain Resource Cooperative at North Carolina State University. The author of four books and over 150 journal articles, Dr. Handfield received his PhD in Opera

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The Imagination Machine

Single-Use Technology in Biopharmaceutical Manufacture

Advances in Production Management Systems. Artificial Intelligence for Sustainable and Resilient Production Systems

A National Imperative

Registries for Evaluating Patient Outcomes

Workshop Summary

Production and Processes

Biopharmaceutical Supply ChainsDistribution, Regulatory, Systems and Structural Changes AheadCRC Press

Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.

Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that have occurred in recent years, finding a way to make prescription medicinesâ€"and health care at largeâ€"more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all

of these factors together. The current high and increasing costs of prescription drugsâ€"coupled with the broader trends in overall health care costsâ€"is unsustainable to society as a whole. Making Medicines Affordable examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.

This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Optimal Planning in Biopharmaceutical Supply Chains

Introduction to Biomanufacturing

Biopharmaceuticals

Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use

Regulatory Practice for Biopharmaceutical Production

New Perspectives in Healthcare

This monograph demonstrates empirically how the free-market system of drug pricing is vital to the development of new breakthrough drugs.

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.

A mixture of original research and thought leadership pieces combine to examine the changing landscape of the US healthcare system. This book provides researchers, professionals, managers and policy makers with a summary of how the US healthcare system has evolved and provides food for thought on how to prepare for the challenges of the future.

On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical

Production. This workshop discussed the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop.

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals

Supply Chain Redesign

Regulatory, Clinical, and Biopharmaceutical Development

Making Medicines Affordable

Regulatory Expectations for the Pharmaceutical Industry

Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade

WHO guideline on country pharmaceutical pricing policies

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.

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.

In this book, experts in the field express their well-reasoned opinions on a range of complex, clinically relevant issues across the full spectrum

of cell and gene therapies with the aim of providing trainee and practicing hematologists, including hematopoietic transplant physicians, with information that is relevant to clinical practice and ongoing research. Each chapter focuses on a particular topic, and the concise text is supported by numerous working tables, algorithms, and figures. Whenever appropriate, guidance is provided regarding the availability of potentially high-impact clinical trials. The rapid evolution of cell and gene therapies is giving rise to numerous controversies that need to be carefully addressed. In meeting this challenge, this book will appeal to all residents, fellows, and faculty members responsible for the care of hematopoietic cell transplant patients. It will also offer a robust, engaging tool to aid vital activities in the daily work of every hematology and oncology trainee.

This book gives an overview of commonly-used disposables in the manufacture of biopharmaceuticals, their working principles, characteristics, engineering aspects, economics, and applications. With this information, readers will be able to come to an easier decision for or against disposable alternatives and to choose the appropriate system. The book is divided into two parts – the first is related to basic knowledge about disposable equipment; and the second discusses applications through case studies that illustrate manufacturing, quality assurance, and environmental influence.

Cell and Gene Therapies

Biosimilars

Supply Chain Management in the Drug Industry

Biochemistry and Biotechnology

Development of Biopharmaceutical Drug-Device Products

GMP in Practice

How to Spark New Ideas and Create Your Company's Future

Drug overdose, driven largely by overdose related to the use of opioids, is now the leading cause of unintentional injury death in the United States. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the rising toll of the harms that can arise from the use of opioid medications. Chronic pain and opioid use disorder both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function. In the context of the growing opioid problem, the U.S. Food and Drug Administration (FDA) launched an Opioids Action Plan in early 2016. As part of this plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic, with a particular focus on informing FDA's development of a formal method for incorporating individual and societal considerations into its risk-benefit framework for opioid approval and monitoring. Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for

treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.

The food industry is a notoriously complex economic sector that has not received the attention it deserves within legal scholarship. Production and distribution of food is complex because of its polycentric character (as it operates at the intersection of different public policies) and its dynamic evolution and transformation in the last few decades (from technological and governance perspectives). This volume introduces the global value chain approach as a useful way to analyse competition law and applies it to the operations of food chains and the challenges of their regulation. Together, the chapters not only provide a comprehensive mapping of a vast comparative field, but also shed light on the intricacies of the

various policies and legal fields in operation. The book offers a conceptual and theoretical framework for competition authorities, companies and academics, and fills a massive gap in the competition policy literature dealing with global value chains and food.

Biotechnology represents a novel and expanding international industry bound by new and ever-changing legislature. This text provides a comprehensive overview of product-specific, international and country-specific licensing requirements and general regulatory issues in biotechnology.

Principles and Case Studies

Impacts of Regulation, Organization, Reform and Change in the United States Health System

Continuous Manufacturing for the Modernization of Pharmaceutical Production

Global Food Value Chains and Competition Law

A User's Guide

The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide "one stop shopping" for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical

field.

A comprehensive exploration of the massive changes in the biopharmaceutical supply chain that have occurred during the past 10 years, and predicted future trends, Biopharmaceutical Supply Chains: Distribution, Regulatory, Systems and Structural Changes Ahead documents the specific impacts of these changes for key players in the supply chain. Based on interviews with industry professionals, the book presents an overview of the key challenges and discusses how leading biopharmaceutical companies handle these challenges. It exposes the underlying structures that support the biopharmaceutical supply chain, focusing specifically on distribution the point at which manufacturers release a finished product to the time that it is administered, and the complicated set of channels that exist between these two points. This overarching view of the supply chain provides an important piece of intelligence that can inform business strategy for life sciences manufacturers and distributors and help them achieve success in this industry.