Biopharmaceutical Supply Chains Distribution Regulatory Systems And Structural Changes Ahead

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Life Science Management National Academies Press
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 Oxford Handbook of Supply Chain Management John Wiley & Sons
The 3D printing (3DP) process was patented in 1986; however, only in the last decade has it begun to be used for medical applications, as well as in the fields of prosthetics, bio-fabrication, and pharmaceutical printing. 3DP or additive manufacturing (AM) is a family of technologies that implement layer-by-layer processes in order to fabricate physical models based on a computer aided design (CAD) model. 3D printing permits the fabrication of high degrees of complexity with great reproducibility in a fast and cost-effective fashion. 3DP technology offers a new paradigm for the direct manufacture of individual dosage forms and has the potential to allow for variations in size and geometry as well as control dose and release behavior. Furthermore, the low cost and ease of use of 3DP systems means that the possibility of manufacturing medicines and medical devices at the point of dispensing or at the point of use could become a reality. 3DP thus offers the perfect innovative manufacturing route to address the critical capability gap that hinders the widespread exploitation of personalized medicines for molecules that are currently not easy to deliver. This Special Issue will address new developments in the area of 3D printing and bioprinting for drug delivery applications, covering the recent advantages and future directions of additive manufacturing for pharmaceutical products.

Global Value Chain Development Report World Health Organization
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.

WHO guideline on country pharmaceutical pricing policies WIPO
The managed flow of goods and information from raw material to final sale also known as a "supply chain" affects everything--from the U.S. gross domestic product to where you can buy your jeans. The nature of a company's supply chain has a significant effect on its success or failure--as in the success of Dell Computer's make-to-order system and the failure of General Motor's vertical integration during the 1998 United Auto Workers strike. Supply Chain Integration looks at this crucial component of business at a time when product design, manufacture, and delivery are changing radically and globally. This book explores the benefits of continuously improving the relationship between the firm, its suppliers, and its customers to ensure the highest added value. This book identifies the state-of-the-art developments that contribute to the success of vertical tiers of suppliers and relates these developments to the capabilities that small and medium-sized manufacturers must have to be viable participants in this system. Strategies for attaining these capabilities through manufacturing extension centers and other technical assistance providers at the national, state, and local level are suggested. This book identifies action steps for small and medium-sized manufacturers--the "seed corn" of business start-up and development--to improve supply chain management. The book examines supply chain models from consultant firms, universities, manufacturers, and associations. Topics include the roles of suppliers and other supply chain participants, the rise of outsourcing, the importance of information management, the natural tension between buyer and seller, sources of assistance to small and medium-sized firms, and a host of other issues. Supply Chain Integration will be of interest to industry policymakers, economists, researchers, business leaders, and forward-thinking executives.

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

Biopharmaceuticals CRC Press
The COVID-19 pandemic has reminded us of how important the life science industry is, and compels us to find efficient management methods specific to the industry. Pharmaceuticals, drug and vaccine development labs, R&D labs, medical instrumentation, and tech companies, hygiene supply companies, medical distribution chains, all form an integral part of this industry. At the interface of scientific research, technology, innovation and management and embedded in regulatory and legal frameworks, life science management is still an under-researched field of practice and science. This edited volume addresses this research gap and offers a wide range of practical and theoretical contributions that provide insights into one of the most exciting industries. The book is primarily directed at practitioners and decision makers in the life science industry. Students and professionals of life science management at all levels as well as policy makers will find valuable insights and inspiration for their daily work and career development.

Pharmaceutical Manufacturing Handbook Open University Press
Edited by three pioneers in the field, each with longstanding experience in the biotech industry, and a skilled scientific writer, this is the first book to cover every step in the development and production of immunoglobulin Fc-fusion proteins as therapeutics for human disease: from choosing the right molecular design, to pre-clinical characterization of the purified product, through to batch optimization and quality control for large-scale cGMP production. The whole of the second part is devoted to case studies of Fc-fusion proteins that are now commercially successful products. In this section, the authors, several of whom were personally involved in clinical development of the products themselves, detail the product?s background and give insight into issues that were faced and how these issues were overcome during clinical development. This section also includes a chapter on promising new developments for the future. An invaluable resource for professionals already working on Fc-fusion proteins and an excellent and thorough introduction for physicians, researchers, and students entering the field.

Healthcare Biotechnology CRC Press
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.

3D Printing of Pharmaceuticals and Drug Delivery Devices John Wiley & Sons
This book discusses the different regulatory pathways for gene therapy (GT) and cell therapy (CT) medicinal products implemented by national and international bodies throughout the world (e.g. North and South America, Europe, and Asia). Each chapter, authored by experts from various regulatory bodies throughout the international community, walks the reader through the applications of nonclinical research to translational clinical research to licensure for these innovative products. More specifically, each chapter offers insights into fundamental considerations that are essential for developers of CT and GT products, in the areas of product manufacturing, pharmacology and toxicology, and clinical trial design, as well as pertinent "must-know" guidelines and regulations. Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective is part of the American Society of Gene and Cell Therapy sub-series of the highly successful Advances in Experimental Medicine and Biology series. It is essential reading for graduate students, clinicians, and researchers interested in gene and cell therapy and the regulation of pharmaceuticals.

Materials for Advanced Packaging Springer
"Abstract: Supply chain management contends with structures and processes for delivering goods and services to customers. It addresses the core functions of connected businesses to meet downstream demand. This innovative volume provides an authoritative and timely guide to the overarching issues that are ubiquitous throughout the supply chain. In particular, it addresses emerging issues that are applicable across supply chains-such as data science, financial flows, human capital, internet technologies, risk management, cyber security, and supply networks. With chapters from an international roster of leading scholars in the field, The Oxford Handbook of Supply Chain Management is a necessary resource for all students and researchers of the field as well as for forward-thinking practitioners. Keywords: supply chain management; value; human society; goods and services; competitive advantage; people and welfare; data and technology; moving goods and services; structure and strategy; growing and sustaining"--

Regulatory Aspects of Gene Therapy and Cell Therapy Products MDPI
This study seeks to reinforce the understanding of the interplay between the distinct policy domains of health, trade and intellectual property, and of how they affect medical innovation and access to medical technologies. The second edition comprehensively reviews new developments in key areas since the initial launch of the study in 2013.

COVID-19: Systemic Risk and Resilience FT Press
This book aims to provide a collection of early ideas regarding the results of applying risk and resilience tools and strategies to COVID-19. Each chapter provides a distinct contribution to the new and rapidly growing literature on the developing COVID-19 pandemic from the vantage points of fields ranging from civil and environmental engineering to public policy, from urban planning to economics, and from public health to systems theory. Contributing chapters to the book are both scholars and active practitioners, who are bridging their applied work with critical scholarly interpretation and reflection. The book's primary purpose is to empower stakeholders and decision-makers with the most recent research in order that they can better understand the systemic and sweeping nature of the COVID-19 pandemic, as well as which strategies could be implemented to maximize socioeconomic and public health recovery and adaptation over the long-term.

Pharmaceuticals in the Environment CRC Press
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.

International Regulatory Harmonization Amid Globalization of Drug Development National Academies Press

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.

Pain Management and the Opioid Epidemic CRC Press

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.

Continuous Manufacturing for the Modernization of Pharmaceutical Production National Academies Press

The first wide-ranging analysis of business trends in the manufacturing segment of the health care industry.

Global Supply Chains in the Pharmaceutical Industry National Academies Press

A radical shift is underway in global value chains as they increasingly move beyond traditional manufacturing processes to services and other intangible assets. Digitization is a leading factor in this transformation, which is being accelerated by the coronavirus disease (COVID-19) pandemic. The Global Value Chain Development Report 2021, the third of a biennial series, explores this shift Beyond Production. This report shows how the rise of services value chains offers a new path to development and how protectionism and geopolitical tensions, environmental risks, and pandemics are undermining the stability of global value chains and forcing their reorganization geographically.

The Global Enabling Trade Report 2008 Springer

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.

Pharmaceutical Manufacturing Handbook Springer Nature

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 Business of Healthcare Innovation World Economic Forum

"The book is highly readable, informative, thought provoking, and educational.At every stage, Walker challenges the reader to move away from conventional supply chain thinking to a broader-view, highly concise approach that focuses on the organization's objectives. The book will help you visualize a supply network and develop a blueprint for your