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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.

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.

The pharmaceutical and healthcare industry is hugely complex because it involves so many markets, products, processes and intermediaries. It is also heavily regulated, global, and used by everyone at some stage in their life. No wonder the supply chain for delivery of healthcare services is often fragmented and understood only in discrete sections. Changes in one area impact upon the others, and environmental factors such as pricing, regulatory change or actions by competitors impact the whole supply chain in ways that are not easily understood or managed. Accelerating technology, the commoditization of healthcare, increasing demands from ageing populations all influence the approach that suppliers of pharmaceutical products and services worldwide need to take if they are to design and manage an effective supply chain that will be capable of: exploiting their intellectual property in a sustainable way; providing safe and continuous provision of drugs or devices; and sustaining with resilience, yet still be flexible and cost efficient. Supply Chain in the Pharmaceutical Industry offers the basis for organizations to develop their own blueprint for managing the opportunities and threats to the pharmaceutical supply chain. Using examples from companies and markets across the world Rob Whewell offers a very vivid picture of the developing trends for pharmaceutical companies; the customers and markets they serve and points to some of the elements that underpin sustainable pharmaceutical strategies. The current global banking and financial crisis illustrates the important role played by regulation. The healthcare industry is similar in scope, and complexity, yet the implications of error are worse - life threatening. This review of key industry parameters will provide senior executives in the industry and policy makers in healthcare with a broad perspective of the issues and illustrates an understanding of the task at hand.

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.

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.

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.

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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.

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.