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Pharmaceutical Supply Chain Management

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PBS NewsHour full episode, Dec. 17, 2020 **What is pharmaceutical Supply Chain Management?**

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Quality

The Drug Quality and Security Act (DQSA), was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic,...

Drug Supply Chain Security Act (DSCSA) | FDA

The United States, in particular, is susceptible to interruptions in the supply chain for pharmaceutical drugs because many of the raw materials, active pharmaceutical ingredients, and manufacturing processes needed to produce domestically marketed prescription drugs have been outsourced beyond U.S. borders.

Fortifying the US Pharmaceutical Supply Chain | Bill of Health

Error-proofing in the production process of pharmaceuticals isn't just a matter of good business, it has life-and-death implications for consumers. To that end, the 2013 Drug Quality and Security Act in large part requires new mandates on tracking and tracing chain of custody in the supply chain.

Pharmaceutical Supply Chain: Drug Quality and Security Act ...

The pharmaceutical supply chain faces its own set of challenges, including supply chain visibility, drug counterfeiting, cold-chain shipping, and raising prescription drug prices, which can significantly increase out-of-pocket costs for patients. In the following article, PharmaNewsIntelligence breaks down the fundamentals of the pharmaceutical supply chain to uncover strategies for overcoming the most common challenges and ways to get patients consistent access to their medications.

Fundamentals of the Pharmaceutical Supply Chain

Pharmaceutical Supply Chain: Drug Quality and Security Act - Kindle edition by Kuglin, Fred A.. Download it once and read it on your Kindle device, PC, phones or tablets. Use features like bookmarks, note taking and highlighting while reading Pharmaceutical Supply Chain: Drug Quality and Security Act.

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To that end, the 2013 Drug Quality and Security Act in large part requires new mandates on tracking and tracing chain of custody in the supply chain. Pharmaceutical Supply Chain: Drug Quality and Security Act overviews the new mandate and its implications, including implementation strategies for track-and-trace programs along with presenting a ...

Pharmaceutical Supply Chain: Drug Quality and Security Act ...

HealthTrust evaluates pharmaceutical supply chains for mission-critical drugs to identify predictors of shortages & key characteristics. HealthTrust Pharmacy Services recently launched its first products for the Supply Interruption Mitigation Strategies (SIMS) project in order to help combat drug shortages, and their

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ensuing price increases, in the generic injectables market.

An Ideal Pharmaceutical Supply Chain: Quality Comes First ...

Pharmaceutical supply chain should provide medicines in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to be consistent with health system's objectives and also it should make benefits for its stockholders.

An Overview on Pharmaceutical Supply Chain: A Next Step ...

Best Practices for Maintaining Pharma Supply Chain Continuity in a Complex & Dynamic Environment. ... Division of Drug Quality; United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA) Each day of the conference has live Q&A sessions with the attendees and the speakers, and identical to last year's inaugural APAC conference ...

Best Practices for Maintaining Pharma Supply Chain ...

Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements September 2015

Drug Supply Chain Security Act - Food and Drug Administration

Supply chain is very critical as it maintains the complex network relationship between drug manufacturers, trading partners, wholesalers and retailers. Pharmaceutical products need temperature...

(PDF) Pharmaceutical Supply Chain Management

By connecting to the Elemica Digital Supply Network, enterprises manage supply chain execution and quality across all of their trading partners, hospitals, and pharmacies, while gaining visibility and insights to the needs of their customers and patients. All networked multi-enterprises can track and manage quality, orders, inventory, and shipments in real-time as products flow through from raw material suppliers all the way to the patient.

Elemica Pharmaceutical Supply Chain Increases Quality ...

According to an executive from the drug development services company, pharma professionals should pay close attention to supply chain continuity and safety in the coming year. Brad Payne (BP), chief operating officer of PCI Pharma Services, talked with Outsourcing-Pharma (OSP) about the factors that shaped the pharmaceutical industry in 2020 ...

Stay on top of your pharma supply chain in 2021: PCI

Generic drug supply chain disruptions and shortages are symptomatic of a dysfunctional business environment caused by predatory pricing and lack of supply chain partnerships. The generic drug...

Unsustainable Low Prices Causing Generic Drug Market ...

The role of the wholesaler in the life sciences supply chain

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management is to make the process of purchasing drug products from pharmaceutical manufacturers more efficient. Wholesale distributors connect 60,000 U.S. pharmacies and outpatient dispensing outlets.

How Does the Pharmaceutical Supply Chain Work?

Flexibility and agility are required across the entire pharmaceutical supply chain, from raw material, intermediate, drug substance, and drug product manufacturing, to the production of materials and components of manufacturing equipment, to the design and manufacture of packaging solutions, and on to warehousing and distribution of all of these important items.

Rethinking the Global Pharmaceutical Supply Chain Post ...

Recently, inspectors from the FDA have issued warning letters to manufacturers abroad at an increasing rate, putting quality and compliance in focus as the pharmaceutical industries in China and India look to move up the value chain into novel drug development. It's not just manufacturing, though.

Top challenges facing drug supply chains | BioPharma Dive

The Drug Supply Chain Securities Act is a great example. The 2013 law requires every drug to be tracked and traced from manufacturer to end user. The law's provisions are phased in through 2023, but the pharmacies that get it aren't waiting until then to put systems in place to comply with the law.

Connecting Pharmaceutical Distribution and Supply Chain ...

Under the Drug Supply Chain Security Act (DSCSA), the U.S. pharmaceutical supply chain will be brought together by an electronic, interoperable system to identify and trace prescription drugs as they're distributed throughout the country. This has radical implications for the entire industry, as regulators and stakeholders all race the clock to transform how drugs reach the patients who need them.

Error-proofing in the production process of pharmaceuticals isn't just a matter of good business, it has life-and-death implications for consumers. To that end, the 2013 Drug Quality and Security Act in large part requires new mandates on tracking and tracing chain of custody in the supply chain. Pharmaceutical Supply Chain: Drug Quality and Security

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

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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 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.

In a rapidly growing global economy, where there is a constant emergence of new business models and dynamic changes to the business ecosystem, there is a need for the integration of traditional, new, and hybrid concepts in the complex structure of supply chain management. Within the fast-paced pharmaceutical industry, product strategy, life cycles, and distribution must maintain the highest level of agility. Therefore, organizations need strong supply chain capabilities to profitably compete in the marketplace. Global Supply Chains in the Pharmaceutical Industry provides innovative insights into the efforts needed to build and maintain a strong supply chain network in order to achieve efficient fulfillment of demand, drive outstanding customer value, enhance organizational responsiveness, and build network resiliency. This publication is designed for supply chain managers, policymakers, researchers, academicians, and students, and covers topics centered on economic cycles, sustainable development, and new forces in the global economy.

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This book provides an insight of relevant case studies and updated practices in "Pharmaceutical Supply Chains" (PharmSC) while addressing the most relevant topics within the COST Action "Medicines Shortages" (CA15105). The volume focuses on the most recent developments in the design, planning and scheduling of PharmSC, broadening from the suppliers' selection to the impact on patients and healthcare systems, addressing uncertainty and risk mitigation, and computational issues. It is directed at MSc/PhD students and young researchers (Post-Docs) in Pharmaceutics/Pharmaceutical sciences, Engineering fields, Economics/Management, as well as pharmaceutical decision makers, managers, and practitioners, and advanced readers demanding a fresh approach to decision making for PharmSC. The contributed chapters are associated with the homonymous COST Training Schools (TS), and the book creates a better understanding of the Action "Medicines Shortages" challenges and opportunities.

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

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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.

Process Systems Engineering for Pharmaceutical Manufacturing: From Product Design to Enterprise-Wide Decisions, Volume 41, covers the following process systems engineering methods and tools for the modernization of the pharmaceutical industry: computer-aided pharmaceutical product design and pharmaceutical production processes design/synthesis; modeling and simulation of the pharmaceutical processing unit operation, integrated flowsheets and applications for design, analysis, risk assessment, sensitivity analysis, optimization, design space identification and control system design; optimal operation, control and monitoring of pharmaceutical production processes; enterprise-wide optimization and supply chain management for pharmaceutical manufacturing processes. Currently, pharmaceutical companies are going through a paradigm shift, from traditional manufacturing mode to modernized mode, built on cutting edge technology and computer-aided methods and tools. Such shifts can benefit tremendously from the application of methods and tools of process systems engineering. Introduces Process System Engineering (PSE) methods and tools for discovering, developing and deploying greener, safer, cost-effective and efficient pharmaceutical production processes Includes a wide spectrum of case studies where different PSE tools and methods are used to improve various pharmaceutical production processes with distinct final products Examines the future benefits and challenges for applying PSE methods and tools to pharmaceutical manufacturing

A NEW YORK TIMES BESTSELLER New York Times 100 Notable Books of 2019 New York Public Library Best Books of 2019 Kirkus Reviews Best Health and Science Books of 2019 Science Friday Best Books of 2019 New postscript by the author From an award-winning journalist, an explosive narrative investigation of the generic drug boom that reveals fraud and life-threatening dangers on a global scale—The Jungle for pharmaceuticals Many have hailed the widespread use of generic drugs as one of the most important public-health developments of the twenty-first century. Today, almost 90 percent of our

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pharmaceutical market is comprised of generics, the majority of which are manufactured overseas. We have been reassured by our doctors, our pharmacists and our regulators that generic drugs are identical to their brand-name counterparts, just less expensive. But is this really true? Katherine Eban's *Bottle of Lies* exposes the deceit behind generic-drug manufacturing—and the attendant risks for global health. Drawing on exclusive accounts from whistleblowers and regulators, as well as thousands of pages of confidential FDA documents, Eban reveals an industry where fraud is rampant, companies routinely falsify data, and executives circumvent almost every principle of safe manufacturing to minimize cost and maximize profit, confident in their ability to fool inspectors. Meanwhile, patients unwittingly consume medicine with unpredictable and dangerous effects. The story of generic drugs is truly global. It connects middle America to China, India, sub-Saharan Africa and Brazil, and represents the ultimate litmus test of globalization: what are the risks of moving drug manufacturing offshore, and are they worth the savings? A decade-long investigation with international sweep, high-stakes brinkmanship and big money at its core, *Bottle of Lies* reveals how the world's greatest public-health innovation has become one of its most astonishing swindles.

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