Pharmaceutical Industrial Management

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Global Supply Chains in the Pharmaceutical Industry - Nozari, Hamed 2018-11-09

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.

Pharmaceutical and Biomedical Project Management in a Changing Global Environment - Scott D. Babler 2011-01-06

Pharmaceutical and Biomedical Portfolio Management in a Changing Global Environment explores some of the critical forces at work today in the complex endeavour of pharmaceutical and medical product development. Written by experienced professionals, and including real-world approaches and best practice examples, this new title addresses three key areas – small molecules, large molecules, and medical devices - and provides hard-to-find, consolidated information relevant to and needed by pharmaceutical, biotech, and medical device company managers.

***Ethics and the Pharmaceutical Industry* - Michael A. Santoro 2005-10-31**

Despite the pharmaceutical industry's notable contributions to human progress, including the development of miracle drugs for treating cancer, AIDS, and heart disease, there is a growing tension between the industry and the public. Government officials and social critics have questioned whether the multibillion-dollar industry is fulfilling its social responsibilities. This doubt has been fueled by the national debate over drug pricing and affordable healthcare, and internationally by the battles against epidemic diseases, such as AIDS, in the developing world. Debates are raging over how the industry can and should be expected to act. The contributions in this book by leading figures in industry, government, NGOs, the medical community, and academia discuss and propose solutions to the ethical dilemmas of drug industry behavior. They examine such aspects as the role of intellectual property rights and patent protection, the moral and economic requisites of research and clinical trials, drug pricing, and marketing.

Project Management for the Pharmaceutical Industry - Laura Brown 2016-04-08

The pharmaceutical industry has encountered major shifts in recent years, both within the industry, and in its external environment. The cost of healthcare rising due to an ageing population, the intensification of regulatory requirements and mergers within the industry have led to an increased need for restructuring, cost reduction and culture change projects. Project management is the key to addressing these needs, and also to effective drug development. Given the costs of development and the critical issue of 'time to market', project

management techniques - appropriately used - are a key factor in bringing a drug to market. In this book, Laura Brown and Tony Grundy's pharmaceutical expertise and experience offers the reader a guide to the most relevant project management tools and techniques and how to rigorously apply them in the pharmaceutical industry. The authors cover the technical, strategic and human aspects of project management, including contingency planning, simulation techniques and different project options. Complete with decision-tree diagrams, checklists, exercises and a full glossary, Project Management for the Pharmaceutical Industry provides clinical research, drug development and quality assurance managers or directors with a one-stop reference for successfully managing pharmaceutical projects. The text has been revised for this edition and now includes some additional material on risk management.

Knowledge Management in the Pharmaceutical Industry - Elisabeth Goodman 2016-04-22

The Pharmaceutical Industry has been undergoing a major transformation since the heady days of 'big pharma' in the 1970s and 80s. Patent expiry, the rise of generics, and the decline of the blockbuster drug have all changed the landscape over the last 10-15 years. It's an environment where products can take 10 years or more to come to market, billions are spent on research and development, jobs are being shed in the western pharma homelands and regulators and the public are more demanding than ever. So what part is Knowledge Management playing and going to play in this vital international industry? Knowledge Management (KM) has many facets from providing comprehensive knowledge bases for workers, through the sharing of advice and problem solving, to providing an environment for innovation and change. This book, focusing on research and development, and manufacturing-based companies, explores how a range of techniques and approaches have been applied in the unique environment of the Pharmaceutical Industry, and examine how it can help the industry in the 21st century. Whilst the book is centered on the Pharmaceutical Industry, its objective will be to discuss and demonstrate how Knowledge Management can be applied in a variety of environments, and with a range of cultural issues. KM practitioners, and potential practitioners, both within and outside the Pharmaceutical Industry, will be able to gain valuable guidance and advice from both the examples of

good practice and the lessons learned by the authors and contributors.

Pharmaceutical Operations Management - Pankaj Mohan 2006-03-16

Publisher's Note: Products purchased from Third Party sellers are not guaranteed by the publisher for quality, authenticity, or access to any online entitlements included with the product. This book brings together a winning team of international operations experts to set the framework for building a world-class manufacturing organization. Pharmaceutical Operations Management focuses on key concepts such as: Policy Execution, Risk Management, Supply chain modeling, Advance process control and Six Sigma for the pharmaceutical industry: critical techniques which will offset cost, increase efficiency and turn any manufacture into financial winner.

Brand Planning for the Pharmaceutical Industry - Janice MacLennan 2004

Brand Planning for the Pharmaceutical Industry is a step-by-step guide, with examples from the pharmaceutical industry directly applicable to your own brand planning. It begins by exploring the definition of branding and why it is of importance, particularly to the pharmaceutical sector. It shows how branding can be successfully integrated into the early stages of the commercialization process for new products, both in theory and in practice.

Emergence of Pharmaceutical Industry Growth with Industrial IoT Approach - Valentina E. Balas 2019-09-24

Emergence of Pharmaceutical Industry Growth with Industrial IoT Approach uses an innovative approach to explore how the Internet of Things (IoT) and big data can improve approaches, create efficiencies and make discoveries. Rapid growth of the IoT has encouraged many companies in the manufacturing sector to make use of this technology to unlock its potential. Pharmaceutical manufacturing companies are no exception to this, as IoT has the potential to revolutionize aspects of the pharmaceutical manufacturing process, from drug discovery to manufacturing. Using clear, concise language and real world case studies, this book discusses systems level from both a human-factors point-of-view and the perspective of networking, databases, privacy and anti-spoofing. The wide variety of topics presented offers readers multiple perspectives on a how to integrate the Internet of Things into pharmaceutical

manufacturing. Covers efficiency improvements of pharmaceutical manufacturing through IoT/Big Data approaches Explores cutting-edge technologies through sensor enabled environment in the pharmaceutical industry Discusses the systems level from both a human-factors point-of-view and the perspective of networking, databases, privacy and anti-spoofing

Concepts of Quality Management in Pharmaceutical Industry - Manohar A Potdar 2017-08-08

In managing the Quality, why we do something is more important than what we do. The purpose of this book is to explain this basis of Quality management to those who need to know in pharmaceutical industry. This book explains the above view with reference to pharma industry with the help of principles of quality advocated by the genius like Dr. Joseph Juran in simple to understand language. The book will be very useful to the postgraduate students of pharmacy and practicing quality managers in pharma industry.

Supply Chain Management in the Drug Industry - Hedley Rees 2011-04-06

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.

Devalued and Distrusted - John L. LaMattina 2013-01-09

An expert's view on solving the challenges confronting today's pharmaceutical industry Author John LaMattina, a thirty-year veteran of the pharmaceutical industry and former president of

Pfizer's Global R&D Division, is internationally recognized as an expert on the pharmaceutical industry. His first book, Drug Truths: Dispelling the Myths About Pharma R&D, was critically acclaimed for clearing up misconceptions about the pharmaceutical industry and providing an honest account of the contributions of pharmaceutical research and development to human health and well-being. As he toured the country discussing Drug Truths, Dr. LaMattina regularly came across people who were filled with anger, accusing the pharmaceutical industry of making up diseases, hiding dangerous side effects, and more. This book was written in response to that experience, critically examining public perceptions and industry realities. Starting with "4 Secrets that Drug Companies Don't Want You to Know," Devalued and Distrusted provides a fact-based account of how the pharmaceutical industry works and the challenges it faces. It addresses such critical issues as: Why pharmaceutical R&D productivity has declined Where pharmaceutical companies need to invest their resources What can be done to solve core health challenges, including cancer, diabetes, and neurodegenerative diseases How the pharmaceutical industry can regain public trust and resuscitate its image Our understanding of human health and disease grows daily; however, converting science into medicine is increasingly challenging. Reading Devalued and Distrusted, you'll not only gain a greater appreciation of those challenges, but also the role that the pharmaceutical industry currently plays and can play in solving those challenges. Get to know the author: Read an interview with John LaMattina or watch a video on ChemistryViews! Interview: John LaMattina: 30 Years in Pharma Video: Can the Pharmaceutical Industry Restory its Broken Image?

Advances in Pharma Business Management and Research - Lars Schweizer 2020-02-19

This open access book presents a unique collection of practical examples from the field of pharma business management and research. It covers a wide range of topics such as: 'Brexit and its Impact on pharmaceutical Law - Implications for Global Pharma Companies', 'Implementation of Measures and Sustainable Actions to Improve Employee's Engagement', 'Global Medical Clinical and Regulatory Affairs (GMCRA)', and 'A Quality Management System for R&D Project and Portfolio Management in a Pharmaceutical Company'. The chapters are summaries of master's theses by "high potential" Pharma

MBA students from the Goethe Business School, Frankfurt/Main, Germany, with 8-10 years of work experience and are based on scientific know-how and real-world experience. The authors applied their interdisciplinary knowledge gained in 22 months of studies in the MBA program to selected practical themes drawn from their daily business.

Pharmaceutical Process Design and Management - Kate McCormick 2016-04-22

A quality product or service is the successful and profitable outcome of organising resources, as judged by the final customer. Every business unit needs processes in order to do this effectively; and all processes must be documented so that achievements can be measured and future improvements planned and implemented. Pharmaceutical Process Design and Management takes a step-wise approach to process management. It presents the various elements comprising a process (man, machine, materials, method and environment); it looks at quality control and quality assurance, tools for quality improvements and ways of structuring a process into discrete, fully accountable elements; it proposes that for processes to run successfully, all operators must be the initial problem-solvers; finally, it illustrates how, with the right tools, every problem can be broken down into solvable elements. Learn how to deploy a science and risk-based approach to pharmaceutical manufacturing, by taking a fundamental approach to process design and management and, as a consequence, keep your customers satisfied and your profits healthy.

Sources of Medical Technology - Institute of Medicine 1995-01-01

Evidence suggests that medical innovation is becoming increasingly dependent on interdisciplinary research and on the crossing of institutional boundaries. This volume focuses on the conditions governing the supply of new medical technologies and suggest that the boundaries between disciplines, institutions, and the private and public sectors have been redrawn and reshaped. Individual essays explore the nature, organization, and management of interdisciplinary R&D in medicine; the introduction into clinical practice of the laser, endoscopic innovations, cochlear implantation, cardiovascular imaging technologies, and synthetic insulin; the division of innovating labor in biotechnology; the government- industry-university interface; perspectives on industrial R&D management; and the growing intertwining of the public and proprietary in medical technology.

Applying Lean Six Sigma in the Pharmaceutical Industry - Bikash Chatterjee 2016-04-08

Bikash Chatterjee emphasizes the criticality of applying the principles of Lean and Six Sigma within the paradigm of the drug development process. His guide to operational excellence in the pharmaceutical and biotech industries is a focused summary of the application of Lean Six Sigma theory to the regulated life sciences. From molecule discovery to the application of PAT Applying Lean Six Sigma in the Pharmaceutical Industry will highlight the importance of framing these initiatives within the key deliverables of drug development manufacturing and quality. Challenging conventional wisdom the author offers a quality and efficiency perspective as a foundation for the principles of Quality by Design, PAT and the new philosophies underlying Process Validation. Each chapter includes discussion around the considerations for applying Lean manufacturing and Six Sigma principles and their tools, culminating in a case study to illustrate the application. The book is organized to reflect the major work centers involved in the drug development lifecycle. Each chapter is stand-alone but together they illustrate the necessary synergy between Lean, Six Sigma and compliance sensibilities required to be successful in the pharmaceutical industry. These design, manufacturing and management techniques are not without their challenges. Bikash Chatterjee's book offers the roadmap for an industry that is struggling to reinvent many of its development and business processes.

Regulatory Affairs in the Pharmaceutical Industry - Javed Ali 2021-11-14

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA

regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance

Business Model Innovation - Nicolai J. Foss 2015

This volume examines the organisational dimension of business model innovation. Drawing on organisational theory and empirical observation, the contributors specifically highlight organisational design aspects of business model innovation, focusing on how reward systems, power distributions, routines and standard operating procedures, the allocation of authority, and other aspects of organisational structure and control should be designed to support the business model the firm chooses.

Pharmaceutical Quality by Design - Walkiria S. Schlindwein 2018-01-05

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This

important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

New Techniques for Brand Management in the Healthcare Sector - Borges, Ana Pinto 2021-01-29

Irrespective of the legal sphere and type of care (primary, secondary, and continuing), providers must ensure that users receive quality healthcare through the efficient use of resources, responsiveness, affordability, and the equal treatment of patients. Management and marketing have been playing an important role in this sector with the importance of branding growing in the healthcare market. The chance for brand in healthcare is determined by the challenges to increase and improve consumer choice. That's something to which providers and health systems, in general, have not been familiarized. New Techniques for Brand Management in the Healthcare Sector is a critical research publication that explores the diffusion of new marketing knowledge, tendencies, and qualitative and quantitative methods for brand management in the private, public, and social health sectors and examines the movement from healthcare as a priceless commodity to one that can be, and is, commodified. Highlighting topics such as e-health, medical tourism, and brand management, this publication is essential for hospital directors, marketers, advertisers, promotion coordinators, brand managers, product specialists, academicians, healthcare professionals, brand strategists, policymakers, researchers, and students.

Quality Assurance And Quality Management In Pharmaceutical Industry - Y. Anjaneyulu 2005

The Global Pharmaceutical Industry - Daniel Hoffman 2020-07-07

The pharmaceutical industry, long thought of as a recession-proof investment, now faces a day of reckoning. The reasons for this impending downfall are not hard to discern. The prices the industry

charges for its prescription drugs have escalated at four to five times the cost-of-living increases during the past two decades and have reached a point where 30% of Americans must choose between filling a prescription, paying for housing, and buying food. This has brought about public pressure on governments around the world to control drug prices, yet the world's twenty largest pharma companies realized 80% of their growth as a result of exorbitant price hikes. Pharma currently enjoys its extraordinary profitability by exploiting the world's most vulnerable populations. Yet even their ability to increase prices in the face of falling demand does not satisfy their profit demands. The breadth and depth of pharma's marketing transgressions exceed those of any other industry and have now reached a point where authorities around the world have found it necessary to take legal action against its violations. Drastic change is needed if the pharmaceutical industry can equitably advance the health of the world's population and regain public esteem. This book illustrates the range and extent of pharma's violations and addresses the actions that should be implemented in order to make the drug industry a more constructive, less venal part of contemporary society. It will be of interest to researchers, academics, practitioners, and students with an interest in the pharmaceutical industry, healthcare management, regulation, and bioethics.

Process Systems Engineering for Pharmaceutical Manufacturing - Ravendra Singh 2018-03-16

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

Industrial Engineering, Management Science and Applications 2015 - Mitsuo Gen 2015-05-18

This volume provides a complete record of presentations made at Industrial Engineering, Management Science and Applications 2015 (ICIMSA 2015), and provides the reader with a snapshot of current knowledge and state-of-the-art results in industrial engineering, management science and applications. The goal of ICIMSA is to provide an excellent international forum for researchers and practitioners from both academia and industry to share cutting-edge developments in the field and to exchange and distribute the latest research and theories from the international community. The conference is held every year, making it an ideal platform for people to share their views and experiences in industrial engineering, management science and applications related fields.

Pharmaceutical Lifecycle Management - Tony Ellery 2012-06-05

A comprehensive guide to optimizing the lifecycle management of pharmaceutical brands The mounting challenges posed by cost containment policies and the prevalence of generic alternatives make optimizing the lifecycle management (LCM) of brand drugs essential for pharmaceutical companies looking to maximize the value of their products. Demonstrating how different measures can be combined to create winning strategies, Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand explores this increasingly important field to help readers understand what they can—and must—do to get the most out of their brands. Offering a truly immersive introduction to LCM options for pharmaceuticals, the book incorporates numerous real-life case studies that demonstrate successful and failed lifecycle management initiatives, explaining the key takeaway of each example. Filled with practical information

on the process of actually writing and presenting an LCM plan, as well as how to link corporate, portfolio, and individual brand strategies, the book also offers a look ahead to predict which LCM strategies will continue to be effective in the future. While the development of new drugs designed to address unmet patient needs remains the single most important goal of any pharmaceutical company, effective LCM is invaluable for getting the greatest possible value from existing brands. Pharmaceutical Lifecycle Management walks you through the process step by step, making it indispensable reading for pharmaceutical executives and managers, as well as anyone working in the fields of drug research, development, and regulation.

Kaizen for Pharmaceutical, Medical Device and Biotech Industries - Shruti Bhat 2017-04-05

Kaizen procedures evolved in the automobile industry. Therefore, most of Kaizen literature, publications, books, cite Kaizen implementation in factories such as Toyota, Ford, Mazda and the like. But work practices within pharmaceutical, medical device and biotech industry are different from the auto sector. Regulations, customer demands, competitor landscape, product criteria, facility and environmental needs as well as employee skills within pharmaceutical (medical devices and biotech) companies are extremely stringent and totally different from the automobile industry. Therefore, 'as is' Kaizen practices from auto sector won't work for pharmaceutical, medical device, and biotech organizations. Kaizen needs to be customized for these life science industries, to achieve its full benefits. So far, there has been no book on Kaizen that is customized for such industries. For over a decade, the author, Dr. Shruti Bhat has successfully completed more than 250 Kaizen, Lean Six Sigma and other continuous improvement projects worldwide within pharmaceuticals NHP, medical devices, biotech and healthcare sectors, and felt it will be beneficial to share those techniques and experiences. In addition to explaining all the general Kaizen process features, implementation, and application, this book also provides a structured approach to designing Kaizen strategies, practices and implementation for pharmaceutical, medical device and biotech companies. This book will be most applicable to small to medium-size companies. It will demystify Kaizen and help business leaders in pharmaceutical, medical device, biotech and all life sciences organizations, irrespective of their

size or workplace culture. It will also provide practical and useful examples and case studies of Kaizen principles that can be executed at various levels across the organization as well as for yourself as an individual to further your personal career. And last but not the least, it will help to improve revenues and create a lasting profitable change by using Kaizen principles and techniques.

Business Development for the Biotechnology and Pharmaceutical Industry - Martin Austin 2016-04-08

Business Development in the biotechnology and pharmaceutical industries accounts for over $5 billion in licensing deal value per year and much more than that in the value of mergers and acquisitions. Transactions range from licences to patented academic research, to product developments as licences, joint ventures and acquisition of intellectual property rights, and on to collaborations in development and marketing, locally or across the globe. Asset sales, mergers and corporate takeovers are also a part of the business development remit. The scope of the job can be immense, spanning the life-cycle of products from the earliest levels of research to the disposal of residual marketing rights, involving legal regulatory manufacturing, clinical development, sales and marketing and financial aspects. The knowledge and skills required of practitioners must be similarly broad, yet the availability of information for developing a career in business development is sparse. Martin Austin's highly practical guide spans the complete process and is based on his 30 years of experience in the industry and the well-established training programme that he has developed and delivers to pharmaceutical executives from across the world.

Research and Development Management in the Chemical and Pharmaceutical Industry - Peter Bamfield 2006-03-06

Mastering management skills is hard to achieve by newcomers starting their careers in the chemical industry. The message coming from there is that good chemists swiftly have to become good managers if they are to survive and progress in today's competitive climate. This book is designed to help guide younger R & D chemists to ways in which they can quickly evolve skills which are built around three factors - people, knowledge and time. It covers the management of scientific personnel, management within a variety of R & D organisational structures, creating a climate of innovation, the management of projects including the time

management and communication aspects of the job. The author, Peter Bamfield, is now working as a consultant. Due to his long experience in the chemical industry, he was elected President of the Royal Society of Chemistry's Industrial Affairs Division. This second edition of the book has been revised and updated to take recent global developments and restructuring in the chemical industry into account, as well as the rising importance of information technology in management.

Textbook of Pharmaceutical Industrial Management - Biren N. Shah 2022-03-30

Written in strict accordance with the prescribed syllabus, this book caters to the needs of B. Pharm. students of different universities in the country.

Polymorphism in the Pharmaceutical Industry - Rolf Hilfiker 2019-01-04

"Polymorphism in the Pharmaceutical Industry - Solid Form and Drug Development" highlights the relevance of polymorphism in modern pharmaceutical chemistry, with a focus on quality by design (QbD) concepts. It covers all important issues by way of case studies, ranging from properties and crystallization, via thermodynamics, analytics and theoretical modelling right up to patent issues. As such, the book underscores the importance of solid-state chemistry within chemical and pharmaceutical development. It emphasizes why solid-state issues are important, the approaches needed to avoid problems and the opportunities offered by solid-state properties. The authors include true polymorphs as well as solvates and hydrates, while providing information on physicochemical properties, crystallization thermodynamics, quantum-mechanical modelling, and up-scaling. Important analytical tools to characterize solid-state forms and to quantify mixtures are summarized, and case studies on solid-state development processes in industry are also provided. Written by acknowledged experts in the field, this is a high-quality reference for researchers, project managers and quality assurance managers in pharmaceutical, agrochemical and fine chemical companies as well as for academics and newcomers to organic solid-state chemistry.

Pharmaceutical Industrial Management - G. Vidya Sagar 2017-10-05

This second edition has been made more useful to the student community by incorporating all the basic tenets of management principles on a platter. Pharmaceutical Industrial

Management focuses on managing the physical, material, financial and human resources of Pharmaceutical Industry in a fittest way. I

Pharmaceutical Management - Mr. Sachin Itkar 2008-01-07

Pharmaceuticals-Issues for Industrial Management - S. Arora

Global Issues in Pharmaceutical Marketing - Lea Prevel Katsanis 2015-07-16

Global Issues in Pharmaceutical Marketing presents a balanced, research-based perspective combined with a practical outlook on the current issues faced by the ethical, biotech, and generic segments of the pharmaceutical industry. It integrates an analytical approach with a global view to examine such issues as market access, digital marketing, emerging markets, branding, and more. The book covers not only the North American and Western European markets, but focuses on non-Western markets, such as Latin America and Asia. Each chapter is written as an individual essay about a given issue, and where relevant, original cases are provided to illustrate how these issues are currently managed by the global industry. This book offers a thoughtful and thorough description of the industry's current situation and integrates the latest scholarly and industry research from different disciplines in one place for convenient reference. It may be used in the following ways: To stimulate class discussions and inspire new streams of research for academics and graduate students; To introduce the industry to those interested in a career, to orient new industry hires, or to provide experienced practitioners with current research that will enhance their knowledge; To provide an understanding of the industry for those in the healthcare sector, such as physicians, pharmacists, as well as medical and pharmacy students; and To present recent and relevant research for those in government, public or private payers, and public policy environments to facilitate their decision making. This book will prove to be a useful resource and an important source of information for academics and their students, professionals, and policymakers around the world.

Portfolio, Program, and Project Management in the Pharmaceutical and Biotechnology Industries - Pete Harpum 2011-09-20

This book describes the way that pharmaceutical projects and programs are currently managed, and offers views from many highly experienced practitioners from within the industry on future

directions for drug program management. The book integrates portfolio, program, and project management processes as fundamental for effective and efficient drug product development. Contributing expert authors provide their view of how the projectization approach can be taken forward by the drug industry over the coming years.

Marketing Planning for the Pharmaceutical Industry - John Lidstone 2017-07-05

Marketing in the pharmaceutical and healthcare sector requires a particular set of skills; its intricacies mean planning is an essential prerequisite. The marketing planning system described in this book has been designed to enable marketing and product executives to produce a plan which serves as a dynamic management tool which will help them to get from where they are now to where they want to be next year and thereafter. Now in its second edition, this bestselling book has become the standard text for all product managers, marketing managers and directors working in this demanding industry. John Lidstone and Janice MacLennan have updated the book to embrace best current practice. A new orientation to external analysis and a reworking of the application of SWOT analysis, along with fresh material on sales forecasting and strategy implementation, bring the book up to date with current thinking and industry trends. Marketing Planning for the Pharmaceutical Industry is based on real life experience built up over many years. Each chapter takes the reader through the sequential stages of planning so that by the end they will be able to produce a practical plan ready for implementation. It is the only book of this type which tailors marketing to those working in the sector and as such is a unique, invaluable and indispensable resource.

Predictive Modeling of Pharmaceutical Unit Operations - Preetanshu Pandey 2016-09-26

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing,

reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

A Textbook of Pharmaceutical Industrial Management - E-Book - Biren Shah 2012-05-14

Textbook of Pharmaceutical Industrial Management Written in strict accordance with the prescribed syllabus, this book caters to the needs of B. Pharm. students of different universities in the country. The book can also be used as a supplementary text for MBA courses in Pharmaceutical Industrial Management. The book has been written in purview of modern requirement of students to keep them abreast with the latest management practices and operational patterns being followed in the pharmaceutical industry. It educates students about the latest techniques of strategic management and their application in the market, preparing them as adept professionals to play vital roles in futuristic global market. Salient Features Student-friendly narrative language Point wise presentation of key concepts Caricatures providing an aesthetic visual impact for understanding vital concepts 107 tables and 110 illustrations to aid students in learning and mastering key concepts Plenty of examples and practice tables to facilitate expertise in accountancy and preparation of financial documents like ledger preparation, balance book/accounts maintenance, etc. Points to Ponder at the end to help students quickly revise the chapter End-of-chapter questions from previous years' examinations to test knowledge and skills

Pharmaceutical Product

Development - Vandana B. Patravale 2016-05-25

Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

Six Sigma in the Pharmaceutical Industry - Brian K. Nunnally 2007-06-13

The pharmaceutical industry is under increasing pressure to do more with less. Drug discovery, development, and clinical trial costs remain high and are subject to rampant inflation. Ever greater regulatory compliance forces manufacturing costs to rise despite social demands for more affordable health care. Traditional methodologies are failing and the industry needs to find new and innovative approaches for everything it does. Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics is the first book to focus on the building blocks of understanding and reducing variation using the Six Sigma method as applied specifically to the pharmaceutical industry. It introduces the fundamentals of Six Sigma, examines control chart theory and practice, and explains the concept of variation management and reduction. Describing the approaches and techniques responsible for their own significant success, the authors provide more than just a set of tools, but the basis of a complete operating philosophy. Allowing other references to cover the

structural elements of Six Sigma, this book focuses on core concepts and their implementation to improve the existing products and processes in the pharmaceutical industry. The first half of the book uses simple models and descriptions of practical experiments to lay out a conceptual framework for understanding variation, while the second half introduces control chart theory and practice. Using case studies and statistics, the book illustrates the concepts and explains their application to actual workplace improvements. Designed primarily for the pharmaceutical industry, Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics provides the fundamentals of variation management and reduction in sufficient detail to assist in transforming established methodologies into new and efficient techniques.

The Law and Ethics of the Pharmaceutical Industry - M.N.G. Dukes 2005-11-04

As one of the most massive and successful business sectors, the pharmaceutical industry is a potent force for good in the community, yet its behaviour is frequently questioned: could it serve society at large better than it has done in the recent past? Its own internal ethics, both in business and science, may need a careful reappraisal, as may the extent to which the law - administrative, civil and criminal - succeeds in guiding (and where neccessary contraining) it. The rules of behavior that may be considered to apply to today's pharmaceutical industry have emerged over a very long period and the process goes on. Even the immensely detailed standards for quality, safety and efficacy laid down in drug law and regulation during the second half of the twentieth century have their limitations as tools for ensuring that the public interest is well served. In particular, national and regional regulatory agencies are heavily dependent on industrial data for their decision-making, their standards and competence vary, and even the existing network of agencies does not cover the entire world. What is more there are many areas of law and regulation affecting the industry, concerning for example the pricing of medicines, the conduct of clinical studies, the health protection of workers and concern for the environment. In some fields it is indeed hardly possible to maintain standards through regulation. Professor N.M. Graham Dukes, a physician and lawyer with long term experience in industrial research management,

academic study and international drug policy, provides here a powerfully documented analysis into the way this industry thinks, acts, and is viewed, and examines the current trends pointing to change. *Provides a balanced picture of the current role of the pharmaceutical industry in society *Includes indices of conventions, laws, and regulations; as well as judicial and disciplinary cases *This is the only book addressing the legal implications of big pharma activities and ethical standards