Pharma Industry

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.

Award-winning journalist and New York Times bestselling author Gerald Posner reveals the heroes and villains of the trillion-dollar-a-year pharmaceutical industry and delivers “a withering and encyclopedic indictment of a drug industry that often seems to prioritize profits over patients (The New York Times Book Review). Pharmaceutical breakthroughs such as antibiotics and vaccines rank among some of the greatest advancements in human history. Yet exorbitant prices for life-saving drugs, safety recalls affecting tens of millions of Americans, and soaring rates of addiction and overdose on prescription opioids have caused many to lose faith in drug companies. Now, Americans are demanding a national reckoning with a monolithic industry. “Gerald’s dogged reporting, sets Pharma apart from all books on this subject” (The Washington Standard) as we are introduced to brilliant scientists, incorruptible government regulators, and brave whistleblowers facing off against company executives often blinded by greed. A business that profits from treating ills can create far deadlier problems than it cures. Addictive products are part of the industry’s DNA, from the days when corner drugstores sold morphine, heroin, and cocaine, to the past two decades of dangerously overprescribed opioids. Pharma also uncovers the real story of the Sacklers, the family that became one of America’s wealthiest from the success of OxyContin, their blockbuster narcotic painkiller at the center of the opioid crisis. Relying on thousands of pages of government and corporate archives, dozens of hours of interviews with insiders, and previously classified FBI files, Posner exposes the secrets of the Sacklers’ rise to power—revelations that have long been buried under a byzantine web of interlocking companies with ever-changing names and hidden owners. The unexpected twists and turns of the Sackler family saga are told against the startling chronicle of a powerful industry that sits at the intersection of public health and profits. “Explosively, even addictively, readable” (Booklist, starred review), Pharma reveals how and why American drug companies have put earnings ahead of patients.

Bored of academia? Sick of publish-or-perish and the grant-chasing treadmill? You've probably thought about building a career in the pharmaceutical industry, only to find a confusing world of unfamiliar terminology, requirements, and job descriptions. This book explains the many complexities of the pharmaceutical industry: the processes, the expectations, the skills you need to know and the careers you can enter - all laid out in an informative and jargon-free manner. For those who have started or want to start in the pharmaceutical industry, this book is a vital resource. What does it include? - An introduction to the entire drug development and manufacturing process. We examine how a drug goes from chemical entity to a final pharmaceutical; how drug batches are made, checked, and released to the market; we look at the marketing process, pharmacovigilance, and how processes change over time. - Industry expectations. We look at the knowledge you should learn during the first few weeks and months, attributes you should be cultivating, and how to work effectively with your manager. - Industry skills you need to succeed. We cover skills such as effective communication in all its forms, how to attend and run a meeting; how to organise information, how to cope with the sudden demands on your time and how to plan and execute projects succesfully. - Starting and building your pharmaceutical career. We describe the most common entry roles taken by life scientists entering industry and how you can develop your career beyond that initial step. - Finally our terminology list helps explain the multitude of pharmaceutical terms which you will come across in your career.

The pharmaceutical industry is broken. From the American hedge fund manager who hiked the price of an AIDS pill from $17.50 to $750 overnight to the children's cancer drugs left intentionally to expire in a Spanish warehouse, the signs of this dysfunction are all around. A system that was designed to drive innovation and patient care has been relentlessly distorted to drive up profits. Medicines have become nothing more than financial assets. The focus of drug research, how drugs are priced and who has access to them is now dictated by shareholder value, not the good of the public. Drug companies fixated on ever-higher profits are being fined for bribing doctors and striking secret price-gouging deals, while patients desperate for life-saving medicines are driven to the black market in search of drugs that national health services can't afford. Sick Money argues that the way medicines are developed and paid for is no longer working. Unless we take action we risk a dramatic decline in the pace of drug development and a future in which medicines are only available to the highest bidder. In this book investigative journalist Billy Kenber offers a diagnosis of an industry in crisis and a prescription for how we can fight back.

Written firmly from the perspective of the pharmaceutical industry, Laura Brown and Tony Grundy offer a guide to the tools and techniques of project management. They cover both the technical and human aspects of project management to provide clinical research, drug development and quality assurance managers or directors with a must-have reference.

As the pharmaceutical industry invests more and more in the development of new drugs, true breakthroughs are few and far between. Into the breach comes a panoply of product-line extensions and me-too drugs aimed at grabbing market share. The industry plows its high profits back into research, but invests an equal or greater sum in flogging its products in every imaginable venue. Research studies are designed to support marketing claims. Many doctors all over the country get their first information about new drugs from a salesperson. And, increasingly, prescription drugs are pitched to consumers on TV and the internet with images of hope, terror, or chic. Evidence-based practice guidelines, which endeavor to get the right medicines to those who will benefit most, can't be heard over the din. Having created an unprecedented number of "megabrands"—blockbuster drugs with huge sales—and undergone an

extraordinary wave of consolidation, some drug companies now find themselves in a precarious position. Patents are expiring on flagship products. In order to sustain the growth Wall Street has come to expect, these companies must produce billions of dollars worth of new revenue—fast. But can Americans continue to bankroll Operation Grow Big Pharma? Must we swallow the bad with the good?

First published in 1984, this book examines corporate crime in the pharmaceutical industry. Based on extensive research, including interviews with 131 senior executives of pharmaceutical companies in the United States, the United Kingdom, Australia, Mexico and Guatemala, the book is a major study of white-collar crime. Written in the 1980s, it covers topics such as international bribery and corruption, fraud in the testing of drugs and criminal negligence in the unsafe manufacturing of drugs. The author considers the implications of his findings for a range of strategies to control corporate crime, nationally and internationally.

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.

NEW YORK TIMES BEST SELLER • A grand, devastating portrait of three generations of the Sackler family, famed for their philanthropy, whose fortune was built by Valium and whose reputation was destroyed by OxyContin. From the prize-winning and bestselling author of Say Nothing, as featured in the HBO documentary Crime of the Century. The Sackler name adorns the walls of many storied institutions—Harvard, the Metropolitan Museum of Art, Oxford, the Louvre. They are one of the richest families in the world, known for their lavish donations to the arts and the sciences. The source of the family fortune was vague, however, until it emerged that the Sacklers were responsible for making and marketing a blockbuster painkiller that was the catalyst for the opioid crisis. Empire of Pain begins with the story of three doctor brothers, Raymond, Mortimer and the incalculably energetic Arthur, who weathered the poverty of the Great Depression and appalling anti-Semitism. Working at a barbaric mental institution, Arthur saw a better way and conducted groundbreaking research into drug treatments. He also had a genius for marketing, especially for pharmaceuticals, and bought a small ad firm. Arthur devised the marketing for Valium, and built the first great Sackler fortune. He purchased a drug manufacturer, Purdue Frederick, which would be run by Raymond and Mortimer. The brothers began collecting art, and wives, and grand residences in exotic locales. Their children and grandchildren grew up in luxury. Forty years later, Raymond’s son Richard ran the family-owned Purdue. The template Arthur Sackler created to sell Valium—co-opting doctors, influencing the FDA, downplaying the drug’s addictiveness—was employed to launch a far more potent product: OxyContin. The drug went on to generate some thirty-five billion dollars in revenue, and to launch a public health crisis in which hundreds of thousands would die. This is the saga of three generations of a single family and the mark they would leave on the world, a tale that moves from the bustling streets of early twentieth-century Brooklyn to the seaside palaces of Greenwich, Connecticut, and Cap d’Antibes to the corridors of power in Washington, D.C. Empire of Pain chronicles the multiple investigations of the Sacklers and their company, and the scorched-earth legal tactics that the family has used to evade accountability. The history of the Sackler dynasty is rife with drama—baroque personal lives; bitter disputes over estates; fistfights in boardrooms; glittering art collections; Machiavellian courtroom maneuvers; and the calculated use of money to burnish reputations and crush the less powerful. Empire of Pain is a masterpiece of narrative reporting and writing, exhaustively documented and ferociously compelling. It is a portrait of the excesses of America’s second Gilded Age, a study of impunity among the super elite and a relentless investigation of the naked greed and indifference to human suffering that built one of the world’s great fortunes.

This book explores why Japan, despite being a world leader in many high technology industries such as automobiles and consumer electronics, is only a minor player in the global pharmaceutical industry. Japan provides a huge market for pharmaceuticals as the second largest consumer of prescription drugs after the United States, and is a massive importer of prescription drugs, relying on discoveries made elsewhere. This book charts the development of the industry, from the devastation resulting from the Second World War to its performance in the present day. Focusing in particular on antibiotics and anticancer drugs, the book analyses factors that have prevented Japan from leading the rapid advances in science and technology that have occurred globally over recent decades. Looking at the pharmaceutical industry, the book argues that the Japanese government’s research and development policies were not sufficiently incentivising. It also shows how the nature of capitalism in Japan - which featured close relations between government and industry as well as between and within firms - was appropriate for nurturing industrial development in the immediate post-war decades, but became much less effective in later years.

The pharmaceutical industry is one of today’s most dynamic and complex industries, involving commercialization of cutting-edge scientific research, a huge web of stakeholders (from investors to doctors), multi-stage supply chains, fierce competition in the race to market, and a challenging regulatory environment. The stakes are high, with each new product raising the prospect of spectacular success—or failure. Worldwide revenues are approaching $1 trillion; in the U.S. alone, marketing for pharmaceutical products is, itself, a multi-billion dollar industry. In this volume, the editors showcase contributions from experts around the world to capture the state of the art in research, analysis, and practice, and covering the full spectrum of topics relating to innovation and marketing, including R&D, promotion, pricing, branding, competitive strategy, and portfolio management. Chapters include such features as: · An extensive literature review, including coverage of research from fields other than marketing · an overview of how practitioners have addressed the topic · introduction of relevant analytical tools, such as statistics and ethnographic studies · suggestions for further research by scholars and students The result is a comprehensive, state-of-the-art resource that will be of interest to researchers, policymakers, and practitioners, alike.

During her two decades at The New England Journal of Medicine, Dr. Marcia Angell had a front-row seat on the appalling spectacle of the pharmaceutical industry. She watched drug companies stray from their original mission of discovering and manufacturing useful drugs and instead become vast marketing machines with unprecedented control over their own fortunes. She saw them gain nearly limitless influence over medical research, education, and how doctors do their jobs. She sympathized as the American public, particularly the elderly, struggled and increasingly failed to meet spiraling prescription drug prices. Now, in this bold, hard-hitting new book, Dr. Angell exposes the shocking truth of what the pharmaceutical industry has become–and argues for essential, long-overdue change. Currently Americans spend a staggering $200 billion each year on prescription drugs. As Dr. Angell powerfully demonstrates, claims that high drug prices are necessary to fund research and development are unfounded: The truth is that drug companies funnel the bulk of their resources into the marketing of products of dubious benefit. Meanwhile, as profits soar, the companies brazenly use their wealth and power to push their agenda through Congress, the FDA, and academic medical centers. Zeroing in on hugely successful drugs like AZT (the first drug to treat HIV/AIDS), Taxol (the best-selling cancer drug in

history), and the blockbuster allergy drug Claritin, Dr. Angell demonstrates exactly how new products are brought to market. Drug companies, she shows, routinely rely on publicly funded institutions for their basic research; they rig clinical trials to make their products look better than they are; and they use their legions of lawyers to stretch out government-granted exclusive marketing rights for years. They also flood the market with copycat drugs that cost a lot more than the drugs they mimic but are no more effective. The American pharmaceutical industry needs to be saved, mainly from itself, and Dr. Angell proposes a program of vital reforms, which includes restoring impartiality to clinical research and severing the ties between drug companies and medical education. Written with fierce passion and substantiated with in-depth research, The Truth About the Drug Companies is a searing indictment of an industry that has spun out of control.

This Case Study defines the global pharmaceutical industry and its „boundaries“, analyses the profitability/attractiveness of the global pharmaceutical industry by using M.E.Porters’ Five-Forces-Model and answers the questions what overall industry trends can be identified and how the profitability/attractiveness of the industry will change in the future. Furthermore, it explains and evaluates Pfizer’s new strategy and examines what Pfizer did in the recent years to maintain their profitability.

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.

The Future of Pharma examines the causes of the industry's potential decline and offers a convincing and rigorous analysis of the options open to it. What emerges is a landscape defined, on the one hand, by the changing marketplace of mass-market consumers, institutional healthcare systems and wealthy individuals; and on the other by the alternate sources of commercial value - innovative therapies; super-efficient processes, supply chains and operations; and closer customer relations and increasingly tailored health services.

The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, Statistics in the Pharmaceutical Industry has been the definitive guide to sorting through the challenges in the industry, and this Third Edition continues that tradition. Updated and expanded to reflect the most recent trends and developments in the field, Statistics in the Pharmaceutical Industry, Third Edition presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post-marketing studies. This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians. Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe, the increasing trend toward non-inferiority/equivalence testing, adaptive design in clinical trials, global harmonization of regulatory standards, and multiple comparison studies. The book also examines the latest considerations in anti-cancer studies. Statistics in the Pharmaceutical Industry, Third Edition demystifies the approval process by combining regulatory and industrial points of view, making it a must-read for anyone performing statistical analysis at any point in the drug approval process.

Argues that doctors are deliberately misinformed by profit-seeking pharmaceutical companies that casually withhold information about drug efficacy and side effects, explaining the process of pharmaceutical data manipulation and its global consequences. By the best-selling author of Bad Science.

By any standard, the pharmaceutical industry's history has been a successful one. In addition to its profits and shareholder dividends, it has been seen by investors as relatively low risk and, largely, counter-cyclical to stock market trends. However, that important contribution appears to be petering out, with significant global implications for employees, shareholders, governments and patients. This is not just caused by the economic crisis. Long before this, several distinct but related streams of evidence emerged that now point to the stalling of the pharmaceutical industry. The Future of Pharma examines the causes of the industry's potential decline and offers a convincing and rigorous analysis of the options open to it. What emerges is a landscape defined, on the one hand, by the changing marketplace of mass-market consumers, institutional healthcare systems and wealthy individuals; and on the other by the alternate sources of commercial value - innovative therapies; super-efficient processes, supply chains and operations; and closer customer relations and increasingly tailored health services. The challenges to the pharmaceutical industry now and in the medium and long-term are very significant. Brian Smith's highly readable research findings are a wake-up call and a first step forward for anyone concerned with the future of the industry; whether executive, customer, policymaker or investor.

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.

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.

The pharmaceutical industry needs a shot in the arm – and not a moment too soon. The executive suite is mired in a bygone era, a time when extensive, well-funded pharmaceutical R&D produced blockbuster drugs, kept everything in-house and reaped the financial rewards. But that way of working needs to change. Executives now need to know what the technologists in their companies are doing in order to survive the next decade. Written for those new to industry, as well as for experienced professionals or specialists looking to expand their knowledge, this book is a must-read for business executives and information technologists alike. Pharma’s Prescription bridges the knowledge gap between current business practices and the most valuable technologies today. This book is filled with practical, real-life examples from industry and is a straightforward guide for all pharmaceutical and information technology executives who need to improve their businesses. Focuses on practical solutions that are easily incorporated in your day-to-day work Integrates business operations and information technology Highlights the industry's top turn-around stories Discusses pharmaceutical industry trends, growth opportunities, innovation drivers, regulatory complexities, and emerging market operations

Forecasting for the Pharmaceutical Industry is a definitive guide for forecasters as well as the multitude of decision makers and executives who rely on forecasts in their decision making. In virtually every decision, a pharmaceutical executive considers some type of forecast. This process of predicting the future is crucial to many aspects of the company - from next month's production schedule, to market estimates for drugs in the next decade. The pharmaceutical forecaster needs to strike a delicate balance between over-engineering the forecast - including rafts of data and complex ’black box’ equations that few stakeholders understand and even fewer buy into - and an overly simplistic approach that relies too heavily on anecdotal information and opinion. Arthur G. Cook's highly pragmatic guide explains the basis of a successful balanced forecast for products in development as well as currently marketed products. The author explores the pharmaceutical forecasting process; the varied tools and methods for new product and in-market forecasting; how they can be used to communicate market dynamics to the various stakeholders; and the strengths and weaknesses of different forecast approaches. The text is liberally illustrated with tables, diagrams and examples. The final extended case study provides the reader with an opportunity to test out their knowledge. The second edition has been updated throughout and includes a brand new chapter focusing on specialized topics such as forecasting for orphan drugs and biosimilars.

The productivity in pharmaceutical research and development faces intense pres sure. R&D expenditures of the major US and European companies have topped US$ 33 billion in 2003 compared to around US$ 13 billion just a decade ago. At the same time, the number of new drug approvals has dropped from 53 in 1996 to only 35 in 2003. Moreover, the protraction of clinical trials has significantly reduced the effective time of patent protection. The consequences are devastating. Monopoly profits have started to decline and the average costs per new drug have reached a re cord level of close to US$ 1 billion today. As a result, any failure of a new sub stance in the R&D process can lead to considerable losses, and the risks of introduc ing a new drug to the market have grown tremendously. Particularly if a company is highly dependent on just a handful of mega-selling blockbuster drugs, the risks can be even greater. For example, Pfizer generated about 90% of its worldwide revenues in 2002 with just 8 products. Any shortfall of a promising late-stage drug candidate would have left Pfizer with a gaping hole in its product portfolio. In order to deal with these risks, many pharmaceutical companies have started to organize their R&D in partnership. In fact, more than 600 alliances in pharmaceutical R&D are signed every year.

An Industrial IoT Approach for Pharmaceutical Industry Growth, Volume Two uses an innovative approach to explore how the Internet of Things (IoT) and big data can improve approaches 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. Using clear 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 in topics presented offers multiple perspectives on how to integrate the Internet of Things into pharmaceutical manufacturing. This book represents a useful resource for researchers in pharmaceutical sciences, information and communication technologies, and those who specialize in healthcare and pharmacovigilance. Emphasizes efficiency in pharmaceutical manufacturing through an IoT/Big Data approach Explores cutting-edge technologies through sensor enabled environments in the pharmaceutical industry Discusses system levels from both a human-factors point-of-view and the perspective of networking, databases, privacy and anti-spoofing

This practical guide for advanced students and decision-makers in the pharma and biotech industry presents key success factors in R&D along with value creators in pharmaceutical innovation. A team of editors and authors with extensive experience in academia and industry and at some of the most prestigious business schools in Europe discusses in detail the innovation process in pharma as well as common and new research and innovation strategies. In doing so, they cover collaboration and partnerships, open innovation, biopharmaceuticals, translational medicine, good manufacturing practice, regulatory affairs, and portfolio management. Each chapter covers controversial aspects of recent developments in the pharmaceutical industry, with the aim of stimulating productive debates on the most effective and efficient innovation processes. A must-have for young professionals and MBA students preparing to enter R&D in pharma or biotech as well as for students on a combined BA/biomedical and natural sciences program.

In recent years, many factors have combined to change the operating environment of the international pharmaceutical industry leading to greater specialisation and sophistication. This new edition will give an update of the different opportunities in drug discovery and development and the scientific, medical or other specialist training needed to accomplish them. The scope of this edition has been broadened to encompass all major roles, including marketing and sales.

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

Modern Pharmaceutical Industry: A Primer comprehensively explains the broad range of divisions in the complex pharmaceutical industry. Experts actively involved in each component discuss their own contribution to a pharmaceutical company's work and success. Divisions include regulatory affairs, research and development, intellectual property, pricing, marketing, generics, OTC, and more. The seventeen chapters included in this resource offer a wide range of topics, from discovery and formulation to post-approval and legal. Readers will be given a detailed look at the structure of a contemporary drug company and a thorough understanding of what goes on behind the scenes. Modern Pharmaceutical Industry: A Primer is a valuable resource for all pharmacy students, new hires at pharmaceutical companies, drug company management, and academic health center libraries. No other text provides a comprehensive look at one of the most dynamic industries related to the modern healthcare system.

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.

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

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

This book is a comprehensive review of the current state of digital innovation, Internet activity and e-business in the life sciences arena and a practical guide for managers planning, developing and implementing e-strategies in the pharmaceutical industry. The authors provide numerous examples of innovative, best practice and lay the strategic foundation for using e-business across the pharmaceutical value chain from drug discovery to physician promotion to direct-to-consumer marketing.

They Do Well Who Do Good is a collection of articles written from 2000 to 2010 that document the changes in the Japan health care system and pharma industry. Changes considered impossible in the past became routine. As the decade ended, optimists and game changers leave the pessimists and status quo keepers behind. An attractive health

care system evolved to care for an aging population with chronic diseases versus a young population with acute diseases. Japan wants the best health care the world has to offer, but choices must be made because resources to pay the bill are limited. In the beginning of the decade, you could compare Japanese pharma companies to a convoy of ships. Some big, some small, some fast, some slow, but all moved together. Ten years later, the convoy analogy was no longer useful. Some went abroad, others stayed home. Some divested noncore businesses; others did not. Some merged; others choose to go alone. Some changed their business models and cultures. Other rejected change and held on to their past. They Do Well Who Do Good is an insiders perspective on what it takes to succeed in Japans pharma market.

The book studies the pharmaceutical industry of India. It is one of the most successful stories of economic expansion and improvements in public health. Indian firms have made access to quality medicines possible and affordable in many developing countries. Indian pharmaceuticals are also exported on a large scale to the United States and other highly regulated markets. A wave of mergers, acquisitions and tie-ups point to growing integration between Indian firms and global pharma multinationals.

Multivariate Analysis in the Pharmaceutical Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resources that addresses an unmet need on how pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

The Era of Artificial Intelligence, Machine Learning and Data Science in the Pharmaceutical Industry examines the drug discovery process, assessing how new technologies have improved effectiveness. Artificial intelligence and machine learning are considered the future for a wide range of disciplines and industries, including the pharmaceutical industry. In an environment where producing a single approved drug costs millions and takes many years of rigorous testing prior to its approval, reducing costs and time is of high interest. This book follows the journey that a drug company takes when producing a therapeutic, from the very beginning to ultimately benefitting a patient’s life. This comprehensive resource will be useful to those working in the pharmaceutical industry, but will also be of interest to anyone doing research in chemical biology, computational chemistry, medicinal chemistry and bioinformatics. Demonstrates how the prediction of toxic effects is performed, how to reduce costs in testing compounds, and its use in animal research Written by the industrial teams who are conducting the work, showcasing how the technology has improved and where it should be further improved Targets materials for a better understanding of techniques from different disciplines, thus creating a complete guide