Fiercepharma

Ramsis F. Ghaly MD

Biosimilars Hiten J. Gutka,Harry Yang,Shefali Kakar,2018-12-13 This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

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.

Bringing Value to Healthcare Rita E. Numerof,Michael Abrams,2016-02-01 In Bringing Value to Healthcare: Practical Steps for Getting to a Market-Based Model, Rita Numerof and Michael Abrams lay out the roadmap to a healthcare system that is accountable for delivering optimal patient outcomes at a sustainable cost. This is the handbook for payer, provider, pharmaceutical, and medical device executives seeking to preserve today's profitability while positioning their organizations for success in the very different markets of tomorrow. The book's guidance is illuminated by case studies and each chapter concludes with a self-assessment tool and key questions.

Overcharged Charles Silver,David A. Hyman,2018-07-03 Why is America's health care system so expensive? Why do hospitalized patients receive bills laden with inflated charges that com out of the blue from out-of-network providers or demands for services that weren't delivered? Why do we pay $600 for EpiPens that contain a dollar's worth of medicine? Why is more than $1 trillion - one out of every three dollars that passes through the system - lost to fraud, wasted on services that don't help patients, or otherwise misspent? Overcharged answers these questions. It shows that America's health care system, which replaces consumer choice with government control and third-party payment, is effectively designed to make health care as expensive as possible. Prices will fall, quality will improve, and medicine will become more patient-friendly only when consumers take charge and exert pressure from below. For this to happen, consumers must control the money. As Overcharged explains, when health care providers are subjected to the same competitive forces that shape other industries, they will either deliver better services more cheaply or risk being replaced by someone who will.

Innovation, Commercialization, and Start-Ups in Life Sciences James F. Jordan,2021-09-27 Innovation is a translation of a new method, idea, or product into reality and profit. It is a process of connected steps that accumulates into a brand reputation required for success. Unlike Fortune 500 companies, whose projects are self-funded, a start-up must simultaneously have a value proposition that attracts a customer (for revenue), investors (for capital), and acquirers (for a liquidity event or IPO). A high percentage of start-ups fail before attaining positive cashflow, due to a variety of reasons that are detailed in this book. Avoiding the pitfalls and wrong turns are the goals of this book. Innovation, Commercialization, and Start-Ups in Life Sciences details the methodologies necessary to create a successful life science start-up from initiation to exit. Written by an expert who has worked with more nearly 500 life science start-ups, this book discusses specific processes and investor milestones that must be navigated to align customer, funder, and acquirer needs. Successful commercialization requires attention to multiple constituents, such as investors, regulators, and customers. Investors require liquidity for their return, which is achieved through selling their stock in a public or private sale. The reader will gain an appreciation for the necessary data, partnerships, and skills needed to create a competitive and sustainable company. The author discusses such specific issues as customer problems, demonstrating sales access, and ensuring intellectual property is impervious to competitive advancement. This book is intended to be suitable for entrepreneurs, venture capitalists, and investors in both business and academic settings. These organizations have specific departments, such as R&D, operations, business development, legal, regulatory, and marketing, that would also benefit from this book. FEATURES Focuses specifically on life science start-ups Examines how to determine a company valuation and future fundable milestones Explores how to align regulatory and clinical strategies Discusses intellectual property derived from a university or individual through formation to exit. Reviews how start-ups must simultaneously meet the needs of multiple constituencies at once: investors, regulators, customers and exit candidates James F. Jordan is an author, consultant, and speaker. He is a Distinguished Service Professor of Healthcare & Biotechnology Management, a former Fortune 100 executive, and a managing director of a venture fund. Access the Support Material: https://healthcaredata.center/ Cover design by Sarah Mailhott.

Citizen Capitalism Lynn A. Stout,Sergio Alberto Gramitto,Tamara Belinfanti,2019-01-29 Corporations have a huge influence on the life of every citizen—this book offers a visionary but practical plan to give every citizen a say in how corporations are run while also gaining some supplemental income. It lays out a clear approach that uses the mechanisms of the private market to hold corporations accountable to the public. This would happen through the creation of what the authors call the Universal Fund, a kind of national, democratic, mega mutual fund. Every American over eighteen would be entitled to a share and would participate in directing its share voting choices. Corporations and wealthy individuals would donate stocks, bonds, cash, or other assets to the fund just like they do to other philanthropic ventures now. The fund would pay out dividends to its citizen-shareholders that would grow as the fund grows. The Universal Fund is undoubtedly a big idea, but it is

also eminently practical: it uses the tools of capitalism, not government, to give all citizens a direct influence on corporate actions. It would be a major institutional investor beholden not to a small elite group of stockholders pushing for short-term gain but to everyone. The fund would reward corporations that made sure their actions didn't harm people, communities, and the environment, and it would enable them to invest in innovations that would take more than a few months to pay off. Which is another reason corporations would donate to the fund—they could be freed from the constant pressure to maximize their quarterly share price and would essentially be subsidized for doing good. The authors demonstrate that our current economic rules force corporations to be shortsighted and even destructive because for most large investors, nothing matters but share price. The Universal Fund is designed to be a powerful positive balancing force, making the world a better place and the United States a better nation.

Vaccine Danger Quackery and Sin Edward Hendrie,2023-03-07 This book reveals the most significant medical fraud in history. The theory that you can prevent illness by injecting poisons into the bodies of healthy people is dangerous quackery and sin. All true science has proven the practice of vaccination to be ineffective and unsafe. But the medical establishment has been lured into the superstitious practice, hook, line, and sinker. It is not merely a matter of ignorance that the debilitating practice flourishes. It is, at its core, being promoted by those who know it is unsafe and ineffective. There is a malevolent spirit behind the practice. It is part of a conspiracy against God and man. While most doctors are unwitting, some are willing minions of that old serpent, called the Devil, and Satan, who are quite happy to kill people for profit. Jesus describes such men: Ye are of your father the devil, and the lusts of your father ye will do. He was a murderer from the beginning, and abode not in the truth, because there is no truth in him. When he speaketh a lie, he speaketh of his own: for he is a liar, and the father of it. John 8:44.

Flow Chemistry Santiago V Luis,Eduardo Garcia-Verdugo,2019-09-18 Historically pharmaceutical and fine chemical products have been synthesised using batch methods, but increasingly chemists are looking towards flow chemistry as a greener and more efficient alternative. In flow chemistry reactions are performed in a reactor with the reactants pumped through it. It has the benefit of being easily scaled up and it is straightforward to integrate synthesis, workup and analysis into one system. Flow chemistry is considered a greener alternative to batch chemistry because it is easier to control and minimise hazardous intermediates and by-products. There is significant interest in the use of flow chemistry both in the lab and on an industrial scale. Flow Chemistry provides an update on recent advances that have been made in the field. Particular emphasis is given to the new integrated approaches that bring together several elements to implement flow processes as a regular green chemistry tool for the chemical industries. With chapter contributions from several well-known experts in the field, this book is a valuable resource for researchers working in green chemistry and synthesis, chemical engineers and industrial chemists working in the pharmaceutical and fine chemicals industries.

Biopharma in China Sven Agten,

Off-label Prescribing David Cavalla,2015-03-16 Today’s medicines are regulated for their efficacy and safety and, once approved, they can be marketed for certain uses as justified by the data. Regulatory bodies in developed countries are constituted by legal statute and operate as parts of government, ostensibly in the interests of the people as patients. But once approved, medicines can be used for any purpose the prescriber thinks fit and appropriate for the patient. One in five prescriptions is therefore written outside regulatory purview. Off-label Prescribing looks into the corners of our medicated lives, where drug regulation runs up against medical practice, and concerns the use of a drug that has been approved for one use (in medical parlance, ‘indication’) being used for a different indication; alternatively, being used on a different set of patients from the ones it is approved for, or at a different dose. Usually the patient is unaware of what is going on, having not been informed by their doctor of this aspect of his or her prescribing choice. The book examines how and why this occurs, what the various medical professions have to say about it, and how pharmaceutical companies benefit by moving into this poorly regulated area. Off-label Prescribing pulls these complex issues together in one volume, to highlight current practice, its advantages and weaknesses and how the author suggests practice should evolve in the future. It will therefore be of interest to all those who prescribe (and receive) medicines, combined with a greater objective to provide more transparency and discussion for professionals.

Mind Thief Han Yu,2021-03-02 Alzheimer’s disease, a haunting and harrowing ailment, is one of the world’s most common causes of death. Alzheimer’s lingers for years, with patients’ outward appearance unaffected while their cognitive functions fade away. Patients lose the ability to work and live independently, to remember and recognize. There is still no proven way to treat Alzheimer’s because its causes remain unknown. Mind Thief is a comprehensive and engaging history of Alzheimer’s that demystifies efforts to understand the disease. Beginning with the discovery of “presenile dementia” in the early twentieth century, Han Yu examines over a century of research and controversy. She presents the leading hypotheses for what causes Alzheimer’s; discusses each hypothesis’s tangled origins, merits, and gaps; and details their successes and failures. Yu synthesizes a vast amount of medical literature, historical studies, and media interviews, telling the gripping stories of researchers’ struggles while situating science in its historical, social, and cultural contexts. Her chronicling of the trajectory of Alzheimer’s research deftly balances rich scientific detail with attention to the wider implications. In narrating the attempts to find a treatment, Yu also offers a critical account of research and drug development and a consideration of the philosophy of aging. Wide-ranging and accessible, Mind Thief is an important book for all readers interested in the challenge of Alzheimer’s.

MoneyBall Medicine Harry Glorikian,Malorye Allison Branca,2017-11-20 How can a smartwatch help patients with diabetes manage their disease? Why can’t patients find out prices for surgeries and other procedures before they happen? How can researchers speed up the decade-long process of drug development? How will Precision Medicine impact patient care outside of cancer? What can doctors, hospitals, and health systems do to ensure they are maximizing high-value care? How can healthcare entrepreneurs find success in this data-driven market? A revolution is transforming the $10 trillion healthcare landscape, promising greater transparency, improved efficiency, and new ways of delivering care. This new landscape presents tremendous opportunity for those who are ready to embrace the data-driven reality. Having the right data and knowing how to use it will be the key to success in the healthcare market in the future. We are already starting to see the impacts in drug development, precision medicine, and how patients with rare diseases are diagnosed and treated. Startups are launched every week to fill an unmet need and address the current problems in the healthcare system. Digital devices and artificial intelligence are helping doctors do their jobs faster and with more accuracy. MoneyBall Medicine: Thriving in the New Data-Driven Healthcare Market, which includes interviews with dozens of healthcare leaders, describes the business challenges and opportunities arising for those working in one of the most vibrant sectors of the world’s economy. Doctors, hospital administrators, health information technology directors, and entrepreneurs need to adapt to the changes effecting healthcare today in order to succeed in the new, cost-conscious and value-based environment of the future. The authors map out many of the changes taking place, describe how they are impacting everyone from patients to researchers to insurers, and outline some predictions for the healthcare industry in the years to come.

Jabbed Brett Wilcox,2018-09-11 Jabbed demonstrates that the medical procedure hailed as the greatest medical advancement in history—vaccines—is a racket run by

criminals and gullible believers who have replaced vaccine science with the religion of vaccinology. Vaccine marketers teach believers to fear, shame, and scapegoat anyone foolish enough to question the sanctity of vaccines. Such an environment is not the domain of science; rather it's the breeding ground of tyranny. Jabbed exposes this tyranny. From polio and smallpox to medical journals, medical curricula, congressional hearings, regulatory policies, White House statements, and executive orders, Jabbed shines light on the dark underbelly of Big Pharma, Big Medicine, and Big Government. A vaccine informed public is the only thing that will have the power to stop vaccine industry sociopaths and to hold them accountable for their crimes. Jabbed informs and immunizes against three of the most dangerous epidemics in history: tyranny, greed, and corruption. Once immunized, the growing vaccine-informed community will have the power to stand up and dismantle the vaccine paradigm and program and to punish the perpetrators of what may well be the greatest medical fraud ever perpetrated on the human race: vaccines.

Problem-Free Diabetes Frank Suarez,2016-09-14 Practical recommendations for improving diabetes and its related conditions. Includes information on how candida albicans, a yeast, can affect diabetics, the 3x1 Diet® for diabetics, how to find aggressor foods that can spike up blood glucose levels, how to read tricky labels, the truth about cholesterol, what to do when blood glucose levels are resistive and won't go down, natural supplements that can help a diabetic, the sleep patterns that affect diabetes, foods that benefit a diabetic condition and more. This book has hundreds of pages on the subject of diabetes and what practical recommendations you can start applying immediately to improve your condition and get it under control. The intent of the book is to explain in simple terms what most medical or technical books detail in a confusing or incomprehensible way. It emphasizes the metabolism as the principle factor to address and improve in order to improve diabetes. The premise of the book is PRACTICALITY, things to DO and IMPLEMENT immediately to start seeing results and measuring more desirable glucose levels immediately.

The Little Wasn't the Least After All! Ramsis F. Ghaly MD,2022-03-31 In the final days of Christmas 2019 I had an epiphany. I will never forget that night when I cried out as I saw a vision of that little! Since then, I have felt so dismal and would rather bury my head in the sand! No matter where I go and how fast I run, I can't forget that dream or catch that invisible little anymore! I found myself running away and I couldn't help it! I would ask myself, To whom should I report to?, What is the remedy other than running away? These questions have brought me to author the fourth book on COVID-19. This series has covered the world's journey, experiences, and views since it all began. It was just a little and wasn't much. Before I knew it, it had infected the world entirely. It was supposed to pass by swiftly with little to be done. Then it proceeded to be remedied by a face mask for two weeks, followed by just one dose of a vaccine. All the while, the nightmare never ended. The little invader of human cells creeped in unnoticed; in the darkness, and left imprinted memories for generations to come. It has changed our day to day lives for more than two years, shaped our daily living, and will affect our future for decades to come. The little wasn't the least as the world thought, and was indeed ignored, as many downplayed its sharp spikes until it killed millions and infected hundreds of millions. The world is living in tears and terrors, broken hearted, and in fear. What is next?'', I would ask myself, as it appears it is only getting worse as the news of wars and economic collapse are already at our door. To make things grave, many forever lost! But now, lessons must be learned and the wisdom of the past shall carry the world to the future. Over 16 sections and 188 chapters, the book represents the last of the author's series of COVID-19 as it covers the last year of the pandemic and the most recent events. It represents the author's views and highlights a wide variety of topics ranging from living stories, medical and political to philosophical views and experiences. The book reflects the author's Christian and medical devotions as it covers many true patients stories, patients' testimonials, medical events, and resident education.

Mega Mergers and Acquisitions B. Kumar,2012-11-14 A casebook that discusses all the mega mergers and acquisitions in terms of value, that have happened in different industry sectors such as pharmacy, technology, telecommunications, media and entertainment, electrical and electronics, energy, finance, consumer goods, metals, and automobile and airlines.

An American Sickness Elisabeth Rosenthal,2018-03-13 A New York Times bestseller/Washington Post Notable Book of 2017/NPR Best Books of 2017/Wall Street Journal Best Books of 2017 This book will serve as the definitive guide to the past and future of health care in America."—Siddhartha Mukherjee, Pulitzer Prize-winning author of The Emperor of All Maladies and The Gene At a moment of drastic political upheaval, An American Sickness is a shocking investigation into our dysfunctional healthcare system – and offers practical solutions to its myriad problems. In these troubled times, perhaps no institution has unraveled more quickly and more completely than American medicine. In only a few decades, the medical system has been overrun by organizations seeking to exploit for profit the trust that vulnerable and sick Americans place in their healthcare. Our politicians have proven themselves either unwilling or incapable of reining in the increasingly outrageous costs faced by patients, and market-based solutions only seem to funnel larger and larger sums of our money into the hands of corporations. Impossibly high insurance premiums and inexplicably large bills have become facts of life; fatalism has set in. Very quickly Americans have been made to accept paying more for less. How did things get so bad so fast? Breaking down this monolithic business into the individual industries—the hospitals, doctors, insurance companies, and drug manufacturers—that together constitute our healthcare system, Rosenthal exposes the recent evolution of American medicine as never before. How did healthcare, the caring endeavor, become healthcare, the highly profitable industry? Hospital systems, which are managed by business executives, behave like predatory lenders, hounding patients and seizing their homes. Research charities are in bed with big pharmaceutical companies, which surreptitiously profit from the donations made by working people. Patients receive bills in code, from entrepreneurial doctors they never even saw. The system is in tatters, but we can fight back. Dr. Elisabeth Rosenthal doesn't just explain the symptoms, she diagnoses and treats the disease itself. In clear and practical terms, she spells out exactly how to decode medical doublespeak, avoid the pitfalls of the pharmaceuticals racket, and get the care you and your family deserve. She takes you inside the doctor-patient relationship and to hospital C-suites, explaining step-by-step the workings of a system badly lacking transparency. This is about what we can do, as individual patients, both to navigate the maze that is American healthcare and also to demand far-reaching reform. An American Sickness is the frontline defense against a healthcare system that no longer has our well-being at heart.

Laboratory Control System Operations in a GMP Environment David M. Bliesner,2020-06-03 Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System (LCS) operations In Laboratory Control System Operations in a GMP Environment, readers are given the guidance they need to implement a CGMP compliant Laboratory Control System (LCS) that fits within Global Regulatory guidelines. Using the Quality Systems Approach, regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS. In this guide, readers learn the fundamental rules for operating a CGMP compliant Laboratory Control System. Designed to help leaders meet regulatory standards and operate more efficiently, the text includes chapters that cover Laboratory Equipment Qualification and Calibration, Laboratory Facilities, Method Validation and Method Transfer, Laboratory Computer Systems, Laboratory Investigations as well as Data Governance and Data Integrity. The text also includes chapters related to Laboratory Managerial and Administrative Systems, Laboratory Documentation Practices and Standard Operating Procedures and General Laboratory Compliance Practices. Additionally, a chapter outlining Stability Program operations is included in the text. In addition to these topics, it includes LCS information and tools such as: ● End of chapter templates,

checklists, and LCS guidance to help you follow the required standards ● Electronic versions of each tool so users can use them outside of the text ● An In-depth understanding of what is required by the FDA and other globally significant regulatory authorities for GMP compliant systems For quality assurance professionals working within the pharmaceutical or biopharma industries, this text provides the insight and tools necessary to implement government-defined regulations.

The Future of Drug Discovery Tamas Bartfai,Graham V. Lees,2013-05-18 The Future of Drug Discovery: Who decides which diseases to treat? provides a timely and detailed look at the efforts of the pharmaceutical industry and how they relate, or should relate, to societal needs. The authors posit that as a result of increasing risk aversion and accelerated savings in research and development, the industry is not developing drugs for increasingly prevalent diseases, such as Alzheimer's disease, untreatable pain, antibiotics and more. This book carefully exposes the gap between the medicines and therapies we need and the current business path. By analyzing the situation and discussing prospects for the next decade, the The Future of Drug Discovery is a timely book for all those who care about the development needs for drugs for disease. Provides an in-depth, broad perspective on the crisis in drug industry Exposes the disconnect between what society needs and what the drug companies are working on Analyses and projects over 10 years into the future Explains what it means for scientists and society Determines what is needed to be done to make sure that the industry responds to society's needs, remains commercially attractive and answers the question as to who decides which diseases to treat

The Price of Global Health Ed Schoonveld,2016-02-24 Public debate on the rising cost of new biotechnology drug treatments has intensified over the last few years as healthcare budget pressures have mounted under a strained economy. Meanwhile, the demand for new, effective medical and drug treatments continues to rise as unhealthy lifestyles cause further increases in diabetes and cardiovascular disease. Global drug pricing is one of the most hotly debated yet least understood aspects of the pharmaceutical industry. How should drug prices be set and what does it mean for patients? Why do governments increasingly get involved, and what is its impact on the global competitive environment? How can a life-saving industry have a poorer image than gun and tobacco industries, whose products are associated with death? Ed Schoonveld explains how pharmaceutical prices are determined in a complex global payer environment and what factors influence the process. His insights will help a wide range of audiences, from healthcare industry professionals to policy makers and the broader public, to gain a better understanding of this highly complex and emotionally charged field. The Price of Global Health is recognized as a valued and unique reference book that covers a complete array of topics related to global pharmaceutical pricing. It contains an in-depth but straightforward exploration of the pharmaceutical pricing strategy process, its underlying market access, general business and ethical considerations, and its implications for payers, physicians and patients. It is a much-needed and invaluable resource for anybody interested or involved in, or affected by, the development, funding and use of prescription drugs. In particular, it is of critical importance to pharmaceutical company executives and other leaders and professionals in commercialization and drug development, including marketing, business development, market access and pricing, clinical development, drug discovery, regulatory affairs, health outcomes, market research and public affairs. The second edition includes new chapters on payer value story development, oncology, orphan drugs and payer negotiations. Furthermore, many country chapters have been substantially updated to reflect changes in the healthcare systems, including the Affordable Care Act in the US, AMNOG in Germany, medico-economic requirements in France and many other country-specific changes. Lastly, almost every chapter has been updated with new examples and illustrations.

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