The Pharmagellan Guide To Biotech Forecasting And Valuation

Optimization of Pharmaceutical R&D Programs and PortfoliosDrugsPharmaceutical Market Access in Developed MarketsScientific Due DiligenceInnovation, Commercialization, and Start-Ups in Life SciencesNew DrugsZero to FiveBiotechnology Valuation & InvestingThe Biotech Investor's BibleThe Strategic Pricing of PharmaceuticalsBiotech InvestingUnderstanding PharmaHealthcare Investing: Profiting from the New World of Pharma, Biotech, and Health Care ServicesThe Pharmagellan Guide to Biotech Forecasting and ValuationArtificial Intelligence for HRThe Biotech PrimerManaging BiotechnologyA Biotech Manager's HandbookBusiness Development for the Biotechnology and Pharmaceutical IndustryRESULTSThe Life Science Executive's Fundraising ManifestoInvesting in BiotechThe Great American Drug DealWhat Would You Wish For?Forecasting for the Pharmaceutical IndustryValuation in Life SciencesShort SellingPharmaceutical Lifecycle ManagementThe AntidoteValuation in Life SciencesBiotechnology ValuationThe FirmBiotechnology EntrepreneurshipThe Generic ChallengeThe Truth in Small DosesLicensing, Selling and Finance in the Pharmaceutical and Healthcare Industries1001 Questions to Ask Before You Get MarriedFrom Science to StartupBiotechnology DemystifiedBioanalytical Chemistry

Optimization of Pharmaceutical R&D Programs and Portfolios

This self-teaching guide explains the basic concepts and fundamentals in all the major subtopics of biotechnology. The content advances logically from the basics of molecular and cellular biology to more complex topics such as DNA, reproductive cloning, experimental procedures, infectious diseases, immunology, the Human Genome Project, new drug discoveries, and genetic disorders.

Drugs

Innovation is the translation of a new method, idea, or product into reality and profit. It is a process of connected steps that accumulates into your brand or reputation. However, there can be many pitfalls and wrong turns on the road to realizing this goal. Innovation, Commercialization, and Start-Ups in Life Sciences details the methodologies necessary to create a successful life sciences start-up from initiation to exit. You will gain an appreciation for the necessary data, partnership, and skills to be acquired and the constituencies that must be satisfied along the way. The book examines how life sciences start-ups can create an exit for their investors by recognizing that a liquidity event is not consummated without due diligence. Due diligence is bigger than validating accounting transactions. It ensures the company is solving an important customer problem, demonstrating sales access, and making sure that intellectual property is impervious to competitive advancement. The due diligence process supports the telling of a compelling story to customers, investors, regulators, and acquirers. Written by an expert who has worked with more than 200 life sciences start-ups during the past decade, the book discusses specific processes and investor milestones that must be navigated to align customer, funder, and acquirer needs. It examines these processes from the perspective of marketing value through a focus on the needs of individual constituents—investors, regulators, customers, and exit candidates. The book presents data and analytical processes articulating the fundable milestones for angel and venture capital. It gives you the tools needed to create branding for public investors and more.

Pharmaceutical Market Access in Developed Markets

A comprehensive overview of the new business context for biopharma companies, featuring numerous case studies and state-of-the-art marketing models Biotechnology has developed into a key innovation driver especially in the field of human healthcare. But as the biopharma industry continues to grow and expand its reach, development costs are colliding with aging demographics and cost-containment policies of private and public payers. Concurrently, the development and increased affordability of sophisticated digital technologies has fundamentally altered many industries including healthcare. The arrival of new information technology (infotech) companies on the healthcare scene presents both opportunities and challenges for the biopharma business model. To capitalize on new digital technologies from R&D through commercialization requires industry leaders to adopt new business models, develop new digital and data capabilities, and partner with innovators and payers worldwide. Written by two experts, both of whom have had decades of experience in the field, this book provides a comprehensive overview of the new business context and marketing models for biotech companies. Informed by extensive input by senior biotech executives and leading consultancies serving the industry, it analyzes the strategies and key success factors for the financing, development, and commercialization of novel therapeutic products, including strategies for engagement with patients, physicians and healthcare payers. Throughout case studies provide researchers, corporate marketers, senior managers, consultants, financial analysts, and other professionals involved in the biotech sector with insights, ideas, and models. JACQUALYN FOUSE, PhD, RETIRED PRESIDENT AND CHIEF OPERATING OFFICER, CELGENE "Biotech companies have long been innovators, using the latest technologies to enable cutting edge science to help patients with serious diseases. This book is essential to help biotech firms understand how they can—and must—apply the newest technologies including disruptive ones, alongside science, to innovate and bring new value to the healthcare system." BRUCE DARROW, MD, PhD, CHIEF MEDICAL INFORMATION OFFICER, MOUNT SINAI HEALTH SYSTEM "Simon and Giovannetti have written an essential user's manual explaining the complicated interplay of the patients who deserve cutting-edge medical care, the biotechnology companies (big and small) creating the breakthroughs, and the healthcare organizations and clinicians who bridge those worlds." EMMANUEL BLIN, FORMER CHIEF STRATEGY OFFICER AND SENIOR VICE PRESIDENT, BRISTOL-MYERS SQUIBB "If you want to know where biopharma is going, read this book! Our industry is facing unprecedented opportunities driven by major scientific breakthroughs, while transforming itself to address accelerated landscape changes driven by digital revolutions and the emergence of value-based healthcare worldwide. In this ever-changing context, we all need to focus everything we do on the patients. They are why we exist as an industry, and this is ultimately what this insightful essay is really about." JOHN MARAGANORE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALNYLAM PHARMACEUTICALS "Since the mapping of the human genome was completed nearly 15 years ago, the biotechnology industry has led the rapid translation of raw science to today's innovative medicines. However, the work does not stop in the lab. Delivering these novel medicines to patients is a complex and multifaceted process, which is elegantly described in this new book."

Scientific Due Diligence

As an authoritative guide to biotechnology enterprise and entrepreneurship, Biotechnology Entrepreneurship and Management supports the international community in training the biotechnology leaders of tomorrow. Outlining fundamental concepts vital to graduate students

and practitioners entering the biotech industry in management or in any entrepreneurial capacity, Biotechnology Entrepreneurship and Management provides tested strategies and hard-won lessons from a leading board of educators and practitioners. It provides a "how-to" for individuals training at any level for the biotech industry, from macro to micro. Coverage ranges from the initial challenge of translating a technology idea into a working business case, through securing angel investment, and in managing all aspects of the result: business valuation, business development, partnering, biological manufacturing, FDA approvals and regulatory requirements. An engaging and user-friendly style is complemented by diverse diagrams, graphics and business flow charts with decision trees to support effective management and decision making. Provides tested strategies and lessons in an engaging and user-friendly style supplemented by tailored pedagogy, training tips and overview sidebars Case studies are interspersed throughout each chapter to support key concepts and best practices. Enhanced by use of numerous detailed graphics, tables and flow charts

Innovation, Commercialization, and Start-Ups in Life Sciences

This book charts the experiences, pitfalls and knowledge behind leading scientific ideas to successful startups. Written by one of Switzerland's top serial entrepreneurs, this book is a must-read for scientists and academicians who want to see their idea turn into a product and change the market. It is also pertinent for finance and business professionals who aspire to become technology entrepreneurs. Starting with personal qualities of an entrepreneur, Anil Sethi discusses successful ideas, technology evaluation, team formation, patents and investor expectations. To guide the entrepreneur, this book also analyzes deal closing, equity conversion and ideal exit strategies to follow. Ultimately Anil Sethi reveals the 'inside track' which helps understand what drives entrepreneurs and what they wouldn't admit.

New Drugs

Investigates the lack of progress in the fight against cancer, citing misspent billions, non-collaboration among researchers, expensive drugs, and brain-drain.

Zero to Five

If you're a biotech executive, investor, deal maker, entrepreneur, or adviser-or aspire to be one-then you need to know how to build and analyze forecasts and valuation models of R&D-stage drugs. The Pharmagellan Guide is a comprehensive, thoroughly referenced handbook for early-stage biopharma assets and companies.

Biotechnology Valuation & Investing

Valuation is a hot topic among life sciences professionals. There is no clear understanding on how to use the different valuation approaches and how to determine input parameters. Some do not value at all, arguing that it is not possible to get realistic and objective numbers out of it. Some claim it to be an art. In the following chapters we will provide the user with a concise val- tion manual, providing transparency and practical insight for all dealing with valuation in life sciences: project and portfolio managers, licensing executives, business developers, technology transfer managers, entrep- neurs, investors, and analysts. The purpose of the book is to explain how to apply discounted cash flow and real options valuation to life sciences p- jects, i.e. to license contracts, patents, and firms. We explain the fun- mentals and the pitfalls

with case studies so that the reader is capable of performing the valuations on his own and repeat the theory in the exercises and case studies. The book is structured in five parts: In the first part, the introduction, we discuss the role of the players in the life sciences industry and their p- ticular interests. We describe why valuation is important to them, where they need it, and the current problems to it. The second part deals with the input parameters required for valuation in life sciences, i.e. success rates, costs, peak sales, and timelines.

The Biotech Investor's Bible

What Would You Wish For? guides readers young and old through an imaginative, inspirational journey to think about how they can change the world for good. Heartfelt and thought-provoking text encourages children to be kind. Rich, whimsical illustrations help girls and boys realize the potential each person has to make the world a more hopeful and more peaceful place. 100% of the author□s royalties are being donated to UNICEF USA. What Would You Wish For? features: An inspiring story that will encourage children of all ages, but particularly children ages 4□8, to make the world a more hopeful and peaceful place Whimsical, thought-provoking text by David Sable, Senior Advisor at WPP, the world□s largest company dedicated to Creative Transformation and formerly Global CEO of Y&R Beautiful illustrations by Emma Yarlett, (whose work has been selected by Amazon.com and Huffington Post as one of the best picture books of 2015, winner of the Sheffield Bok Award 2017, Oxfordshire Book Award 2017, Stockport Picture Book Award 2017, and nominated for the Kate Greenaway Medal 2017)

The Strategic Pricing of Pharmaceuticals

The relationship expert from the Ladies' Home Journal, the Wall Street Journal, and Lifetime Television shows how to prevent marriage problems before they start There's nothing wrong with starter jobs and starter homes, but starter marriages? Relationship expert Monica Mendez Leahy is on a mission to help readers make their marriage last. Her 1,001 Questions to Ask Before You Get Married offers a reality check for couples on the marriage path, helping them realize how much they have yet to discover about their partner's nature, thought processes, lifestyle, and marital expectations. Engaged couples learn to discuss issues deeper than "chicken or fish" and to broach subjects that are often ignored before the nuptials yet essential for the foundation of an intimate, long-lasting relationship. Posed in a variety of fun formats, including multiple choice, fill-in-the-blank, and hypotheticals, these questions include topics such as: "Does your partner feel that you're too attached to your parents?" "Is there such a thing as innocent flirting?" "Is it OK to cheat on your taxes?" And more

Biotech Investing

This book is the first complete guide to valuation in life sciences for industry professionals, investors, and academics. It introduces the characteristics of drug and medical device development, explains how to translate these into the valuation, and provides valuable industry data. Special emphasis is put on the practicability of the proposed methods by including many hands-on examples, without compromising on realistic results.

Understanding Pharma

The latest theoretical and empirical evidence on short selling inthe United States and

throughout the world To get the most success out of what the finance community regardsas a risky business, short sellers need high-level information. TheTheory and Practice of Short Selling offers managers and investorsthe information they need to maximize and enhance their shortselling capabilities for bigger profits. Frank Fabozzi collects agroup of market experts who share their knowledge on everythingfrom the basics to the complex in the world of short sales,including mechanics of short selling, the empirical evidence onshort-selling, the implications or restrictions on short sellingfor investment strategies, short-selling strategies pursued byinstitutional investors, and identifying short-sellingcandidates. Frank J. Fabozzi, PhD, CFA (New Hope, PA), is the Frederick FrankAdjunct Professor of Finance at Yale University's School ofManagement and Editor of the Journal of Portfolio Management. He isthe author or editor of over 100 books on finance and investing.

Healthcare Investing: Profiting from the New World of Pharma, Biotech, and Health Care Services

A timely, accessible survey of the multidisciplinary field of bioanalytical chemistry Provides an all in one approach for both beginners and experts, from a broad range of backgrounds, covering introductions, theory, advanced concepts and diverse applications for each method Each chapter progresses from basic concepts to applications involving real samples Includes three new chapters on Biomimetic Materials, Lab-on-Chip, and Analytical Methods Contains end-of-chapter problems and an appendix with selected answers

The Pharmagellan Guide to Biotech Forecasting and Valuation

Is your portfolio in peak health? Ranking among the world's largest markets, the $2.5 trillion health care industry is growing at an unprecedented rate. According to Miller Tabak + Co.'s health care strategist Les Funtleyder, major structural renovations to the system are imminent. "Health care is entering an era of reform," Funtleyder writes, "and with reform comes change and the opportunity for investment gain." Health-Care Investing provides a thorough explanation of how the industry's mammoth size and complexity can be worked to your advantage and why health care is more resistant to changes in economic cycles than other markets. Funtleyder gives you a comprehensive overview of the industry, from both macro and micro points of view, so you can make informed decisions regarding your investments. You'll find critical information concerning The natural inelasticity of health care and how to profit from it How to take advantage of the market's complexities and inefficiencies Issues and policy changes you need to know The social responsibility aspect of investing in health care Why this market is essential for diversified portfolios In Health-Care Investing, Funtleyder provides the tools you need to dig up the richest opportunities possible and build them into your investment strategy. You'll get a detailed look at traditional market patterns and the events that have shaped--and will continue to shape--the industry. Then you'll find specific strategies you can use to maximize your profits, whether you invest in pharma, biotech, managed services, or a combination of them. This informative and practical guide also includes a list of questions you can use as an investment "template," which will help guide your decision-making process. With Health Care Investing, you'll be armed with the know-how to make the right decisions today in order to fully capitalize on events of the future.

Artificial Intelligence for HR

It barely existed until the 1990s, but [medical] biotechnology is now a multi-billion dollar

industry producing windfall profits. Everyone is talking about human genomes and a cure for cancer or AIDS, but who can you to believe? Investing in Biotech is for anyone interested in profiting from this new, knowledge-based economy.Whether you're an individual with a $1,000 to invest or a wealthy manager responsible for million-dollar accounts, Investing in Biotech helps you understand one of the most discussed but least understood sectors of the new economy. Get beyond the genetics jargon and learn how to rate a company's chances of developing new medications or treatments.If there's truth in the old adage "Invest in what you know," then Investing in Biotech gives you the knowledge you need to make a profit in the new economy's healthiest sector.

The Biotech Primer

HR professionals need to get to grips with artificial intelligence and the way it's changing the world of work. From using natural language processing to ensure job adverts are free from bias and gendered language to implementing chatbots to enhance the employee experience, AI has created a variety of opportunities for the HR function. Artificial Intelligence for HR empowers HR professionals to leverage this potential and use AI to improve efficiency and develop a talented and productive workforce. Outlining the current technology landscape as well as the latest AI developments, this book ensures that HR professionals fully understand what AI is and what it means for HR in practice. Covering everything from recruitment and retention to employee engagement and learning and development, Artificial Intelligence for HR outlines the value AI can add to HR. It also features discussions on the challenges that can arise from AI and how to deal with them, including data privacy, algorithmic bias and how to develop the skills of a workforce with the rise of automation, robotics and machine learning in order to make it more human, not less. Packed with practical advice, research and case studies from global organizations including Uber, IBM and Unilever, this book will equip HR professionals with the knowledge they need to leverage AI to recruit and develop a successful workforce and help their businesses thrive in the future.

Managing Biotechnology

This Sixth Edition of The Generic Challenge provides important new updates on current regulatory, legal and commercial issues affecting brand and generic pharmaceutical products, including new laws establishing generics for biologics, and changes brought about by the recently enacted America Invents Act. It explains clearly and understandably the roles of patents, FDA regulation of drugs and the Hatch Waxman Act in commercial drug development in light of generic challenges and how improvements in innovative drug products provide benefits to patients while extending the commercial lives of the drugs. There is simply no other book of its kind on this important subject.

A Biotech Manager's Handbook

Business Development for the Biotechnology and Pharmaceutical Industry

RESULTS

Licensing, Selling and Finance in the Pharmaceutical and Healthcare Industries is an

assessment of the turbulent state of pharmaceutical and biotechnology markets as we enter the second decade of the 21st Century. At the same time, the book offers a cautionary evaluation of the future financing of innovation in terms of what's gone wrong and how to succeed in the future. Martin Austin explores the challenge that the pharmaceutical (and related) industries face in terms of balancing short term, cost containment and expenditure control in areas such as internal research and development; whilst embracing in-licensing and the acquisition of innovative therapies to counteract their impending portfolio weaknesses in the mid to longer term. The first part of the book provides an engaging and convincing perspective on the context in which the industry currently finds itself; the second part is a pragmatic guide to commercialising your intellectual property; including how to recognise and value what you have as well as the new ways of working that you will need to adopt when negotiating, collaborating and contracting in partnership and alliance with others. Commentators have described in great detail the cocktail of commercial, clinical and social issues that threaten to overwhelm the pharmaceutical industry; Martin Austin's book offers a very distinctive perspective on these issues and their solution.

The Life Science Executive's Fundraising Manifesto

The first book to provide a simple and practical means of valuing biotech companies The book begins with a short history of the biotechnology industry; this is important as although it is about 30 years old, the first company went public only in 1996, so it is possible to plot the course of investment waves and dips It examines the European industry and its evolvement, and draws parallels between the similarities and differences between that and the US Looks at the various companies which make up the biotech industry (therapeutic; life sciences; and the medical technology company) and gives tools for the investor to properly evaluate them Praise for Biotechnology Valuation "Keegan states that the valuation of Biotech companies is as much an art as a science. This brief but comprehensive review of the skills and knowledge required, not of just the financial market and sentiment, but also of the technical attributes of a company and the drug development and regulatory hurdles that must be overcome, highlights the importance of the breadth of understanding required. Biotech investing is not for the timid, but it can bring substantial returns. Keegan's book, punctuated with his personal experience and opinions, is a good place to start." —Chris Blackwell, Chief Executive, Vectura Group plc "A user-friendly, yet thorough discussion of a notoriously difficult topic. Dr Keegan's book is a fine resource for both business types and academicians." —Steve Winokur, Managing Director, CanaccordAdams "A highly readable and comprehensive explanation of the technical and commercial parameters that influence biotechnology companies at all stages of development, providing clear context for selection from the toolkit of valuation methodologies the author recommends to assess company and product performance, or ascribe value." —Dr L.M. Allan, Director, Bioscience Enterprise Programme, University of Cambridge "A fabulous approach to a difficult topic." —Deirdre Y. Gillespie, MD, President & CEO, La Jolla Pharmaceutical Company

Investing in Biotech

When you're a new parent, the miracle of life might not always feel so miraculous. Maybe your latest 2:00 a.m., 2:45 a.m., and 3:30 a.m. wake-up calls have left you wondering how "sleep like a baby" ever became a figure of speech—and what the options are for restoring your sanity. Or your child just left bite marks on someone, and you're wondering how to handle it. First-time mom Tracy Cutchlow knows what you're going through. In Zero to Five: 70 Essential Parenting Tips Based on Science (and What I've Learned So Far), she takes dozens of parenting tips

based on scientific research and distills them into something you can easily digest during one of your two-minute-long breaks in the day. The pages are beautifully illustrated by award-winning photojournalist Betty Udesen. Combining the warmth of a best friend with a straightforward style, Tracy addresses questions such as: Should I talk to my pregnant belly / newborn? Is that going to feel weird? (Yes, and absolutely.) How do I help baby sleep well? (Start with the 45-minute rule.) How can I instill a love of learning in my child? (By using specific types of praise and criticism.) What will boost my child's success in school? (Play that requires self-control, like make-believe.) My baby loves videos and cell-phone games. That's cool, right? (If you play, too.) What tamps down temper tantrums? (Naming emotions out loud.) My sweet baby just hit a playmate / lied to me about un-potting the plant / talked back. Now what? (Choose one of three logical consequences.) How do I get through an entire day of this? (With help. Lots of help.) Who knew babies were so funny? (They are!) Whether you read the book front to back or skip around, Zero to Five will help you make the best of the tantrums (yours and baby's), moments of pure joy, and other surprises along the totally-worth-it journey of parenting.

The Great American Drug Deal

The Strategic Pricing of Pharmaceuticals explains how pharmaceutical prices are, and should be set, in the US and international markets. The book discusses how pharmaceuticals are different from other products in terms of value and why typical assumptions and approaches to pricing fail to consider the true nature of pharmaceuticals or to capture their value. This book provides pharmaceutical marketers with needed guidance through the use of in-depth discussions and analyses of the factors that should be considered when setting and managing pharmaceutical prices.

What Would You Wish For?

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.

Forecasting for the Pharmaceutical Industry

Biotechnology is indisputably one of the fastest-growing and most promising industries.

Virtually immune to swings in the economic cycles, biotech stocks continue to perform steadily as high-tech stocks lose their steam.In Biotech Investing, Jim McCamant offers proven strategies and savvy advice on how to capitalize on the unprecedented opportunities in this high-potential sector. Written by a recognized authority, this book dissects biotech business models from start-up to IPO and discusses in detail the most important factors that affect biotech research. Comprehensive in scope, it looks at the best and worst biotech contenders, discusses all the most newsworthy developments in the field, and shows how they translate into business success or failure. It outlines simple criteria for choosing the best biotech stocks and for understanding the sometimes complicated dynamics of this sector.

Valuation in Life Sciences

The selection of biotech stocks for investment is more difficult compared with the selection of other stocks and industries that possess historical data, since biotechnology is a recently new science. In the first edition of this book, we described the crucial parameters for the valuation of an early stage biotech company without a drug in the market. In this edition, we analyze novel financial models that can value stocks of biotech companies with products in the market or products under development (in pre-clinical and clinical studies). All of these parameters should be helpful to potential new investors when creating a stock portfolio that includes highly promising biotech companies. Our strategy of selecting highly promising stocks based on all parameters described in this book and of performing a basic financial modeling analysis with DFC and/or real options valuation models has proven very successful, as this strategy provides returns higher than 100% in most cases. In the first edition of this book, based on our strategy, we suggested that Juno Therapeutics and Kite Pharma were "hot" stocks. At that time, Kite's stock was $50.19, while Juno's stock was $54.21. Since then, Kite's stock reached $179.79, with the company acquired by Gilead for $11.9 billion, while Juno's stock reached $86.96, with the company acquired by Celgene for $9 billion. Furthermore, Moderna Therapeutics, a private company that we valued at $5.5 billion in 2016 based on our real options financial model, today has a $7.5 billion valuation. This newly revised and expanded version was written to help investors in the selection of biotech stocks based on different scientific and financial criteria.

Short Selling

Do we really have to choose between affordability of drugs and lifesaving innovation? No. In The Great American Drug Deal, Peter Kolchinsky offers clear-eyed analysis, compelling stories, and vital ideas for closing loopholes, dealing with bad actors, supporting patients, and fueling discoveries that ease suffering now and for generations to come.

Pharmaceutical Lifecycle Management

A behind-the-scenes, revelatory history of the controversial consulting firm traces its decades-long influence in both business and political arenas, citing its role in the establishment of mainstream practices and modern understandings about capitalism while evaluating the failures that have compromised its reputation. 60,000 first printing.

The Antidote

Drug development, the processes by which a chemical compound becomes a □drug□ and is

approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success.Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If you're involved in the pharmaceutical industry, NEW DRUGS will provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compound's development. If you're a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with promising products.

Valuation in Life Sciences

A biotech manager's handbook lays out - in a simple, straightforward manner - for the manager or would-be entrepreneur the basic principles of running a biotech company. Most managers in biotechnology companies are working in their first company or in their first managerial role. Their expertise and experience in the scientific part of the work can be taken as a given but there is a whole range of other skills to be learned and areas of expertise to come to terms with. Small companies do not have big budgets to hire people or time to become an expert in so many areas. The book starts by outlining the state of the biopharmaceutical industry and goes on to explain the importance of planning (no matter what the size of the company). Succeeding chapters deal with the basics of intellectual property, perspectives from a university technology transfer office and how to raise some initial funding from an investor and entrepreneur. No other 'how to' manual exists for this sectorWritten by a range of expert professionals in each area, all in one bookIs the only 'bench to bedside' book covering the whole spectrum of development

Biotechnology Valuation

A primary objective for life science executives is raising capital. Very often, however, a lack of marketing and sales skills impedes their efforts. Focusing regionally, rather than globally, only compounds the challenge. "The Life Science Executive's Fundraising Manifesto" helps scientists understand the fundamental skills needed to brand and market their companies. It discusses how to use a consistent message to achieve compelling results from a fundraising campaign, and it teaches you how to aggregate a list of potential global investors that are a fit for your company's products and services. The book also explains how to efficiently and effectively reach out to potential investor targets, start a dialogue that fosters a relationship, and ultimately secure capital allocations. Raising capital is not a one-time event. It must be an ongoing part of your business strategy. This book reveals the expertise required to continually fundraise and bring your ideas to market. For more information about the book, please visit www.fundraisingmanifesto.com.

The Firm

Many a blockbuster drug began in the mind of a single entrepreneur. From start-ups to spin-offs, there are no lack of options for a company or venture capitalist to license or invest into. But how can you know that this is the correct investment? The correct option to choose? The one which will lead to financial success and a nice end-of-year bonus? This is where scientific due diligence comes in, the independent, realistic and critical review of a potential technology. From early development data through to clinical study results, patents to competitor analysis, the due diligence process is essential for any investment decision. We have developed this handbook to guide investors and due diligence investigators through the minefield of scientific due diligence in the pharmaceutical world. It covers best-practice approaches, traps to avoid, and the most important areas to focus your limited time on. Investing in pharma? Then this is the book for you. --- Book contents --- The book has been divided into sections which cover the entire due diligence process. The first section covers the basics of due diligence: - Chapter 1 introduces due diligence investigations, including the attributes of good due diligence investigators, the basic rules to follow, and commonly-seen licensing approaches. - Chapter 2 covers the initial steps of assessment, including the preliminary screening for potential licenses and the secondary screen to identify true opportunities. - Chapter 3 shows the preparation for the on-site scientific due diligence investigation, including typical organisational tasks and team set-up. Next, the specific requirements for each area of expertise are covered in more depth: - Chapter 4 covers the investigation from the regulatory affairs perspective, including factors such as approval risk, regulatory planning, and useful special pathways. - Chapter 5 deals with quality, the assurance that the technology has been developed and manufactured to the required quality levels. The chapter covers typical GMP documents and important GxP requirements which will need to be verified. - Chapter 6 covers chemistry, manufacturing and control, the details of the product and the production process. This includes manufacturing-site specific documents and the process development and validation requirements. - Chapter 7 describes preclinical trials, the preliminary work prior to human testing. This includes approaches for evaluating preclinical studies as well as more specific information for toxicology and pharmacology work. - Chapter 8 involves clinical trials, the most important test of any new drug. This section covers both general trial requirements as well as those specific to individual clinical phases. - Chapter 9 deals with marketing, the ability to sell the new product. This includes determining market position, analysing potential competitors, and determining reimbursement options. - Chapter 10 describes the intellectual property factors which may be involved, covering both patenting and data exclusivity approaches to IP protection. - Chapter 11 finishes the scientific due diligence process by providing the final set of questions to ask prior to making the final recommendation. Finally the five appendices provide reference information which will help when conducting a due diligence investigation, from example checklists to work from through to advice for when you are being audited.

Biotechnology Entrepreneurship

DISRUPTION CREATES OPPORTUNITY FOR THOSE WHO EMBRACE CHANGE. NEW WINNERS AND LOSERS WILL EMERGE. THIS BOOK WILL HELP YOU AND YOUR COMPANY THRIVE IN THE AGE OF DISRUPTION. The informational and technological revolutions have forever changed the practice of medicine. We analyze data in a flash and marketers deliver it with pinpoint accuracy at just the right moment. When patients put their trust in our brands and place their lives in our hands, marketers have to quickly analyze the data accessible to us so we can deliver the right information at the right time, all while navigating the complexities of industry regulations. Timely messaging through the patient

journey provides marketers today with an unprecedented opportunity. We must capitalize on this opportunity in order to stay relevant and profitable in the changing landscape. Results shows you the biggest trends happening now so you can be heard above the noise, deliver meaningful value, and to build real brand loyalty to drive your pharmaceutical and healthcare marketing far into the future. This book is essential reading for developers, manufacturers, and marketers of pharmaceutical and healthcare companies as well as the agencies, partners, publishers, suppliers and other service providers that support them in their marketing efforts. Authors RJ Lewis, Scott Weintraub, Brad Sitler, Joanne McHugh, and Roger Zan each share key insights into the growing trends in healthcare that you need to understand in order to better market your products. Join them at the front line as they speak to over a dozen executives of global pharmaceutical manufacturing companies to hear the technology, regulation, and the ever-shifting marketing challenges they see in front of them that could spell big opportunities for your company.

The Generic Challenge

Market access is the process by which a pharmaceutical company gets its product available on the market after having obtained a marketing authorization from a regulatory agency and by which the product becomes available for all patients for whom it is indicated as per its marketing authorization. It covers a group of activities intended to provide access to the appropriate medicine for the appropriate group of patients at the appropriate price (in most countries). Market Access may also be seen as activities that support the management of potential barriers, such as non-optimal price and reimbursement levels, the restriction of the scope of prescribing for the drug or complicated prescription writing or funding procedures. Since there are cultural differences among countries, any Market Access strategy needs to be culturally sensitive. Pharmaceutical Market Access in emerging markets has been extensively discussed in our previous book, published in 2016. The present book focuses on developed markets with the goal of helping students, academics, industry personnel, government workers, and decision makers understand the environment in developed markets.

The Truth in Small Doses

A one-stop source for investing in biotech-with detailed coverage of the science, the business, the players, and the strategies for one of today's most promising (and volatile) industries To invest in biotech is to invest in the future, and as such, investors need to learn the nuances of the science they're putting their money on. The core asset of biotech companies is knowledge, and sound investment decisions are impossible without an understanding of this complex science. That's where The Biotech Investor's Bible fits in. This much-needed, one-of-a-kind resource simplifies the complex science surrounding the business of biotech and clarifies subtle distinctions within the context of their financial repercussions. The book explains the basics of genetics, patents, and therapies; and teaches investors how to value biotech companies and their state-of-the art products and technology. The Biotech Investor's Bible offers an informative summary of the relatively short history of the industry and provides a comprehensive review of various industry sectors. George Wolff (St. Pete Beach, FL) is a successful consultant advising clients who are investing in biotech stocks. He has assessed well over 150 biotech companies and has issued a number of valuable white papers that have charted the success of the hottest biotech companies.

Licensing, Selling and Finance in the Pharmaceutical and Healthcare Industries

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.

1001 Questions to Ask Before You Get Married

Very little has been published on optimization of pharmaceutical portfolios. Moreover, most of published literature is coming from the commercial side, where probability of technical success (PoS) is treated as fixed, and not as a consequence of development strategy or design. In this book there is a strong focus on impact of study design on PoS and ultimately on the value of portfolio. Design options that are discussed in different chapters are dose-selection strategies, adaptive design and enrichment. Some development strategies that are discussed are indication sequencing, optimal number of programs and optimal decision criteria. This book includes chapters written by authors with very broad backgrounds including financial, clinical, statistical, decision sciences, commercial and regulatory. Many authors have long held executive positions and have been involved with decision making at a product or at a portfolio level. As such, it is expected that this book will attract a very broad audience, including decision makers in pharmaceutical R&D, commercial and financial departments. The intended audience also includes portfolio planners and managers, statisticians, decision scientists and clinicians. Early chapters describe approaches to portfolio optimization from big Pharma and Venture Capital standpoints. They have stronger focus on finances and processes. Later chapters present selected statistical and decision analysis methods for optimizing drug development programs and portfolios. Some methodological chapters are technical; however, with a few exceptions they require a relatively basic knowledge of statistics by a reader.

From Science to Startup

Documents the story of maverick pharmaceutical company Vertex and a small team of entrepreneurial scientists who after dissociating themselves from Merck endeavored to create breakthrough medicines and transform the pharmaceutical industry. By the award-winning author of The Billion-Dollar Molecule.

Biotechnology Demystified

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.

Bioanalytical Chemistry

The Biotech Primer takes an in-depth look at the biotech industry, and in particular, the science that drives it. From cell structure to protein structure; gene expression to genetic variation and genetic engineering; the human immune response to the production of antibodies for biotech application; and finally drug discovery, drug development, and biomanufacturing: we discuss the key concepts and technologies that impact current biotechnology developments. This book will support your growth as a biotechnology professional. Although the industry itself is constantly changing, these fundamental concepts upon which it is built will remain important for years to come: and decision-makers who understand these fundamentals will be better able to evaluate and predict new trends. More than anything else, we hope that your understanding of the science behind biotechnology will serve to increase your enthusiasm for this exciting and truly life-changing industry. The future is here and you should be a part of it.

Read More About The Pharmagellan Guide To Biotech Forecasting And Valuation