Project Management In Pharmaceuticals

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.

The Art & Science of Project Management. This is the third edition, which is updated for the PMBOK 6th edition. Master project management with this book from authors experienced in practice, teaching, and research. You will learn: the foundations of Project Management, explained with dozens of examples; what works and what doesn't; and how the latest research applies to your project. This Third Edition: Covers Projects and their Environment; Programs, Portfolios, and Project Selection; and the Project Manager. This third edition: covers the essential Technical, Behavioral, Business and Strategic Skills; includes a new section on Agile Project Management; includes the case of a mobile app following the scrum framework; and includes several worked projects and a visual tutorial for Microsoft Project(R).

This is the second book in the series of three. These three books will be based upon the idea to tailor PMI’s Project Management methodologies to the typical pharmaceutical projects. This book mainly discusses launch of drug products in EU market which are manufactured in countries like India or china by supplier manufacturer. It is specially designed for Project Managers, team members and pharmacy students. Format of book is purposely kept simple. This book includes various useful flow charts and templates that can be used during the project life cycle. Information provided in this book is obtained from highly authentic sources, and links of data sources is provided for reference. Surely this is the kind of book every pharmaceutical personnel will want to be on their shelf.

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

This book describes the way that pharmaceutical projects and programs are currently managed, and offers views from many highly experienced practitioners from within the industry on future directions for drug program management. The book integrates portfolio, program, and project management processes as fundamental for effective and efficient drug product development. Contributing expert authors provide their view of how the projectization approach can be taken forward by the drug industry over the coming years.

Successful projects are the basis for the business many successful organisations, but many professionals lack the basic skills required to manage projects successfully. This book shows how to maximise the outcomes of projects and to ensure that the benefits arising from projects -- large or small -- are fully realized by the business. This key outcome can be easily overlooked or sidelined by the need to keep projects on track. Visually lead, to the point, with case studies and best practice guidelines throughout, the hard-won real world experience found in this book makes it a powerful PM resource for anyone involved in project management. Links project management to business goals for career project managers and those involved with project intermittently Focuses on the needs of engineering, industrial and process projects

Highlighting key issues and differences among GMPs of Europe, Canada, and the WHO, this reference examines US law and governmental policy affecting domestic and multinational pharmaceutical manufacturing. The book recommend pragmatic ways to interpret and comply with FDA CGMP regulation and related criteria. They focus on geographical redistribution of manufacturing facilities, accommodation of a diversity of regulatory and statutory governance, adaptation to disparate human resources, and new growth areas of manufacture and distribution of homeopathic remedies and dietary supplements, in addition to the greater quality control required of pharmacists and other authorized dispensers.

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

As a growing number of healthcare organizations implement project management principles to improve cost and service efficiencies, they are in desperate need of resources that illustrate the project management needs of today's healthcare professional. Project Management for Healthcare fills this need. Using easy-to-follow language, it expl

Project Management for the Pharmaceutical Industry

A practical handbook for career project managers and those involved intermittently with projects throughout their career. Brief and visually led, Managing Project Delivery gets to the point, giving you the knowledge and confidence to manage project benefits and increase the certainty of success. Focused on the needs of engineering and technical Project Managers, but generic enough to support projects in other areas such as business change, IT and product development. Supported by downloadable on-line project benefits management tool templates that enable the techniques developed in the book to be applied in practice. Comprehensive real world case studies demonstrate the use of tools. Successful projects are the basis for the business many successful

organisations, but many professionals lack the basic skills required to manage projects successfully. This book shows how to maximise the outcomes of projects and to ensure that the benefits arising from projects -- large or small -- are fully realized by the business. This key outcome can be easily overlooked or sidelined by the need to keep projects on track. Managing Project Delivery provides simple yet powerful tools to ensure that projects deliver on their goals in a controlled and accountable manner. It is the first of four project management titles that separately build skills and together provide a powerful project management resource. * A practical handbook for career project managers and those involved intermittently with projects throughout their career. * Brief and visually led, Managing Project Delivery gets to the point, giving you the knowledge and confidence to deliver projects and increase the certainty of success. * Focused on the needs of both engineering and technical Project Managers, but generic enough to support projects in other areas such as business change, IT and product development. * Supported by downloadable on-line project delivery tool templates that enable the techniques developed in the book to be applied in practice. * Comprehensive real world case studies demonstrate the use of tools. * Project delivery is the third stage of the project lifecycle. This book shows how to maintain control and forecast the project outcome. Provides expert advice, tried-and-tested techniques and a delivery toolkit to address: • Business alignment • Value delivery • Control and forecasting

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.

This book bridges the gap between practitioners of supply-chain management and pharmaceutical industry experts. It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply-chains within the globally important pharmaceutical sector. Scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until a drug has been registered, but should start as early as possible in the development process and before registration or clinical trials. The author suggests that CMC (chemistry manufacturing controls) drug development must reset the line of sight – from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.

Industry is dependent on projects to develop new and improved products and processes for producing them, necessitating the need for them to be completed right first time and on time. Objectives, safety, environmental awareness, quality, cost and speed are all things which need to be considered when implementing a project, which is why process plants have project managers/engineers. This book is aimed at everyone who has responsibilities for some or all of a project, giving a better understanding of the subject. It describes best practice and offers guidance on how principles and techniques can be applied to all aspects of a projects. This information is presented in chapters arranged in three sections: phases of a project; tools and techniques relevant at every stage; and skills and knowledge required by the project manager.

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

Therapeutic risk management of medicines is an authoritative and practical guide on developing, implementing and evaluating risk management plans for medicines globally. It explains how to assess risks and benefit-risk balance, design and roll out risk minimisation and pharmacovigilance activities, and interact effectively with key stakeholders. A more systematic approach for managing the risks of medicines arose following a number of high-profile drug safety incidents and a need for better access to effective but potentially risky treatments. Regulatory requirements have evolved rapidly over the past decade. Risk management plans (RMPs) are mandatory for new medicinal products in the EU and a Risk Evaluation and Mitigation Strategy (REMS) is needed for certain drugs in the US. This book is an easy-to-read resource that complements current regulatory guidance, by exploring key areas and practical implications in greater detail. It is structured into chapters encompassing a background to therapeutic risk management, strategies for developing RMPs, implementation of RMPs, and the continuing evolution of the risk management field.The topic is of critical importance not only to the pharmaceutical and biotechnology industries, but also regulators and healthcare policymakers.Some chapters feature contributions from selected industry experts. An up-to-date practical guide on conceiving, designing, and implementing global therapeutic risk management plans for medicines A number of useful frameworks are presented which add impact to RMPs (Risk Management Plans), together with regional specific information (European Union, United States, and Japan) A comprehensive guide for performing risk management more effectively throughout a product’s life-cycle

Although the pharmaceutical industry has long used project management practices to control drug development and clinical trial processes, only recently are more drug development companies looking for ways to exploit project management in their efforts to

accomplish strategic objectives. This article--presented in a question-and-answer format, profiling the new vice president of project leadership at Neuromed Pharmaceuticals (Philadelphia, PA, USA--discusses how Neuromed is expanding its project management practice to include implementing a project management office (PMO) that is charged with helping the company establish itself as a world leader in the pharmaceutical industry. In doing so, it explains how Neuromed's executives view project management and how they are using it to help the company realize its strategic vision. It identifies the two elements that distinguish Neuromed's project management approach from the approach that pharmaceutical industry firms typically employ, elements that directly integrate project and corporate activities.

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. 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.

This unique guide and professional reference presents a structured framework for practitioners and students of project, program, and portfolio management to enhance their strategic and analytic capabilities in the evolving discipline of project portfolio management (PPM). It provides a practical, step-by-step approach to building competencies in categorizing, evaluating, optimizing, prioritizing, and managing an IT, pharmaceutical, biotech or other complex R&D-oriented portfolio of investments. Drawing on the experience of project managers from international pharmaceutical companies, this work reviews up-to-date strategic, operational and organizational procedures for drug development in today's competitive industry. It includes details of how target product profiles are established and used to direct drug development; and project definition and risk management, including analytical techniques and asset valuation at the project and portfolio levels.

Although United States (U.S.) pharmaceutical companies experienced a sharp decline in their overall international market share during the latter half of the twentieth century, these companies were globally revered as paradigms for business excellence, esteem that was garnered due to their philosophical approach to managing risk, innovation, research and development, quality, and dynamics. This article examines the techniques that one, U.S.-based Stuart Pharmaceuticals, uses to manage its project resources and risks when developing new products. In doing so, it describes the business success of the top U.S. pharmaceutical companies and explains the difficult process of developing new projects in this highly competitive and regulated industry. It then analyzes the management styles used in U.S. industries and describes the project activities practiced within pharmaceutical companies. It summarizes Stuart's history and its drug development process, a process that integrates project management into two areas: research development and commercial development. It subsequently details Stuart's research development process, outlining the project team's structure, activities, and procedures, identifying the project manager's authority, responsibilities, and relationships, and listing the project management methodology's techniques, tools, and goals. It concludes by describing the organizational benefits Stuart has realized by practicing project management.

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.

Driven by such tools as big data, cognitive computing, new business models, and the internet of things, the overall demand for innovation is becoming more critical for competitiveness and emerging technologies. These technologies have become real alternatives for the market and offer new perspectives for modern project management applications. The Handbook of Research on Emerging Technologies for Effective Project Management is an essential research publication that proposes innovations for firms and markets through the exploration of project management principles and methods and the effective integration of knowledge and innovation. It encompasses academic and scientific propositions, reviews for conceptual bases, applications of theories in new market solutions, and cases of successful insertion of disruptive technologies and business models in new competitive market offers. Featuring a range of topics such as innovation management, business administration, and marketing, this book is ideal for project managers, IT specialists, software developers, executives, practitioners, managers, marketers, researchers, and industry professionals.

Effective Project Management in easy steps will show you how to make sure your project is successful. It focuses on the key skills a manager needs to develop for a smooth running project, and a timely arrival at the finishing line. It includes examples for most

key documents such as the terms of reference, business case and project plan. It addresses team building and good communications. It covers the typical project stages with helpful lists of applicable tasks and deliverables, which effectively provides a blueprint for planning an entire project. This up-to-date primer covers all key trends in project management including a chapter on Agile Project Management. If you're a first time project manager, let this book take you through the essential project stages in easy steps, and take note of the applicable tasks and deliverables. If you're an experienced project manager, this book provides a valuable source of inspiration for making projects run smoothly and satisfactorily. Covering risk-management together with insights on how to plan, lead, organize and control a project - simply a fountain of knowledge!

Market_Desc: Program managers and project managers in IT, New Product Development, Pharmaceuticals, R&D and Engineering, CIOs, CTOs, as well as students in PM programs or PM certification programs Special Features: · Levine has 42 years experience in project management and is a respected member of the PM community, he writes frequently for PM web sites and journals, is a frequent speaker and consultant· This book is chock full of tips, tactics & tools and will cover the fundamentals as well as case studies that show how PPM can be handled in new product development, IT, pharmaceutical companies and R&D About The Book: Project Portfolio Management is an increasingly hot topic in New Product Development, IT, Pharmaceuticals, R&D and Engineering. Harvey Levine has compiled the first guide to help program managers and managers of project offices sort through their existing projects and create a healthy portfolio of projects that will lead to increased ROI for the organization. Levine answers the following questions: § How do you select projects?§ How do you manage risk while selecting projects? § How do you weed out bad projects? § How do you tie projects to organizational strategy? § How do you tie projects to cash flow? § How do you implement PPM?

This book contains both the theory and practice of risk management (RM) and provides the background, tools, and application of risk in pharmaceutical and biologics manufacturing and operations. It includes case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding.

Unique in approach, exhaustive in coverage: this book provides information usually not available to scientists. It explains the basic scientific and technical requirements which apply to the patenting and registration of human or veterinary vaccines and therapeutic biomedicinal products. Pragmatic and practice-oriented, it helps users select and manage successfully the most attractive research and development projects. An impressive number of topics is covered, including: * planning and managing product development * product development phases * requirements for a patentable invention * patent costs * user safety * ecotoxicity The book will rapidly pay for itself by more successful fund applications,increased protection and remuneration of intellectual property, and by faster and more efficient product development.

This book examines the sequence of events and methodology in the industrial clinical research process; a reference for multidisciplinary personnel. It is the conceptual framework involving the philosophical, economic, political, historical, regulatory, planning, and marketing aspects of the process.

Pharmaceutical giants have been doubling their investments in drug development, only to see new drug approvals to remain constant for the past decade. This book investigates and highlights a set of proactive strategies. The authors focus on three sources of pharmaceutical innovation: new management methods, new technologies, and new forms of internationalization. Their findings are illustrated in the case of the Swiss pharmaceutical industry, the leading exporter of pharmaceutical products in percentage of GDP, and some of its main pharmaceutical firms such as Novartis and Hoffmann-La Roche.

A guide for engineers and designers new to the field of bio-pharmaceutical process control. For the experienced automation professional, it outlines the unique design and application issues for the bio-pharmaceutical industry. For those already familiar with this industry, it provides specific advice for automating these processes.

This is the first book in the series of three. These three books will be based upon the idea to tailor PMI’s Project Management methodologies to the typical pharmaceutical projects. This book includes generic drug development project in detail. It is specially designed for Project Managers, team members and pharmacy students. Format of book is purposely kept simple. This book includes various useful flow charts and templates that can be used during the project life cycle. Information provided in this book is obtained from highly authentic sources, and links of data sources is provided for reference. Surely this is the kind of book every pharmaceutical personnel will want to be on their shelf.

This book provides you with the tools required to approach and manage projects. These effective skills will impact positively on the success of both the projects you are involved with and of your organization. Key features * A practical handbook for both career project managers and those involved intermittently with projects throughout their career * Provides simple step-by-step tools for understanding and managing each of the project value-add stages: - Developing a business case - Robust planning - Staying in control - Delivering benefits * Focused on the needs of engineering and other technical project managers, but generic enough to support projects in other areas * Brief and visually led, the Toolkit is designed to get you up and running fast and to increase the certainty of a positive project outcome from day one * Comprehensive real world case studies demonstrate the use of tools Project Management Toolkit introduces the whole project life-cycle. It is the first of four project management titles that separately build skills in critical PM areas and together provide a powerful project management resource. Focused on the needs of engineering and other technical project managers, this book recognises that most non-routine work completed by an organization is a project A practical, hands-on guide to aid those tasked with real industry projects – not a lengthy theoretical textbook, it gets to the point and delivers REAL benefits The book is suitable for both career project managers and those involved with projects intermittently

Issues in Engineering Research and Application: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Engineering Research and Application. The editors have built Issues in Engineering Research and Application: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Engineering Research and Application in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in

Engineering Research and Application: 2011 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.
Project managers are no longer judged by the technical success oftheir projects alone. They're also held accountable for theircontributions to the company's financial goals. Yet most projectmanagers don't have the business knowledge necessary to makeproject-based decisions that lead to bottom-line success. In thisbook, Dennis Cohen and Robert Graham, both former universityprofessors and experienced project management consultants, providethe skills that, until now, could only be gained through a graduatedegree and years of hands-on experience. Cohen and Graham walk project managers through basic businessconcepts such as value creation, accounting and finance, strategy,and marketing. They connect these concepts to the decisions projectmanagers face every day. And they make it easy to apply theresulting solutions on the job through a unique business systemscalculator. Readers can use the online calculator in conjunctionwith the book to understand how different project variables affectbusiness outcomes, to determine the overall impact of proposedproject changes, and to evaluate the economic results of manydecisions they make. Cohen and Graham's principles apply equally to projects inbusiness, non-profit, and government organizations. And each one isillustrated through case studies drawn from a range of industries,including pharmaceuticals, the technology sector, even thewinemaking business. Whether the mandate is to get new products tomarket, improve the infrastructure, or better serve customers andclients, this book teaches project managers how to make day-to-daydecisions from an upper-management perspective. And it provides ablueprint for planning and pitching potential projects thatdemonstrates a higher level of business savvy.
Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards, and applicable regulatory authority’s requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book, which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.
Successful projects are the basis for a successful company, but many professionals lack the basic skills required to accomplish this. The IChemE Project Management Subject Group has recognized the need to provide resources to deliver these skills, and has developed a series of books to share the latest best practice – engineering essentials. This second title, though primarily written from the perspective of engineering projects within the process industries, is generic enough to support project managers in many other disciplines. It provides for those starting out in project management, is ideal for students as a university textbook, and is also an indispensable reference for established project managers. Get up and running on your project quickly and effectively Focuses one step at a time on the needs of engineering, industrial and process projects for career project managers and those involved with projects intermittently
The twentieth century has been a great success for modern medicine, and has resulted in the generation of a plethora of drugs to treat most common illnesses. However, in the light of increasing regulatory demands, spiralling costs and diminishing commercial returns, the question of how, when, where and whether to conduct pharmaceutical R&D has profound implications, and not just for those within the pharmaceutical industry. In response to these and other dilemmas, the authors define the processes involved in drug research, and examine the advantages and disadvantages of collaborative methods of drug research, and examine the roles that academia, CROs, small "biotechnology" companies and "research boutiques," and possibly even the "virtual research company" might play as contractors and collaborators.