

Pharmaceutical Project Management

Mr Bikash Chatterjee

Project Management for the Pharmaceutical Industry Laura Brown, Tony Grundy, 2016-04-08 The pharmaceutical industry has encountered major shifts in recent years, both within the industry, and in its external environment. The cost of healthcare rising due to an ageing population, the intensification of regulatory requirements and mergers within the industry have led to an increased need for restructuring, cost reduction and culture change projects. Project management is the key to addressing these needs, and also to effective drug development. Given the costs of development and the critical issue of 'time to market', project management techniques - appropriately used - are a key factor in bringing a drug to market. In this book, Laura Brown and Tony Grundy's pharmaceutical expertise and experience offers the reader a guide to the most relevant project management tools and techniques and how to rigorously apply them in the pharmaceutical industry. The authors cover the technical, strategic and human aspects of project management, including contingency planning, simulation techniques and different project options. Complete with decision-tree diagrams, checklists, exercises and a full glossary, *Project Management for the Pharmaceutical Industry* provides clinical research, drug development and quality assurance managers or directors with a one-stop reference for successfully managing pharmaceutical projects. The text has been revised for this edition and now includes some additional material on risk management.

Portfolio, Program, and Project Management in the Pharmaceutical and Biotechnology Industries Pete Harpum, 2011-09-20 This book describes the way that pharmaceutical projects and programs are currently managed, and offers views from many highly experienced practitioners from within the industry on future directions for drug program management. The book integrates portfolio, program, and project management processes as fundamental for effective and efficient drug product development. Contributing expert authors provide their view of how the projectization approach can be taken forward by the drug industry over the coming years.

Pharmaceutical and Biomedical Project Management in a Changing Global Environment Scott D. Babler, 2011-01-06 *Pharmaceutical and Biomedical Portfolio Management in a Changing Global Environment* explores some of the critical forces at work today in the complex endeavour of pharmaceutical and medical product development. Written by experienced professionals, and including real-world approaches and best practice examples, this new title addresses three key areas - small molecules, large molecules, and medical devices - and provides hard-to-find, consolidated information relevant to and

needed by pharmaceutical, biotech, and medical device company managers.

Project Management for the Pharmaceutical Industry Mr Tony Grundy, Ms Laura Brown, 2012-09-28 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.

Generic Drug Development Project Management Pmp Sandeep Narayan Patil, 2021-03-31 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.

Pharmaceutical Lifecycle Management Tony Ellery, Neal Hansen, 2012-06-05 A comprehensive guide to optimizing the lifecycle management of pharmaceutical brands The mounting challenges posed by cost containment policies and the prevalence of generic alternatives make optimizing the lifecycle management (LCM) of brand drugs essential for pharmaceutical companies looking to maximize the value of their products. Demonstrating how different measures can be combined to create winning strategies, *Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand* explores this increasingly important field to help readers understand what they can—and must—do to get the most out of their brands. Offering a truly immersive introduction to LCM options for pharmaceuticals, the book incorporates numerous real-life case studies that demonstrate successful and failed lifecycle management initiatives, explaining the key takeaway of each example. Filled with practical information on the process of actually writing and presenting an LCM plan, as well as

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

Project Management for Healthcare David Shirley, 2016-04-19 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

Pharmaceutical Project Management Anthony Kennedy, 2008-03-17 Encompassing the full spectrum of project management's role and responsibility encountered in the pharmaceutical industry, Pharmaceutical Project Management outlines the key objectives, risks, and challenges of each stage of the pharmaceutical lifecycle, from discovery and preclinical phases through clinical development, manufacturing, registration

Value Creation in the Pharmaceutical Industry Alexander Schuhmacher, Markus Hinder, Oliver Gassmann, 2016-04-11 This practical guide for advanced students and decision-makers in the pharma and biotech industry presents key success factors in R&D along with value creators in pharmaceutical innovation. A team of editors and authors with extensive experience in academia and industry and at some of the most prestigious business schools in Europe discusses in detail the innovation process in pharma as well as common and new research and innovation strategies. In doing so, they cover collaboration and partnerships, open innovation, biopharmaceuticals, translational medicine, good manufacturing practice, regulatory affairs, and portfolio management. Each chapter covers controversial aspects of recent developments in the pharmaceutical industry, with the aim of stimulating productive debates on the most effective and efficient innovation processes. A must-have for young professionals and MBA students preparing to enter R&D in pharma or biotech as well as for students on a combined BA/biomedical and natural sciences program.

The Clinical Research Process in the Pharmaceutical Industry Gary M. Matoren, 2020-08-18 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.

Polymorphism in the Pharmaceutical Industry Rolf Hilfiker, Markus von Raumer, 2019-01-04 Polymorphism in the Pharmaceutical Industry - Solid Form and Drug Development highlights the relevance of polymorphism in modern

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

Sterile Product Facility Design and Project Management Jeffrey N. Odum, 2004-03-29 Knowing how to deal with the regulatory issues, understanding the impacts of cleanliness, and recognizing the affect that poor facility layout will have on GMP spaces are only some of the issues an experienced Project Manager must focus on. Completely revised and updated, Sterile Product Facility Design and Project Management, Second Edition provid

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A Biotech Manager's Handbook M O'Neill, M M Hopkins, 2012-05-02 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 sector - Written by a range of expert professionals in each area, all in one book - Is the only 'bench to bedside' book covering the whole spectrum of development

Project Management, Planning and Control Albert Lester, 2007 This fifth edition provides a comprehensive resource for project managers. It describes the latest project management systems that use critical path methods.

Project Management for Research and Development Lory Mitchell Wingate, 2014-08-05 Today's leading organizations recognize the importance of research and development (R&D) to maintain and grow market share. If companies want to survive into the future, they must accelerate their R&D-to-market cycles or find themselves behind the competition. **Project Management for Research and Development: Guiding Innovation for Positive R**

Implementing Project Portfolio Management Dr. Panos Chatzipanos, Dr. Te Wu, 2018-10-18 **Implementing Project Portfolio Management** addresses the how-tos of portfolio management. It is designed for three primary audience groups: Business Executives, Portfolio Leaders and Practitioners, and Portfolio Thinkers. The authors provide insights on how to apply the performance management domains covered in the standard that are in practice today by introducing tools and templates into their discussion. Far-reaching in its impact on portfolio management practitioners, thinkers, stakeholders, and the wider project management community, this guide envisions the continued transformation of portfolio management with the changing needs of organizations and advances in technology.

Applying Lean Six Sigma in the Pharmaceutical Industry Mr Bikash Chatterjee, 2014-07-28 Bikash Chatterjee emphasizes the criticality of applying the principles of Lean and Six Sigma within the paradigm of the drug development process. His guide to operational excellence in the pharmaceutical and biotech industries is a focused summary of the application of Lean Six Sigma theory to the regulated life sciences. From molecule discovery to the application of PAT **Applying Lean Six Sigma in the Pharmaceutical Industry** will highlight the importance of framing these initiatives within the key deliverables of drug development manufacturing and quality. Challenging conventional wisdom the author offers a quality and efficiency perspective as a foundation for the principles of Quality by Design, PAT and the new philosophies underlying Process Validation. Each chapter includes discussion around the considerations for applying Lean manufacturing and Six Sigma principles and their tools, culminating in a case study to illustrate the application. The book is organized to reflect the major work centers involved in the drug development lifecycle. Each chapter is stand-alone but together they illustrate the necessary synergy between Lean, Six Sigma and compliance sensibilities required to be successful in the pharmaceutical industry. These design, manufacturing and management techniques are not without their challenges. Bikash

Chatterjee's book offers the roadmap for an industry that is struggling to reinvent many of its development and business processes.

Research Methods for Pharmaceutical Practice and Policy Rajender R. Aparasu, 2011 This text provides the theory and practice for conducting pharmaceutical policy research. It covers all aspects of scientific research from conceptualising to statistical analysis. It also provides scientific basis and a good understanding of the principles and practice of conducting pharmaceutical policy research.

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