

PHARMA PRODUCT LIFE CYCLE



Discovery & Preclinical Research

- Discovery
- Preclinical Testing



Regulatory Approval

- Submission to Regulatory Authorities
- Regulatory Review
- Post-Approval (Phase IV) Monitoring



Growth and Maturity

- Sales Growth
- Market Maturity
- Lifecycle Management



Withdrawal or Discontinuation

- Voluntary Withdrawal
- Regulatory Withdrawal



Clinical Development

- Phase I (Safety & Dosage)
- Phase II (Efficacy & Side Effects)
- Phase III (Large-Scale Efficacy and Monitoring)



Market Introduction & Commercialization

- Launch
- Market Penetration
- Patent Protection



Patent Expiry and Decline

- Patent Expiration
- Generic Competition
- Revenue Decline

Project Management In Pharmaceuticals

Sebastian Brünink



Project Management In Pharmaceuticals:

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.

Portfolio, Program, and Project Management in the Pharmaceutical and Biotechnology Industries Pete Harpum, 2010-04-05 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.

Project Management for Drug Developers Joseph P. Stalder, 2022-12-29 Project managers in drug development are the driving force behind the coordination of efforts. This book provides a practical reference for project managers in the pharmaceutical and biotech drug development industry with the goal of assisting in creating an efficient and effective team structure and environment. The text details the role of project managers at each stage of drug development, the key interfaces that the PM will need to work closely with and essential tools of the trade including frequently used techniques and methodologies. This book is useful for both entry level and advanced level PMs as well as non project managers from other functions. Features: Includes authors recent experience with improved tactics and technologies; software at various stages of drug development; Provides the most up to date and best practices techniques and methodologies in project management; Details the role of the PM at each stage of drug development including working with the key interfaces throughout the process; Diverse audience including nonproject managers in clinical development, clinical operations, regulatory affairs, medical affairs, clinical pharmacology and biostatistics; Provides templates

and timelines for critical paths from development to commercialization and has potential as a textbook on relevant courses

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

Application of Project Management Principles to the Management of Pharmaceutical R&D Projects Thomas Catalano, 2020-11-06 Dr Catalano has for the last ten years been doing consulting for the Pharmaceutical Industry During his consulting he discovered that small businesses such as generic startups and virtual companies do not have the budget or the resources to apply the computer software utilized in project management and therefore do not apply project management principles in their business model This reduces their effectiveness and increases their operating cost *Application of Project Management Principles to the Management of Pharmaceutical R D Projects* is presented as a paper based system for completing all the critical activities needed apply the project management system This will allow these small business to take advantage of the project management principles and gain all the advantages of the system This book will be beneficial for beginners to understand the concepts of project management and for small pharmaceutical companies to apply the principles of project management to their business model

Pharmaceutical Project Management, Second Edition 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 and launch New updated material includes expert recommendations and informative articles on decision making planning principles and planning systems management of subcontracted development manufacturing project management team leadership and skill sets drug development strategies It covers primary project management objectives functions and descriptions of the nature and execution of work

activities in a clear and reader friendly format to illustrate key characteristics and objectives assist managers in projecting the risks and challenges of each development option and supply concise recommendations for successful project planning

Project management in the pharmaceutical industry, 1989 **Leading Pharmaceutical Innovation** Oliver

Gassmann, Gerrit Reepmeyer, Maximilian von Zedtwitz, 2008-02-19 Pharmaceutical giants have doubled their investments in drug development in the past decade only to see new drug approvals remain constant This book investigates and highlights a set of proactive strategies aimed at generating sustainable competitive advantage based on value generating business practices We focus on three sources of pharmaceutical innovation new management methods in the drug development pipeline new technologies as enablers for cutting edge R D and new forms of cooperation and internationalization such as open innovation in the early phases of R D Our findings are illustrated by cases from Europe the US and Asia

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 **Pharmaceutical Project**

Management--is it Different? Patrice L. Murphy, 1989 Just how different are the project management processes practiced in the pharmaceutical industry from those used in other industries such as construction engineering and aerospace This article examines this question and in doing so it briefly discusses the project management tools and skills common to all industries before it focuses on the practices that are common to managing pharmaceutical research and development efforts It describes the process of pharmaceutical projects and the structure and nature of pharmaceutical project teams It then explains the key differences between pharmaceutical projects and projects in other industries differences related to the nature of the final product and the focus of the project approach It also identifies the challenges unique to pharmaceutical projects challenges such as clinical costs and incompressibility product stability product shelf life patient dosing and unallocable experts and specialized resources Accompanying this article is a sidebar outlining the process for obtaining the United States U S Government s approval to market and distribute pharmaceutical products within the U S

Pharmaceutical Project Management Kennedy Tony, 1997-10-24 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 **Food and Drug Law Journal**, 1997 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

Generic Drug Development Project Management Sandeep Narayan Patil, PMP,2021-04-17 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

Operations Management for MBAs Jack R. Meredith,Scott M. Shafer,2007 Designed for MBA students this book offers a brief introduction to the basic concepts of operations management It provides a strategic conceptual view of OM and the basics to complement class activities

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Medicines and Transitions Salmaan Keshavjee,1998

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New Scientist ,1969

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