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# Pharmaceutical Project Management

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A Guide to Measuring and Monitoring Project Performance  
Analytical Scientists in Pharmaceutical Product Development  
Perspectives on Risk, Assessment and Management Paradigms  
Applying Lean Six Sigma in the Pharmaceutical Industry  
Generic Drug Development Project Management  
Pharmaceutical Project Management  
How Drug Companies Mislead Doctors and Harm Patients  
Research and Development of Vaccines and Pharmaceuticals from Biotechnology  
A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry  
Solid Form and Drug Development  
Project Management for the Pharmaceutical Industry  
Pharmaceutical and Biomedical Project Management in a Changing Global  
Environment  
Task Management and Practical Knowledge  
Delivering Patient Value for Pharmaceuticals and Biologics

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A Guide to Effective Project Management, Patenting and Product Registration  
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Volume 1  
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## **CABRERA GAVIN**

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### A Guide to Measuring and Monitoring Project

Performance Routledge

Projects have always been essentially human endeavours. Large modern projects are

generally highly complex, fraught with technical difficulties and supported by diverse, often apparently conflicted stakeholders. The spirituality that originally defined some of the great construction projects of the classical era surely has a role in project

management today. The Spirit of Project Management explains the context for spirituality in projects and explores how it can be used to create a larger sense of purpose and achievement; to help encourage an esprit de corps amongst all those involved; to act as a

touchstone for ethical and sustainable decision-making. This is a very pragmatic book. The first part includes an explanation and a variety of useful models for understanding the significance and value of spirituality in projects. Judi Neal and Alan Harpham devote the second part of the book to help you integrate these ideas into your day-to-day management of projects. Thus there are chapters on spirituality from the perspective of the individual, the project

team, the project organization and even project management within a sustainable world framework. Read this book, use the ideas to help you articulate your projects; engage and sustain your project team and your stakeholders; and frame how you work in terms of your organisation, society and the environment. [Analytical Scientists in Pharmaceutical Product Development](#) John Wiley & Sons  
Discover how biomarkers can boost the success

rate of drug development efforts As pharmaceutical companies struggle to improve the success rate and cost-effectiveness of the drug development process, biomarkers have emerged as a valuable tool. This book synthesizes and reviews the latest efforts to identify, develop, and integrate biomarkers as a key strategy in translational medicine and the drug development process. Filled with case studies, the book demonstrates how biomarkers can improve

drug development timelines, lower costs, facilitate better compound selection, reduce late-stage attrition, and open the door to personalized medicine. Biomarkers in Drug Development is divided into eight parts: Part One offers an overview of biomarkers and their role in drug development. Part Two highlights important technologies to help researchers identify new biomarkers. Part Three examines the characterization and validation process for both

drugs and diagnostics, and provides practical advice on appropriate statistical methods to ensure that biomarkers fulfill their intended purpose. Parts Four through Six examine the application of biomarkers in discovery, preclinical safety assessment, clinical trials, and translational medicine. Part Seven focuses on lessons learned and the practical aspects of implementing biomarkers in drug development programs. Part Eight explores future trends and

issues, including data integration, personalized medicine, and ethical concerns. Each of the thirty-eight chapters was contributed by one or more leading experts, including scientists from biotechnology and pharmaceutical firms, academia, and the U.S. Food and Drug Administration. Their contributions offer pharmaceutical and clinical researchers the most up-to-date understanding of the strategies used for and

applications of biomarkers in drug development.

Perspectives on Risk,

Assessment and

Management Paradigms

John Wiley & Sons

PMBOK® Guide is the go-to resource for project management practitioners. The project management profession has significantly evolved due to emerging technology, new approaches and rapid market changes.

Reflecting this evolution, The Standard for Project Management enumerates 12 principles of project

management and the PMBOK® Guide &–

Seventh Edition is structured around eight project performance domains. This edition is designed to address practitioners' current and future needs and to help them be more proactive, innovative and nimble in enabling desired project outcomes. This edition of the PMBOK® Guide:

• Reflects the full range of development approaches (predictive, adaptive, hybrid, etc.);

• Provides an entire section devoted to tailoring the development approach and processes;

• Includes an expanded list of models, methods, and artifacts;

• Focuses on not just delivering project outputs but also enabling outcomes; and

• Integrates with PMI standards+™ for information and standards application content based on project type, development approach, and industry sector.

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Applying Lean Six Sigma in the Pharmaceutical Industry CRC Press

This book describes the

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Applying Lean Six Sigma in the Pharmaceutical Industry CRC Press

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.  
*Generic Drug Development Project Management* Macmillan  
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.  
**Pharmaceutical Project Management** John Wiley & Sons  
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 provides comprehensive guidance on how to develop and execute biotech and other sterile drug facilities based on current industry best practices. Each chapter highlights a specific issue centered on managing biotech facilities projects in a GMP environment. The author uses real-world examples of common industry

practice to lead you through the idiosyncrasies of a biotech project in an effort to answer some of the more common, and often perplexing, questions that can stand in the way of success. You get a mini seminar on each topic covered. Breaking the project life-cycle into four phases, the text takes you through each phase from the Project Manager's viewpoint. Unlike other books that cover design, technology, and validation in general terms, this book addresses the

industry specific issues that make biotech facilities so costly and difficult to deliver. It puts the pieces of the puzzle together in a manner that increases your opportunity for success. **How Drug Companies Mislead Doctors and Harm Patients** Taylor & Francis  
Harold Kerzner's essential strategies on measuring project management performance With the growth of complex projects, stakeholder involvement, and advancements in visual-



based technology, metrics and KPIs (key performance indicators) are key factors in evaluating project performance. Dashboard reporting systems provide accessible project performance data, and sharing this vital data in a concise and consistent manner is a key communication responsibility of all project managers. This third edition of Kerzner's groundbreaking work, *Project Management Metrics, KPIs, and Dashboards: A Guide to*

*Measuring and Monitoring Project Performance*, helps functional managers gain a thorough grasp of what metrics and KPIs are and how to use them. Plus, this edition includes new sections on processing dashboard information, portfolio management PMO and metrics, and BI tool flexibility. • Offers comprehensive coverage of the different dashboard types, design issues, and applications Provides full-color dashboards from some of the most successful project

management companies, including IBM, Microsoft, and others Aligns with PMI's PMBOK® Guide and stresses value-driven project management PPT decks are available by chapter and a test bank will be available for use in seminar presentations and courses Get ready to bolster your awareness of what good metrics management really entails today—and be armed with the knowledge to measure performance more effectively. Research and

Development of Vaccines and Pharmaceuticals from Biotechnology John Wiley & Sons

This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science,

degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide

enough of a benefit to justify the cost and time in a fast-paced product development environment. This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition,

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effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment.

### **A Lifecycle Approach to Knowledge Excellence in the**

### **Biopharmaceutical Industry**

Gower Publishing, Ltd. 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. *Solid Form and Drug Development* CRC Press This book provides practical guidance for corporate decision makers, project managers, project engineers, and for those wishing to grasp the key issues that define project success. The book represents a distillation of

years of practical experience and offers a clear and concise 'blueprint' for how to approach projects and their management. This book is designed to be 'clean and simple' in its delivery - allowing the reader to immediately have 'take aways' that could be implemented within a project, adding value to any approach dealing with the key common problems and issues that arise within the project medium. The book can be applied to a wide range of scenarios in

which project management is required - from setting up an organisation, creating distribution networks, bringing new technology to market, and to designing a leadership and training architecture within an organisation. The book, in addition to being a go-to reference book on project management for professional project managers and business leaders, is also ideal for postgraduate and undergraduate students studying project

management. It is written to be user friendly, yet provides a wealth of information and tips that will enhance the readers knowledge and understanding of managing projects.

**Project Management for the Pharmaceutical Industry** Routledge

The concept of sustainability has grown in recognition and importance. The pressure on companies to broaden their reporting and accountability from economic performance for shareholders, to

sustainability performance for all stakeholders is leading to a change of mindset in consumer behaviour and corporate policies. How can we develop prosperity without compromising the life and needs of future generations?

Sustainability in Project Management explores and identifies the questions surrounding the integration of the concepts of sustainability in projects and project management and provides valuable guidance and insights.

Sustainability relates to multiple perspectives, economical, environmental and social, but also to responsibility and accountability and values in terms of ethics, fairness and equality. The authors will inspire project managers to be aware of these considerations, and to apply them to the role they play in projects, not just 'doing things right' but 'doing the right things right'.

**Pharmaceutical and Biomedical Project Management in a Changing Global**

**Environment** CRC Press  
A new edition of the most popular book of project management case studies, expanded to include more than 100 cases plus a "super case" on the Iridium Project  
Case studies are an important part of project management education and training. This Fourth Edition of Harold Kerzner's Project Management Case Studies features a number of new cases covering value measurement in project management. Also included is the well-received "super case,"

which covers all aspects of project management and may be used as a capstone for a course. This new edition: Contains 100-plus case studies drawn from real companies to illustrate both successful and poor implementation of project management Represents a wide range of industries, including medical and pharmaceutical, aerospace, manufacturing, automotive, finance and banking, and telecommunications Covers cutting-edge areas

of construction and international project management plus a "super case" on the Iridium Project, covering all aspects of project management Follows and supports preparation for the Project Management Professional (PMP®) Certification Exam Project Management Case Studies, Fourth Edition is a valuable resource for students, as well as practicing engineers and managers, and can be used on its own or with the new Eleventh Edition of Harold Kerzner's

landmark reference, Project Management: A Systems Approach to Planning, Scheduling, and Controlling. (PMP and Project Management Professional are registered marks of the Project Management Institute, Inc.) Task Management and Practical Knowledge CRC Press 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.

Delivering Patient Value for Pharmaceuticals and Biologics Routledge  
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 biomedical 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.

*The Silver Bullets of Project Management* John Wiley & Sons  
This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation's knowledge

assets can provide a path towards business excellence.

*Mastering Technology from Planning to Launch and Beyond* Springer Nature

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.

**Engineering Fundamentals: An Introduction to Engineering, SI Edition**  
CRC Press  
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. *Polymorphism in the Pharmaceutical Industry* John Wiley & Sons  
As a companion guide to portfolio management, this book is primarily grounded with the Standard for Portfolio Management -4th Edition. This book is designed for three primary audience groups: Business Executives, Portfolio Leaders and Practitioners, and Portfolio Thinkers. *Business Development for the Biotechnology and*

*Pharmaceutical Industry* John Wiley & Sons  
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. [A Guide to Effective Project Management, Patenting and Product Registration](#) John Wiley & Sons  
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 healthcare professional. Using easy-to-follow  
needs of today's Project Management for language, it expl  
Healthcare fills this need.

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