Wiley Series on Technologies for the Pharmaceutical Industry
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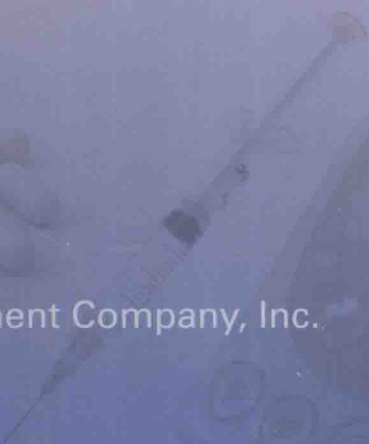
# PHARMACEUTICAL AND BIOMEDICAL PROJECT MANAGEMENT IN A CHANGING GLOBAL ENVIRONMENT



Edited by
**Scott D. Babler**
Integrated Project Management Company, Inc.

WILEY

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Edited by

**SCOTT D. BABLER, MA, MBA, PMP, CSSBB**
Integrated Project Management Company, Inc.

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# FOREWORD

Within the past decade, many books have been written on the science, profession, and application of project management. Most organizations have recognized that, regardless of the level of innovation, intellectual property, resources, and capital, nothing matters without quick, reliable, and effective execution. Additionally, today we face a new and imposing reality: the need to compete in a very turbulent and global economy—a situation that will not likely change; it is the new normal. While this condition may have been aggravated by the economic recession that began in 2008, the downturn only accelerated the inevitable. Globalization of world markets, a shift in wealth and economic power, political instability, natural resource constraints, expanded and diverse supply chains, and accelerated technological advancements are but a handful of influences that will directly or indirectly impact businesses for the foreseeable future. Our new normal requires organizations to be globally insightful, innovative, flexible, and extraordinarily responsive to new and better information that may impact business or strategy. Organizations will need to create cultures that thrive on uncertainty and rapidly changing competitive scenarios. As stated in Philip Kotler and John A. Caslione's recently published book, *Chaotics: The Business of Managing and Marketing in the Age of Turbulence*, "The economic downturn is part of a continuous oscillating Age of Turbulence, where both risk and opportunity are quickly felt around the world, now inexorably linked by globalism and technology. It's a world that chews up the unprepared, but rewards the prepared—those robust companies that have the ability to quickly anticipate and effectively respond to potential threats."[1]

Complex, highly regulated industries with globally dispersed organizational structures will face an unprecedented challenge to synchronize efforts to elicit the greatest benefit from its talent pool and produce better, sustainable results faster than ever. Synchronization is the process and cultural tendency by which organizations endeavor to drive collaboration and knowledge-sharing among internal cross-functional groups, while maintaining functional focus,

[1]Kotler, Philip and Caslione, John A. (2009). New York, *Chaotics: The Business of Managing and Marketing in the Age of Turbulence*, Book jacket.

innovation, and continuous improvement. Ironically enough, high performing functional organizations often tend to misuse internal competition to motivate functional members at the expense of overall organizational performance. The sensibility of synchronization is intuitively obvious. Notwithstanding, many companies continue to operate with models and cultures that are hindered by silos that continue to measure performance and contributions within the referenced functional borders. The ability of organizations to establish and maintain functional excellence while creating even greater functional synchronization is essential if organizations expect to capitalize on their capabilities while evolving an agility to maneuver quickly and effectively.

This book, *Pharmaceutical and Biomedical Project Management in a Changing Global Environment*, focuses on one of the most complex industries on this planet ... an industry designed to provide unparalleled benefits to mankind. It is also an industry that is fraught with extraordinary risks, regulatory controls, and fierce competition, yet offers great financial and humanitarian opportunities. This book examines the progressive role of professional project management and its impact as viewed through the eyes of several industry leaders who have personally experienced the trials and tribulations associated with prioritizing and managing portfolios designed to rapidly move from innovative research to discovery to commercialization in a complex and shrinking world.

With diverse operating companies spread across the globe and an increasing number of mergers and acquisitions, many life sciences companies have learned to create synchronicity among a myriad of cross-functional teams whose goals are to drive innovation from the labyrinth of laboratories, alliances, suppliers, and regulators, to medical professionals and consumers across broad and diverse markets. The coincidental evolution of professional project management has provided a methodology to convert the forces of turbulence into productive energy and measurable results.

We thank the brilliant and extraordinarily busy individuals who agreed to collaborate with Integrated Project Management Company, Inc. (IPM) team members to make this book possible. It is our hope that the experiences shared within this text either reinforce an understanding or establish a new-found perspective on the impact that process, discipline, and leadership, delivered through professional project management competency, can have on an organization's ability to sustain and thrive in both good and difficult economic times.

*Founder and CEO*
*Integrated Project Management Company, Inc.*

C. RICHARD PANICO

# PREFACE

The development and support of biomedical products has always been a complex challenge because of the very stringent requirements for quality, patient safety, product efficacy, and regulatory compliance. Hundreds of professionals are needed to take a promising technology and product concept through a successful launch, and then support the product throughout its lifecycle. Thousands of activities and deliverables must occur in the right sequence. Companies continually strive to reduce the costs of creating novel products and speed their entry into the marketplace, while maintaining requisite high quality standards. However, the best technologies and product concepts will not reach the marketplace without effective, efficient management of the development process and outstanding execution of well-designed plans.

This book is part of Integrated Project Management Company, Inc.'s (IPM) continual efforts to advance the project management discipline in biomedical industries (BMIs). The goal of this volume is to describe the significant impact that professional project management has made on developing and supporting these highly technical, regulated, lifesaving products. We have seen its positive effect on catalyzing organizations' capabilities, improving synergy, accelerating execution, and assuring delivery of efficacious products to the market, both quickly and cost effectively. The intent of this book is to provide an educational source that can be referenced by industry leaders, project managers, and decision makers to improve the application of project management tools and approaches on the challenging problems faced by their companies. Students of the biomedical industry and project management will also find this a valuable reference.

The biomedical industry thrives only through true innovation and continually adapting to the moving boundaries imposed by breakthrough technologies. Each new product can require significant process changes from earlier ones. Globalization, changing regulatory requirements, continual quality improvements, and ever-changing competition define the rapidly evolving BMI landscape. Teams must reinvent their processes as the environment evolves. Change management has become a critical core competency for project success that managers must master. These are but a few of the forces that must be controlled and harnessed by project teams.

The book discusses the application of BMI project management in as many settings as possible. Authors were invited from across the BMI landscape to share their practical experiences and approaches, which have been tested in many different organizations. These expert contributors come from pharmaceutical, medical device, biotechnology, venture capital, consulting, and nonprofit organizations, with a wealth of experience from dozens of companies. They come from large, long-established, multi-national companies and small start-ups. Their expertise covers most functional disciplines involved in managing BMI enterprises and provides a very broad yet detailed understanding of the challenges and solutions faced by this industry. The authors have selected concepts, ideas, and examples that provide a framework for understanding the use of project management tools for achieving superior results. The insights they share are best practice solutions that have been tested in the real world and proven to be successful.

Writing this book in many ways paralleled the process and characteristics of the BMI projects that are described in it. It required a highly cross-functional team of experts focused on delivering a well-defined product. This virtual alliance team was geographically dispersed throughout the United States and Europe. The design goals for the product components (chapters) needed to be clearly communicated. Process stage gates helped focus team member energy and the timely delivery of the prototypes (chapter drafts). Risk management was used to accommodate necessary changes that inevitably occur.

The topics discussed here cover many of the key challenges involved in making BMI products. The authors have shared their seasoned expertise to prepare this composite view of achieving project excellence. We hope this volume provides leaders, practitioners, management, and students of BMI a valuable guide to the application of project management in these industries.

*Senior Project Manager*
*Integrated Project Management Company, Inc.*

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MA MBA PMP CSSBB

# ACKNOWLEDGMENTS

As with any of the complex BMI projects described in this book, an excellent outcome is dependent on the efforts of the team. This book was no different. The hard work and dedicated efforts of all who participated have made the result greater than the sum of its parts. The authors brought enthusiasm, creativity, clear thinking, extensive knowledge, and a wealth of experience to their chapters. I want to thank each of them for their participation and contribution. They found time in their extremely hectic schedules to discuss, write, and finalize the chapters. Their stimulating conversations, diligent work, and good humor resulted in the wide range of ideas that have been included and made the process very enjoyable. It has been a professional and personal pleasure to work with each of them. Their insights have produced a book that accurately reflects the realities of work in biomedical product companies.

I want to thank IPM's founder and CEO, Rich Panico, for his enthusiastic support and encouragement for this project. His vision and inspiration serve as a model to all who know him. I also want to thank Jo Jackson for her enthusiastic help in setting up the relationship with Wiley and her strong support of this project.

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| AIDS | acquired immunodeficiency syndrome |
| API | active pharmaceutical ingredient |
| APM | Association for Project Management |
| CAGR | compounded annual growth rate |
| CCP | critical control points |
| CDSCO | Central Drugs Standard Control Organization |
| CEDD | Centers of Excellence for Drug Development |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendment |
| CLOGS | creams, liquids, ointments, gels, and suspensions |
| CMC | chemistry, manufacturing, and controls |
| CNF | change notification form |
| COGS | cost of goods sold |
| CRAs | clinical research associates |
| CRF | case report forms |
| CRO | clinical research organization |
| CTA | clinical trial application |
| CTD | common technical document |
| DCGI | Drugs Controller General of India |
| DDP | design and development plan |
| DHR | device history record |
| DIRs | design input requirements |
| DMF | drug master file |
| DP | development plan |
| DSI | Division of Scientific Investigation (FDA) |
| eCTD | electronic common technical document (drug registration) |
| EMEA | European Medicines Agency |
| eNPV or ENPV | expected net present value |
| FD and C Act | Federal Food, Drug and Cosmetic Act |
| FIPNet | fully integrated pharmaceutical network |
| FMEA | failure modes and effects analysis |
| FO | functional outsourcing |

| | |
|---|---|
| FSFV | first subject first visit |
| FSP | full service provider |
| FTE | full time employee or full time (employee) equivalents |
| GCP | good clinical practice |
| GLP | good laboratory practice |
| GMP | good manufacturing practice |
| GSK | Glaxo SmithKline |
| GxPs | good X practice (X can be clinical, manufacturing, pharmaceutical, etc.) |
| HMSC | Health Minister's Steering Committee |
| IB | investigator's brochure |
| IC | innovator company |
| ICF | informed consent form |
| ICH | International Conference on Harmonization |
| ICMR | Indian Council of Medical Research |
| IEC | independent ethics committee |
| IMPD | investigational medicinal product dossier |
| IND | investigational new drug (application) |
| IP | intellectual property |
| IRB | institutional review board |
| IRR | internal rate of return |
| ISO | International Organization for Standardization |
| IVD | *in vitro* diagnostics |
| IVDMIA | *in vitro* diagnostic multivariate index assay |
| IVRS | interactive voice response system |
| JSC | joint steering committee |
| KPI | key performance indicator |
| LCP | life cycle plan |
| LOE | loss of exclusivity |
| LSLV | last subject last visit |
| M2M | machine to machine communications |
| MAA | Marketing Authorization Application |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| MNEs | named new molecular entities |
| MSA | master service agreement |
| NDA | new drug application |
| NICPBP | National Institute for the Control of Pharmaceutical and Biological Products |
| NIH | National Institutes of Health |
| NPV | net present value |
| O & I | opportunities and ideas |
| OEM | original equipment manufacturer |
| OTCs | over the counter drugs |
| PDR | prototype design requirements |
| PET | positron emission tomography |

| | |
|---|---|
| Pharma | pharmaceutical (or pharmaceutical industry) |
| PhRMA | Pharmaceutical Research and Manufacturing Association |
| PI | principal investigator |
| PMA | pre-market approval |
| PMBOK | Project Management Book of Knowledge |
| PMC | post-marketing commitments |
| PMI | Project Management Institute |
| POC | proof of concept |
| PRAM | project risk analysis and management |
| PRM | project risk management |
| PSD | particle size distribution |
| QA | quality assurance |
| QC | quality control |
| QSR | quality systems regulations |
| RC | traditional contract manufacturing company |
| RFP | request for proposal |
| RL | receiving labs |
| RNAi | RNA (ribonucleic acid) interference |
| ROC | return on cost |
| Rx | prescription (pharmaceutical) |
| SFDA | State Food and Drug Administration |
| SGP | stage gate process |
| shRNA | short hairpin RNA |
| siRNA | small interfering RNA |
| SL | sending labs |
| SLA | service level agreement |
| SOP | standard operating procedure |
| SPECT | single photon emission computed tomography |
| TFL | study tables, figures, and legends |
| TGA | Therapeutic Goods Administration |
| TMF | trial master file |
| TPD | Therapeutic Products Directorate |
| TPP | target product profile |
| Tufts CSDD | Tufts University Center for the Study of Drug Development |
| UK | United Kingdom |
| US | United States |
| VDPC | virtual drug product company |

# CONTENTS