Portfolio, Program, and Project Management in the Pharmaceutical and Biotechnology Industries
For the six diamonds in my life:
Inge, Emily, Bill, Alex, Alex, Hendrik
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Integrated Portfolio, Program, and Project Management (P³M) is recognized across industry sectors as the most effective way to get things done. This is as true for large capital projects, found in civil engineering, defense-aerospace, and building, as it is for new product development, and organizational change initiatives. Driven by the need for well-controlled delivery of work, the art and science of P³M has been developing inexorably since the late 1950s, when the idea of project management as a distinct discipline began to become accepted by government and commercial organizations.

Project management in the life science sector did not become established as a credible approach to managing product development work until the early 1980s. The adoption of project management across the sector has been patchy and inconsistent, despite the huge business benefit that this approach has brought to almost every other industry. The number of books available on P³M as applied to drug development is very limited. Few journal articles are available on the subject, and there is almost no research published. Medical device project management fares better. This is unsurprising given the established project approach to managing product design with strong engineering and technical content.

The book is about the current and future way that the life science sector (pharmaceutical, biopharmaceutical, biotechnology, and biotherapeutic) projects and programs can be managed. All application of P³M is context dependent, and the pharmaceutical and biotechnology sector has a more challenging context than many others. There is, however, increasing appetite within the industry to embrace the advantages that a project-oriented approach to managing drug development work can bring.

Driving the move toward further and deeper projectization of product development in the sector are several factors. The industry is struggling to provide sufficient numbers of people with the knowledge and experience required to develop enough of the compounds coming out of discovery to meet patients’ needs. This lack of capacity is arguably one of the biggest inhibitors to development of new drugs and devices. There are tremendous revenue pressures on the industry, coming from both generics competition, and Government and other payers. The time scales for products to reach market have not decreased significantly, especially not when viewed in comparison to other new product development sectors. Many of these same factors led other sectors to adopt P³M as a core organizational competence to manage product development. As the industry faces up to the need for more efficient usage of resources (people and materials), better control of development cost, and reduced timelines, the adoption of high-quality P³M is bound to accelerate.
This book brings together the views of many experts on P^3M in life science product development. Some have been, or currently are, academics. Some are practitioners, working to deliver drugs and devices to patients. Some are consultants, working as trusted advisors to life science companies, large and small, to help develop world class P^3M. Yet others have held executive-level positions and write with authority as internal customers of drug program and project teams. When bringing together such a group of writers, with such a wide range of experiences, it is inevitable that there will be a mixture of writing styles. The editing has been deliberately kept to a minimum to ensure that the authenticity of the authors’ voices has been retained. This allows the writers’ authority in their fields to shine through.

The book is formed of three parts. Part One with three chapters sets the scene for the rest of the book by providing the context for P^3M in the life science sector. There are reflections on the current state of project management in life science organizations, the impact of organizational size on P^3M, as well as the specific subsector (pharmaceutical, biotechnology, etc.). Part Two of the book, comprising eight chapters, addresses the major organizational aspects of portfolio and program management, as well as covering the important processes of planning and control, managing program uncertainty, controlling product safety risk, developing program strategy, and managing value throughout the product development life cycle. In Part Three of the book, the final four chapters cover two themes. Two chapters discuss alternative perspectives of the integration of the work for product development. The two final chapters provide insight on the approaches needed to bring about high-quality, high-effectiveness P^3M in life science companies. A bibliography is provided to direct the reader to the literature available, for P^3M generally.

This book can be viewed as the end of the beginning of the application of consistent, formal project management in the life sciences sector. Steady progress over the last 20 years has been made, albeit uneven and often localized. The fact is that other industry sectors with very high levels of uncertainty in their product development processes have adopted P^3M successfully. The outcomes for these sectors include increased profit margins, reduced overall life-cycle time, and more efficient utilization of people and resources. This leads to more products reaching the market. Translated to the drug development sector, this means more diseases can be treated, and more people with the diseases are able to receive drugs. Best practice P^3M will also lead to increased reliability of timelines to deliver products to market, reducing company stock price volatility due to missing promised launch dates.

Life science companies that embrace best practice P^3M will gain significant competitive advantage. The authors in this book provide the knowledge and insight to help create that competitive advantage.

Pete Harpum
First and foremost, I would like to thank all the authors for their contributions to the book. They all work hard in their different roles within the life sciences sector, and they have each made significant contributions of knowledge, insight, thought, and much effort with their chapters. This book project has taken a great deal of time to put together (with much schedule slippage!), and all the authors have shown great patience with me as I have worked through the editing process. My naïve belief that adopting a “less is more” approach to the editing would keep the book to Wiley’s original deadlines has been cruelly exposed to all involved. I have also had the pleasure of working with an equally patient editor from Wiley-Blackwell, Jonathan Rose, who has remained polite and reassuring at all times, despite my constant requests for just another few months. Lauren Hilger, Editorial Assistant at Wiley-Blackwell, also deserves many thanks for her continuous advice and support as the manuscript was finalized.

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For permission to use copyrighted material, I wish to thank the following: John Wiley & Sons Inc., for the reproduction of Figures 7.1, 7.2, and 7.12; Merriam-Webster Inc., for the definition of “uncertainty”; INSEAD, Fontainebleau, France for the reproduction of a Case Study: The Development of Nopane, and Macmillan Publisher Ltd., for the license to use Figure 11.14.

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Stephen has over 30 years of experience in the pharmaceutical and health-care sector, latterly working with GlaxoSmithKline (GSK). A pharmacologist by training, he has extensive international operational, project management, and portfolio management experience.

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Dr. Bennett worked for Pfizer Global Research and Development for 21 years, starting in the research laboratories before moving to project management where he shepherded many candidates at all stages of development. He then spent a period designing and implementing project management processes and systems, knowledge management, risk and resource management systems, as well as making significant contributions to a number of global process improvement initiatives as Head of Project Management Operations and Development. He spent the last 9 years as a portfolio manager, initially looking after exploratory development candidates and, more recently, the pain, allergy and respiratory, genitourinary, and gastrointestinal therapeutic areas. He is currently an independent pharmaceutical consultant specializing in the design of drug development programs, project, portfolio, and risk management.
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Dunson has over 20 years of combined project management and clinical development experience at both public and private pharmaceutical and contract research organization companies. Dunson possesses a strong working knowledge of contemporary project management standards and practices, and is a certified Project Management Professional. He has authored or co-authored over 30 peer-reviewed manuscripts, book chapters, and monographs on a wide variety of topics as well as delivered numerous project management training sessions. Randy has served as First Vice Chair of the Project Management Institute (PMI) Pharmaceutical Specific Interest Group since 2004.

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Fisher is a seasoned management consultant, with specialist expertise in the assessment and development of people, across a wide range of industries, in both private and public sectors. She has led interventions at all levels of the organization, from restructure, through team development activities, to individual coaching assignment with senior managers. Fisher’s approach to supporting organizational success is to emphasize the critical role of individual employee’s motivation and competence in achieving the desired outcomes of structures and processes.

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Grogan is currently Senior Director, Strategic Planning, for Becton Dickinson’s bioscience division in San Jose, California. He is responsible for strategic planning, portfolio management, and strategic marketing for their pharmaceutical and software businesses. Grogan’s earlier experience includes bench scientist, university research associate, biotechnology marketing consulting, and later, portfolio management at...
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Jamieson has many years of project management experience in global aerospace. He has worked with Professor Peter Morris on research projects including translating corporate strategy to project strategy, and revising the APM Body of Knowledge. In 2009, he completed a research project in best practice project management life science R&D. Jamieson is a consultant with Harpum Consulting. He contributed to the Wiley Guide to Managing Projects (2004), the Gower Handbook of Project Management (2007), and co-authored Translating Corporate Strategy into Project Strategy: Achieving Corporate Strategy through Project Management (2004).

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Susan is currently Executive Director, Global Project Management at Novavax, Inc., with responsibility for integrating planning and operations across discovery, pre-clinical, clinical, manufacturing, and commercial development. Linna’s prior experience includes Vice President of Project Management Office at Emergent BioSolutions; Director of Project Management, Human Genome Sciences; and Project Manager at Merck. Susan has worked on many drug compounds, including Aggrastat®, Trusopt®, Vaqta®, Varivax®, Merck’s Hepatitis A and Varicella vaccines, as well as alliance projects for LymphoStat-B and Albuferon.

Robert (Bob) Moore
Moore has spent over 30 years in a broad spectrum of Clinical Research and Development areas, from the Cardiovascular Lab, to Clinical Information and IT, to Project and Portfolio Management. He retired from Pfizer Global Research & Development as Executive Director, Worldwide Project Management in 2007. After relocating to the southern coast of North Carolina, he continues to provide consulting assistance to other pharmaceutical companies, carefully balanced with boating and golfing recreation.

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Morfin is a drug and device project executive, and has been a life sciences project manager since 1987. Morfin has been published many times in project management magazines and pharmaceutical publications, and founded the independent BioPharmaPM network. As Chief Partner at Critical Skills, Eric has worked and consulted with small start-up biotechnologies as well as global pharmaceuticals for
over 20 years, making him well qualified to compare project management for drug development best practices across a wide range of companies and countries.

**Martin Powell**

Martin Powell is Director of Projects at the London Development Agency, the Mayor of London’s agency for economic development. He is responsible for the delivery of the agency’s capital projects, ranging from physical infrastructure projects to environmental and climate change initiatives, and also for the agency’s project management improvement program. He is also Managing Director of Cambridge Management & Research Ltd., which specializes in a range of project management solutions from process gap analyses through to project reviews and hands-on project delivery.

**Pauline Stewart-Long**

Pauline Stewart-Long is Vice President of Global Project Management for GSK R&D. She is responsible for the long-term capability development of project management as a professional discipline at the company. Prior to this role, Stewart-Long’s work has included positions as a portfolio manager and project manager, and early on in her career, as a clinical research assistant. She has a PhD in Biochemical Nutrition from Cambridge University. She is a member of the Pharmaceutical Industry Project Management Group, the Drug Information Association, and PMI, and represents GSK on the Human Systems Project Management Knowledge Network.
Part One

The Life Science Industry Context for Portfolio, Program, and Project Management

Since context is vital to understanding the application of portfolio, program, and project management (P3M) – in any sector – the first three chapters in this section provide this background. The authors remind us of the complexities of the product development environment, including:

- Great uncertainty of the outcome of experiments
- High rates of attrition, particularly in the early stages of the life cycle for drugs
- Fluidity of the regulatory environment
- High costs of development through the life cycle to launch
- Long time frames from new chemical entities (NCEs) coming out of discovery to new drug application (NDA) submission
- Great variation in size of firms in the sector, from “big pharmaceutical” companies with tens of thousands of employees, to start-ups and virtual biotechnologies with less than 10
Significant differences between pharmaceutical, biotechnology, biopharmaceutical, biotherapeutics, medical devices, and diagnostic and imaging subsectors.

In Chapter 1, Thomas R. Dunson provides a comprehensive overview of the application of P³M across the different life science sectors. He also discusses the fundamentals underpinning the notion of project management itself, in the process describing the two most well-established bodies of knowledge for project management.

Eric Morfin follows with a chapter that presents the implications of organizational size on the way P³M is operationalized. He covers the impact of organizational culture, styles of leadership, the impact of the need to prioritize resources in larger companies with bigger pipelines of products, and the way in which different organizational structures intersect with P³M processes.

The final chapter in the section by Susan Linna looks specifically at the challenges of bringing effective P³M to product development in the biotechnology sector. Linna covers the specifics of the transition from research to development (regulatory regimes, manufacturing and control, routes of administration, and others). She also describes how P³M can support decision making and capacity management. The need for senior management support for effective P³M is also described, with a detailed explanation of why this is so important.
Chapter 1

A Review of Project Management in Life Science Industry Sectors

Thomas R. Dunson

This chapter aims to provide an overview of the way project management differs in its application across the pharmaceutical, biotechnology, and contract research organization (CRO) sectors.

Considering the complex nature of drug development projects and the high cost of being late to market (or failing late in the development life cycle), it would seem intuitive that project management would flourish in the life science sector. However, the industry has been slow to implement project management practices and is thus behind other industries in this area [1, 2].

Still, the importance of project management is recognized: it is seen by many companies as a pivotal contributor to getting products to market and achieving excellence in drug development [2, 3], and more emphasis is being placed on the application and development of project management practices in the industry than at any previous time.

PROJECTS AND PROJECT MANAGEMENT

Projects have a definitive start and end, and their end products should be different from other products and services.

A project is a temporary endeavor undertaken to create a unique product or service [4].
Many organizations use projects to do those activities that cannot be performed with normal operations or processes (often referred to as “business as usual”). By definition, as projects are unique, there is more uncertainty, and thus, risk and opportunity in project-oriented work compared with normal operations. Turner [5] states that organizations use projects when their business objectives are achieved more effectively by projects, that is, when benefits are bigger than the risks associated with the work.

Changes in the business environment generally have promoted the use of projects. Rapid technological change has made the future of businesses unpredictable, globalization has changed market structures, and deregulation has transformed industry structures [6]. Organizational structures need to be flexible to enable fast responses to changes, and projectization is a key way to create flexibility in organizations [7]. In addition, in a networked business environment, projects support knowledge-intensive operations that now form the core of many organizations [8].

Projects can be divided roughly into two groups: external and internal projects. For example, research and development (R&D), internal process development, business change, and reengineering projects represent internal projects, while customer delivery projects are external projects [8]. All these projects are different in nature and their special features must be taken into account when managing projects.

Turner [9] created a classification that distinguishes four project types according to how well project goals are defined and how well the working methods used for reaching the goals are defined (see Fig. 1.1). Turner also suggests that when goals and methods are well defined, the chance of success increases, while the chance of success is smaller when goals and methods are not well defined. New product development projects are located in the upper left quadrant while research projects are situated in the upper right corner of the figure.

There are differences in the way project processes, stages, and life cycles are defined. Turner identifies four stages [10]:

1. Proposal and initiation
2. Design and appraisal
Chapter 1 A Review of Project Management in Life Science Industry Sectors

Table 1.1 Project Management Knowledge Areas (Adapted from PMI) [11]

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Table 1.2 Project Management Knowledge Areas (Adapted from APM) [12]

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3. Execution and control
4. Finalization and closing

On the other hand, the Project Management Institute (PMI) [11] defines these stages to be also management process groups (see Table 1.1) that appear at all project life-cycle stages. After each stage, a tangible product should be completed, for example, a feasibility study or a prototype. All stages start with initiation and planning and move through execution and control to closing. After each stage, there is a review of project performance and deliverables, and it is determined whether the project should continue to the next stage.

The PMI in the United States (Table 1.1) and the Association for Project Management (APM) in the United Kingdom (Table 1.2) both publish bodies of knowledge regarding what is considered to be core project management knowledge.

Risk management is one of the knowledge areas, but its importance is great in completing projects successfully mainly because of the inherent uncertainty prevalent in them. Turner [5] states that risk management is “the essence of project management.” Also, in Artto’s [6] opinion, risk management is a vital function of project management. The importance of risk management has grown lately because of the increased uncertainty in doing business and risk management’s potential value for business.
Programs and their management represent a further consideration of project management. A program is defined to be:

A group of related projects managed in a coordinated way. Programs usually include an element of ongoing work. [13]

Many methods and tools that are used in project management are also used when managing programs. There are, however, slight differences in the focus areas and importance of the methods. A project manager must concentrate on the special features of projects, on managing people, and on the desired results. Project management can be seen to consist of different knowledge areas and processes (Table 1.1). They are all highly interconnected, some dealing with performing project work and some supporting the work.

Project management is the application of knowledge, skills, tools, and techniques to project activities to meet project requirements. [14]

LIFE SCIENCES NEW PRODUCT DEVELOPMENT PROJECTS

Most life science projects are huge in terms of money and time consumed, and human resources required. In fact, a drug development or medical device project constitutes managing many subprojects performed by different line organizations such as the preclinical studies, clinical studies, process development, and marketing planning. Even most Phase III studies (large clinical studies) would be regarded as big projects in other industries. Thus, the drug development project particularly could also be viewed as a program [15]. (See Stewart-Long in Chapter 6 for a detailed discussion of life science program management.)

Particular Issues Facing Life Science Projects

Problems facing particular life science projects should be detected as early as possible, and it is an achievement and not a failure to terminate a project early [16]. According to Lead [17], there are four main causes of life science project problems:

1. Poor resource management
2. Poor project management
3. Insufficient scientific experience
4. Unexpected and difficult technical issues

First, insufficient resources can lead to several problems in executing a project. For example, poor resource management can cause inadequate planning, starting activities too late, corner cutting leading to repetition of tasks, poor quality and mistakes under too much pressure, and overwork resulting in reduced morale and low levels of personal commitment to the project [17].

Second, problems from poor project management usually start from inadequate planning and communication. All project participants should understand who is
responsible for each activity. Communication is also important between various
departments engaged in the development so that no unnecessary delays are passed
on to other departments. To avoid delays in authorization processes, good knowledge
of regulatory requirements is needed. Detection of early warning signals of problems
starting to occur should be one of the main tasks in project management [17].

Third, insufficient scientific expertise is a serious problem. Inexperienced team
members need proper support to plan studies or design work and testing adequately,
and interpret correctly the results gained from the work. A failure in either of the
tasks will result in repetition of activities.

Fourth, unexpected technical problems can occur in every project no matter how
well it was planned. Still, a good project manager can minimize the effects of these
problems by early detection and good problem-solving skills [17]. On the other hand,
Kennedy [18] outlines technical reasons for project failures. As much as 46% of
projects fail because of lack of efficacy. Animal toxicity and adverse effects in man
account for the second biggest reasons for project failures.

The reasons for project problems outlined above do not seem to be different
from problems occurring in other industries. Thus, it could be concluded that life
science projects, even though long, risky, and costly, do not differ too significantly
from the general understanding of project nature. The importance of scientific
knowledge and early detection of problems may be more significant, however, to
avoid repeating expensive and long trials, and to terminate poor performing projects
as early as possible.

Differences between Life Science and Other Sectors’
Project Management Capability

Cooke-Davies and Azymanow [19] studied the differences between project manage-
ment maturity in the pharmaceutical industry and five other industries. Also, big and
medium-sized pharmaceutical companies were compared with each other. The
results showed that medium-sized companies perform better than bigger companies
in three dimensions:

- Strength of project versus functional matrix
- Strength of project culture
- Organizational leadership

The main reason for this was stated as the closeness of project management
to senior management and the proximity of the upper management, in time and
hierarchy, to the management of drug development projects.

However, big pharmaceutical companies scored better in matching the
project team to project stage and type, and in the capability of project management
staff. When pharmaceutical companies were compared with the industries
from which project management practice once initiated, it was clear that these
industries, that is, defense and petrochemicals, performed better. However, the
defense industry scored lower than medium-sized pharmaceutical companies in organizational leadership.

Pharmaceutical companies were also compared with other industries with regard to project management maturity. On average, engineering-based industries of the study, that is, telecommunications and construction, scored better than the pharmaceutical and financial services industries. Pharmaceutical companies performed lowest of all in the extent to which project information is centralized and is under the project’s control. Moreover, big pharmaceutical companies scored extremely low on organizational leadership compared to others. However, as the bright spots for the pharmaceutical industry, medium-sized companies scored second highest, right after construction, in the strength of the project matrix and the project culture [20]. (See also Morfin and Linna, Chapters 2 and 3, respectively, on the impact of organizational size and industry subsector on project management maturity.)

Project Planning Considerations in Life Science Projects

One of the major milestones in drug development projects, if not the most important milestone, is to get marketing authorization from relevant regulatory bodies. Thus, it can be said that in addition to the drug itself, a major end product of the project is the documentation for authorization application. The target is moving constantly during the development time and thus, it is difficult to make specific plans on how to reach the project objectives. Actually, the project team must be prepared to cope with constant changes and failures. Therefore, it is fair to say that planning is at the same time an extremely important and difficult part of project management in the life sciences industry. A further complication is that even though time to market is usually the main objective, many of the critical development activities are incompressible [21].

The opportunities to decrease development time by planning are thus limited. Clinical and toxicology studies are usually those determining the critical path of the project. On the other hand, regulatory guidelines facilitate the planning significantly by giving specific instruction on what studies need to be done, and in which order, to gain the required authorizations [22].

Rolling wave planning [23] is usually used so that only the next phase is planned in detail and the rest of the phases are planned in outline. Before moving to the next phase, detailed planning is conducted. Planning is a team effort with representatives from all line organizations involved in the project.

Development strategies are directed by the target product profile determined at the beginning of the project. The target product profile is the specification of the product that is going to be introduced into the market. It includes the required efficacy and side-effect profile of the drug, how it should be supplied and used, in which patient groups, for what purpose, the time of market introduction, and the cost of goods [24]. (See Chapter 7 by Powell on project control.)
Uncertainty in R&D Projects

All areas of uncertainty are interrelated and define the decision milestones and criteria as well as identify the data that need to be collected. Together, these uncertainties codetermine the data to be collected and the information to be processed to ensure R&D project success.

The information processing capability of an organization is a function of the effectiveness of the organizational infrastructure and the capabilities of its people. These, in turn, are related to the resources allocated to projects, management support, organizational climate/culture, and the interfunctional integration [25].

The more an organization has reduced uncertainty, that is, the more it has closed the gap between the required and available information, the better will be its decision making and implementation of adequate R&D project management [26–30]. Improvement of availability of information and reduction of uncertainty do not in themselves, however, ensure that the “right” decisions will be made or that the “right” outcome will be achieved. Retrospectively defined “bad” decisions will still be made, and they will have an impact on project assessment and project prioritization. Therefore, reduction of uncertainty through the adequate processing of information directly impacts the quality of project management, but cannot guarantee “success.” (See Chapter 8 by Harpum and Dunson, and Chapter 9 by Dunson and Morfin, on project and product uncertainty.)

Role of Project Manager

Because of the highly specialized skills required in the execution of project work, the project manager is responsible only for making sure that the skills within the project team are used and that a good plan for the project is developed. Often, the project manager has no direct authority on the project team members, but rather has an influencing role [21].

The project team is composed of individuals with narrow specialty areas, which makes it more difficult for them to communicate with each other and realize how the contributions of different line organizations fit together. The gaps between team members are further widened by the fact that historically, R&D has been performed in an organizational structure based on strong functional lines [21].

For this reason the project manager needs to have very good interpersonal, leadership, and communication skills to manage the cross-functional project team. As the drug development projects last a long time, the project team develops a strong sense of ownership for the project, and thus it may become extremely hard for them to detect and admit there are problems and to recommend the project should be stopped – or “killed.”

The PMI’s Pharmaceutical Special Interest Group reports interesting results regarding the role of project managers in a survey conducted within the member companies [31]. According to the results, experienced project managers are mainly
viewed as good technicians who can keep track of time and cost but who do not provide the leadership skills of communication and risk management. Additionally, experience in project management has mainly come from other industries. Practitioners in the industry still continue to believe project management is different in the pharmaceutical industry.

Considering the important role of innovation and new product development for life sciences companies and the risks inherent in the projects, it seems surprising that project managers do not enjoy a privileged and recognized position of leading the most vital long-term operations of the firm. Because of the great impact of drug development projects, success and failure for the long- and short-term health of the company project managers should, without doubt, be empowered more to be able to ensure that enough suitable resources and senior management support are given to new product development projects.

It can be concluded that project management practices are not significantly different from other industries. Other sectors have long projects, with significant change over the life cycle, and have tight regulatory requirements affecting the planning process (aerospace is a good example). The level of technical uncertainty does pose significant challenges for planning and monitoring practices in life science new product development projects. Furthermore, project management is less mature, especially in the big pharmaceutical companies, than in other industries.

OVERVIEW OF PORTFOLIO MANAGEMENT IN LIFE SCIENCE ORGANIZATIONS

Pharmaceutical portfolio management is discussed at length by Bennett in Chapter 5; therefore, only an overview is presented here.

The late 1990s and early 2000s have emerged as periods of change. It is an era in which rapid changes are a pervasive characteristic of life science markets [32, 33]. There will be rewards for companies that develop strategies and practices that thrive within this evolving, complex, and dynamic environment. Keys to success include effective and efficient business practices and the effective use of sound, competitive intelligence [34, 35]. The awareness of these trends and potential discontinuities and how they affect firms have a direct impact on R&D project selection and organizational focus.

The Need for Effective Portfolio Management in All Sizes of Life Science Companies

The chaotic nature of the environment, for life science particularly, holds true also for the lengthy and complex drug R&D process. In all organizations, there are finite resources, budgets, and capacity. Likewise, organizations often have more work to do than can be done within those limitations. Therefore, an efficient and effective process to determine which projects should be fully resourced and funded internally, which should be outsourced, and which should be stopped can lead to true competi-
tive advantage. On the other hand, R&D, by definition, is not an “absolute,” nor does carrying it out well guarantee, success. R&D is a process designed to minimize uncertainty and gain clarity. A limited number of compounds achieve a “success,” that is, a market launch [36].

Based on these real-life issues, there is a growing commercial pressure to increase R&D productivity while controlling costs. An effective R&D project portfolio management process can help achieve this objective [37–41]. Regardless of company size, new product development portfolio management should be an integral part of corporate culture and business processes.

An effective R&D portfolio management process is essential to all companies regardless of size. Large companies often have numerous projects at various stages of development. Therefore, if an error is made and a few of the “wrong” projects are pursued, the overall negative impact can be minimized because of the depth of a large portfolio.

On the other hand, small companies generally only have one project or “platform” upon which to grow their company. Therefore, there is a tremendous amount of focus and knowledge on that key project or platform. In these cases, there is no real R&D portfolio to manage, but rather, there is a need to manage very limited resources on the critical aspects of the development of the lead project or platform technology. If a wrong decision is taken, the consequences can be devastating.

For medium-sized companies, a critical mass has been established, but wrong decisions about R&D projects can lead to a significant business downturn. Medium-sized companies, by definition, do not have a large R&D project portfolio so there is a limited ability to absorb mistakes. For these companies, an effective R&D project management process is essential. Based on this scenario, it appears that medium-sized organizations have the most to lose from making the wrong choice or ignoring the need for portfolio management overall.

**Specific Portfolio Management Challenges for Biotechnology Companies**

For a biotechnology firm, the portfolio is typically a complex assortment of internal product development projects, partnerships, and out-licensing agreements. Companies are tasked with determining the right mix of internal and external efforts in the face of staff and funding constraints. They face continual challenges:

- How can they best leverage their technology to create value?
- Should they focus on several large projects, or on a greater number of smaller efforts?
- What are the resource forecasts across all projects, and where is the uncertainty?
- Should biotechnology companies seek additional funding to tackle more projects, and if so, how and when?
The rapid growth of the biotechnology industry as the backbone of high-technology, highly specific, and effective new medicinal therapies have had a profound effect on the life science industry. The ability to genetically modify living organisms to produce a range of medicines has contributed to a plethora of biopharmaceuticals being developed. In 2000, 28 major protein-based products generated US$13.3 billion of sales and in 2002, there were 99 protein-based therapeutics in Phases III and II clinical testing [42]. However, the process of bringing these products to the market is a costly and risky business. On average, it takes 7.7 years to bring a biopharmaceutical product to market [43] and costs over US$800 million, and this cost of R&D for new drugs has been on the rise for the past two decades [44].

Given the uncertainty associated with drug development, biotechnology and biopharmaceutical companies usually require a constant pipeline of drugs to remain in business. Speed to market and pressure to reduce costs are critical factors driving the need for more effective means of assessing the value and risks of such drug portfolios.

**Portfolio Management for CROs**

Portfolio management in CROs is entirely different when compared to other life science sectors. CROs do not plan on specific projects and how they will affect their pipelines. Rather, portfolios are an amalgam of all of the projects that a particular CRO might be managing at any point in time.

Portfolio management in these companies is driven by revenue recognition. Although the actual process may vary across companies, individual projects are frequently assessed and “rolled up” to all projects for assessment on a monthly or quarterly basis. Forecasting is frequently utilized to determine revenue at points in time and going forward on a yearly basis. A CRO can then make fairly reasonable projections on resource utilization and revenue recognition based on overall project forecasting.

**MANAGING VALUE**

Regardless of the development stage of a given project, an objective assessment of its potential value and strategic fit needs to be done. It is not uncommon for new product development projects to be obsessively pushed by project champions. Although project champions provide a very valuable service to every organization, their unbridled enthusiasm for “their” projects often leads to a biased view of project value and overall strategic fit. A new compound that is highly attractive from a scientific point of view may or may not be a promising candidate from the marketing and business perspective. A new mechanism of action that does not translate into a competitive advantage is interesting but may not be a good or profitable product.

If the proposed product targets a competitive advantage in an existing, well-defined market, then it will be easier to forecast its potential commercial success and benefit. If the product is extremely novel and will create a new market, it will be harder, but not impossible, to forecast commercial benefit at any stage of devel-