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 (P^3M) – 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

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- 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].

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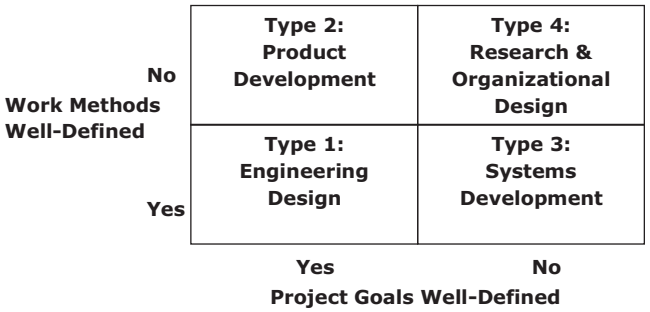

Figure 1.1 Goals and methods matrix (adapted from Turner) [9].

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

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

Project management knowledge areas
Project integration management
Project scope management
Project time management
Project cost management
Project quality management
Project human resource management
Project communications management
Project risk management
Project procurement management

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

Project management knowledge areas
Project management in context
Planning the strategy
Executing the strategy
Techniques
Business and commercial
Organization and government
People and the profession

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 management 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-

opment. This, however, is where an in-depth understanding of R&D portfolio management and effective use of detailed "competitive intelligence" needs to occur. A balance needs to be struck between long- and short-term strategic business needs with an eye toward what is best for the company, and what offers the greatest medical benefit to customers, physicians, and patients.

An integrated R&D portfolio management process needs to incorporate both early stage projects (ESPs) and development projects (DPs). Due to the distinct differences between them, however, they need to be treated differently. ESPs are pre-investigational new drug (pre-IND) projects and DPs are those in human pharmacology and/or clinical research but have not obtained regulatory approval.

Because of the length-of-time-to-market differences between ESPs and DPs, there is an inherent difference in level of uncertainty between these groups of projects. Therefore, in any comparative financial calculation, ESPs will always be at a disadvantage and come out low in the priority ranking (assuming that financial measures are the only parameter used for prioritization). Although in general DPs have a lower degree of uncertainty, each project is unique and needs to be treated as such. In spite of this dilemma, the focus of portfolio management efforts should include both ESPs and DPs. (See Brown and Allport in Chapter 11 for a detailed discussion on value management.)

BUILDING CORE COMPETENCIES TO REDUCE RISK

Life science product development portfolios should represent a portfolio of projects covering a substantial range in respect to difficulty of achievement, time to fruition, and expected magnitude of payoffs (i.e., creation of a balanced portfolio). This applies to all types of projects: drug development, device design, and service products. However, examination of actual product development portfolios from many companies reveals a heavy skewing toward short-term, low-risk projects with relatively modest expected benefits. This reflects an understandable response to the broad pressure on firms from financial markets for maintaining attractive short-term returns, which in turn encourage reliance on a net present value (NPV) capital budgeting approach toward project selection and allocation of resources.

Diversity of therapeutic areas, disease states, and/or discovery platforms in R&D is often regarded as a means of reducing risk. Some feel, however, that companies that concentrate their efforts and resources on a selected number of R&D areas are more likely to achieve breakthroughs more frequently and thus manage to outstrip diversified organizations [45]. It is believed that through focus and concentration of scarce resources coupled with cumulative knowledge, the probability of success can be enhanced. This can be true, but taken to its extreme, can be equally devastating if a given line of research fails or a competitive technology hits the marketplace. Again, the issue of balance needs to be employed. Enhanced probability of successful molecule identification can be achieved through focused efforts and capacity, as long as the focused efforts do not eliminate capitalization on serendipity, or that through concentration of resources and direction that the organization is placed at risk from external market dynamics.

Organizations can facilitate their movement along the experience curve by building core competencies in focused R&D line areas [46]. Concentrated efforts allow organizations to gather cumulative know-how, competencies, and capability. Therefore, a project portfolio focused in the areas of core competencies has a cumulatively greater probability of success. Likewise, a diverse portfolio moves an organization away from its experience curve, reducing the overall aggregated probability of success and potential value. This is not meant to imply that diversification is bad, or should not be pursued, but the risks, costs, and implications of such efforts must be clearly defined and understood prior to embarking upon such a path.

R&D project portfolio management does not end with its outcome. Organizations are capable of learning, if they take the time to do so. Organizational memory is created through the acquisition, communication, and interpretation of organizationally relevant knowledge used in decision making. Before a project is classified as a failure, its contribution to organizational growth, market development, or technological advancement must be estimated. The knowledge gained and experience with current projects strongly influence the performance of their successors, and in turn are a function of the victories and defeats of their predecessors.

The experience and know-how of project teams acquired during the life cycle of one particular project can and should be transferred to subsequent projects. As an organization works its way through development and completes more and more projects, certain aspects of technical, commercial, and competitive uncertainty can be reduced while hands-on experience accumulates [25]. The continuous observation and consequent rectification of errors and misinterpretations help improve the decision-making quality and the ability to implement adequate R&D project portfolio management.

PROJECT MANAGEMENT AT CROS

Successful management of research projects in a CRO can mean different things to different people. If project timelines, costs, and performance levels are not defined in advance, any outcome may be regarded as acceptable! People often misunderstand the concept of delivering projects to external customers. They have ongoing projects within their company, and they consider project management as “the art of creating the illusion that any outcome is the result of a series of predetermined, deliberate acts when, in fact, it was dumb luck.” [47] In a CRO project environment, above all other life science project arenas, project managers need to be outcome-oriented and be capable of achieving predefined target results within the time constraints set by the project scope, while ensuring commercial agreements between their company and the client are met – as well as delivering expected profit margins on the work.

CRO project managers must:

- Achieve project objectives within time and cost parameters
- Do so at the desired performance and quality level
- Utilize the assigned resources effectively and efficiently

- Deliver an acceptable project with a win-win philosophy
- Meet or exceed the customer's expectations

Today's CRO managers not only have to consider the short-term objectives of the projects in the pipeline but should also think strategically about their company's position globally and about future business. They have to consider the impact of changing environmental demands on the company. The project manager has to be result-oriented and must monitor the external situation of the life science industry closely enough to know when benchmarking results indicate the necessity for strategy changes to be instituted.

Competitors in the pharmaceutical and CRO markets are acquainted with the same fundamental concepts, techniques, and approaches. Available for all to follow, the information and techniques can be used by every company manager. Thompson and Strickland [48] are of the opinion that the difference in the level of success between competitors lies in the relative thoroughness and self-discipline with which managers develop and execute their strategies for present and future projects.

Visionary leadership is needed to evaluate quality, performance, and price because it is of utmost importance in a competitive market. In a CRO with a low throughput time and excellent quality, the revenue generated will not have to cover the overhead cost created by additional time a competitor with a longer throughput and additional reworks will have to cover. The lower the throughput time and number of reworks and related costs, the higher the profitability in relation to a competitor with a longer throughput. Managing time and performance within budget constraints emphasizes the trade-off between these critical factors, which are vital for successful innovation, and management through the instigation of best practices.

Trade-offs are always based on the constraints of the project. This is especially true of activities undertaken in a CRO. A delay in one service-providing division pressurizes all downstream activities in the other divisions to cut back on timelines to ensure that the final date for project completion will be met. Effective project management is therefore a prerequisite in a CRO where excellence is a part of its mission statement, and project completion within predefined timelines can be met without the necessity of crisis management and trade-offs between cost and performance inevitably having to be made. Qualitative project performance data are inadequate to demonstrate the potential of meaningful improvements, particularly in an environment in which revenue and work hours are major determinants of performance and efficiency.

The quantitative characteristics of project management process analysis, in relation to time particularly, can make the technique a key component in the evaluation of performance of CRO-managed projects. It is essential for successful project management of a CRO to:

- Trace costs
- Quantify time data generated on the main activities and processes undertaken by the operational divisions
- Differentiate and allocate costs to the respective activities of each project

Should an overrun of time seem to be evident, the project manager must know exactly what the cost to the company per day will be and which best practice remedial actions to initiate. At the same time, risk factors, for example, unused capacity due to project cancellation, should be assessed and managed.

Despite the best efforts of regulatory authorities, pharmaceutical, biotechnology, medical devices companies, and the associated service industry (mainly composed of CROs), the time associated with bringing drugs to the market continues to rise. This is due not only to the complexity of developing new drug entities, but also to the ever-increasing *paper war* involved in the bureaucratic red tape of regulatory requirements and approvals to be obtained for clinical trial execution and the submission of a myriad of data and results, before marketing of a new product is possible. The U.S. and EU governmental regulation processes for drug registration are extensive and demanding. They require standardized processes and documentation on clinical research projects to demonstrate the bioavailability of drugs before they can be approved for marketing.

A CRO's business depends on sustaining understanding, and complying with, the comprehensive global and governmental regulatory processes. The guidelines regulating marketing authorization, of which the FDA and the International Committee for Harmonization (ICH) are the most general ones, are applicable to every CRO globally, executing clinical research projects to be presented as part of the dossier for the registration submission in Western countries. The conclusion to be drawn regarding an industry that is heavily regulated globally by legislation and guidelines is that CROs competing for a market share should generally follow the same processes and encounter the same risk factors. The guidelines regulate the larger picture of *how*, *when*, and *where*, but the finer detail that determines the competitive edge and profitability depends on effective management of the CRO within the constraints of this heavily regulated industry.

Costs continually have to be readdressed so that wastage is kept to a minimum, in terms of both direct and indirect costs, while maintaining and even enhancing customer satisfaction. Excess costs feed on themselves, creating further excesses and inefficiencies [49]. The bottom line is that winning in the evolving life science market for services of the twenty-first century is about being *smarter*, *faster*, and *different*. In the current environment, the big and the slow will be consigned to the margins, where large-volume commodity markets offer *the only* opportunity to sell undifferentiated services, and at declining margins. The real opportunities for CROs lie in pioneering new approaches to business management, technology, competitors, and customers [50]. There are creative strategic options for management to instigate smarter, faster, and creatively different innovative services to customers.

The aforementioned briefly describes the environmental demands evident in the pharmaceutical industry. Over and above the competitive environment, it is clear that the cycle time from discovery to market determines the profitability of a new drug. As key stakeholders in the value chain, CROs need to manage time, costs, and performance to guarantee commitment in realizing these vital objectives, because ultimately, they determine sales at maximum profits for their clients. To streamline drug development, the clinical evaluation process is outsourced to CROs whose core

business is to render clinical research services as part of the global value chain of drug development. They form an integral part of the pharmaceutical drug development effort.

SUMMARY

This chapter has provided an overview of how projects and project management are viewed in the life sciences. Corollaries were drawn with the management of projects in other industry sectors. The life sciences industry has been slow to implement project management practices and is behind other industries in this business critical management approach. The importance of project management is shown to have been recognized in that it is seen by many companies as a pivotal contributor to getting products to market and achieving excellence in drug development. More emphasis is being placed on the application and development of project management practices in the industry than at any previous time.

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