2 Project Management's Place in Drug Development and the Various Project Management Roles in Biopharma

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2.1   INTRODUCTION

As biopharma companies shifted in the late 1990s from independently managed functional activities to centrally managed cross-functional projects, the need to coordinate and integrate these cross-functional teams and work streams has given rise

to having dedicated project management practitioners. Despite being a late adopter of project management, the biopharma industry has quickly embraced the systematic and formalized approach that project managers bring to planning and executing complex projects. Nowadays, project management has become a standard practice in the biopharma industry, and most biopharma leaders today would consider Project Management as a core business function just as much as Chemistry, Clinical Science, or Regulatory Affairs.

Not only has the application of the project management discipline become standard to the clinical development stage, but it is also now being applied to many other stages of drug development (e.g., preclinical, commercial) and even to specialized functions within clinical development (e.g., Regulatory, Chemistry, Manufacturing and Controls (CMC), Medical Affairs). Furthermore, while the standard aspects of planning, coordination, scheduling, monitoring, and managing the risks of various drug development activities is still appreciated, the role of project managers has also expanded into areas of project leadership, team effectiveness, governance, strategic value optimization, process improvement, and more.

This chapter describes the evolution of the project management function in the biopharma industry, some of the current roles and responsibilities that project managers fulfill, and the skills and competencies that project managers need to be effective in biopharma.

2.2 WHAT IS PROJECT MANAGEMENT AND WHAT DOES A PROJECT MANAGER DO?

There are many ways to describe what project management is, and none are complete or always accurate for every company. In general, project management is concerned with how a project will run. This can include such things as

- Scope management
- Timeline management
- Cost management
- Risk management
- Resource management
- Team management
- Stakeholder management
- Process management
- Value management

Project management can be viewed as one of the three components, along with appropriate project governance and line management disciplines, that are necessary to successfully deliver a project. In this construct, project management is responsible for delivering projects using resources (staff and funds) provided by functional line management, which is committed to the project by a governing body. This construct has arisen as biopharma companies have moved toward a matrix organizational structure where project team members are drawn from functional departments, in effect creating lines of accountability both to the department or function and to the project. Overseeing and aligning the needs of projects with those of departments or functions is the role of the governing bodies (Figure 2.1).
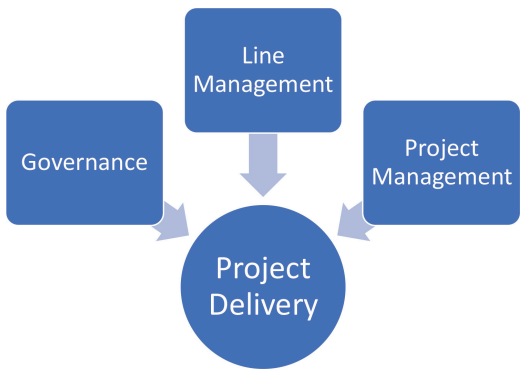
FIGURE 2.1   Three components of effective project delivery: Governance, Line Management, and Project Management
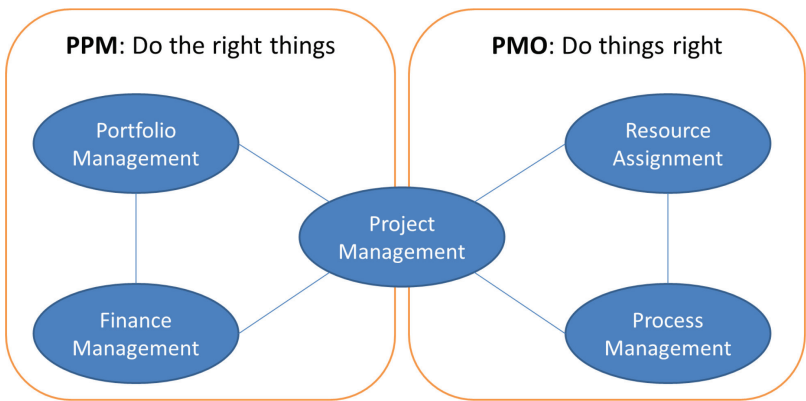

FIGURE 2.2   Conceptual representation of Project Management as the interface of project planning via Project Portfolio Management and project execution via the Project Management Office.

Another way to define project management is in the context of project planning (project portfolio management, PPM) and project execution (project management office, PMO). The project management function straddles both disciplines and interfaces with other functions that support both PPM and PMO activities (Figure 2.2).

These definitions still do not cover all the things a project management function will do across all companies. For example, at a small company, the project management function may also serve as the bridge between two partners in a strategic collaboration. Hence, rather than trying to define what project management is for a biopharma company, it is more accurate to say that project management can provide value whenever the coordination of a complex set of activities is needed to deliver an output or outcome.

Before we get into what a project manager does in biopharma, it is helpful to step back and consider what a project manager does in general, regardless of the industry he/she is in. According to the Project Management Institute's PMBOK (7/e), a **project manager** is "the person assigned by the performing organization to lead the team that is responsible for achieving the project objectives". However, a single definition like this does not fully describe what a project manager does because the role varies so widely across industries and across organizations. In particular, for biopharma, the term "lead" can be confusing because many biopharma projects have a project manager as well as a project leader, as we will see in Chapter 3. A better description of what a project manager does may be found in Figure 2.3.

A further definition of what a project manager does may include a list of skills and competencies that project managers possess. These skills are not unique to a project manager, but instead, it is the unique combination and focused application of these skills that makes a project manager valuable to a project team and to an organization.

- **Plan the Work**: Project managers convert broad corporate strategies into action plans that the project team can deliver. "Big-picture" plans are broken down into discrete work packages that are dispersed among various subteams and functional lines, and the project manager is responsible for coordinating and monitoring the progress of these activities across the team.
- **Work the Plan**: Project managers oversee the execution of work according to the plan. After high-level plans are approved, they create more detailed schedules (e.g., Gantt charts), resource plans, cost management plans, risk management plans, etc., and they determine the critical path, monitor progress, identify variances in cost and time, escalate potential problems early, and adjust plans to ensure delivery on or ahead of schedule. As the project progresses, the project manager evaluates the project status against the broader business strategy to make sure they still align, and, if not, escalates issues for governance awareness and change control decision making. When plans go off track, project managers evaluate downstream

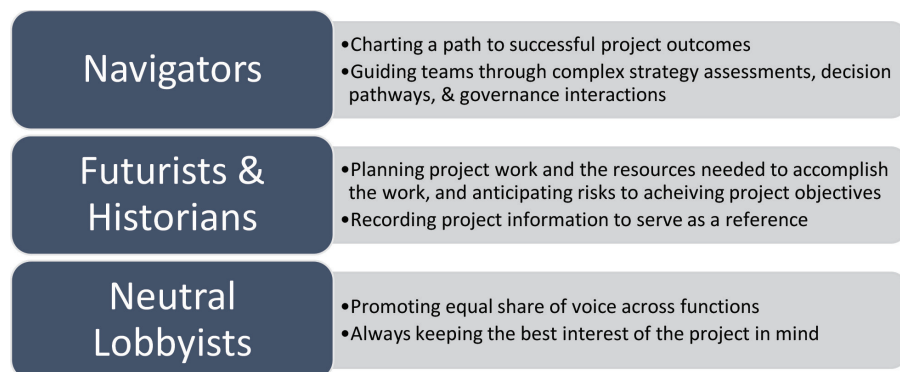| Navigators | •Charting a path to successful project outcomes
•Guiding teams through complex strategy assessments, decision pathways, & governance interactions |
| Futurists & Historians | •Planning project work and the resources needed to accomplish the work, and anticipating risks to acheiving project objectives
•Recording project information to serve as a reference |
| Neutral Lobbyists | •Promoting equal share of voice across functions
•Always keeping the best interest of the project in mind |

FIGURE 2.3   Laypersons definition of what a project manager does.

implications and build and analyze scenarios, including cost requirements and resource needs, to get the plan back on track.

- **Manage project risks**: Project managers keep a watchful eye on things that could disrupt the project plan. The project manager solicits concerns from team members and then works with the team to assess risks, evaluate response strategies, and implement plans to avoid, accept, mitigate, or transfer the risk. The project manager serves as the conduit for communicating risk response strategies to stakeholders so that they can be aware of and potentially address the risk.
- **Manage the flow of project information**: The project manager is the unifying point of project information and serves as the central point of contact for project team members and management when it comes to operational information. In addition, with their comprehensive, long-term view of the project's goals, they help the team understand how the discrete work packages and short-term activities fit into the big picture. As such, the project manager needs to manage information exchanges across the project team system and up to senior management. This includes preparing presentations, updating systems, and generating progress reports for the project team, functional management, and governing bodies.
- **Manage team dynamics**: Project managers are the glue that keeps project teams together. Whereas project leads are outward-focused, keeping external stakeholders informed of project progress, project managers are inward-focused, keeping the project team's health and performance front of mind. To this end, the project manager helps define the project team structure and ways of working, including evolving the team as the project moves through different stages of development. The project manager needs to define how the team members will interact with each other through charters and meeting management, as well as maintaining team health through team-building activities and conflict resolution between functional lines when needed. The project manager also needs to be aware of issues with team members that could put the project at risk and work with the functional manager to address the issues. Chapter 3 describes in detail the responsibilities a project manager takes on in managing team dynamics.
- **Implement best practices:** As described in Chapter 4, the project manager has responsibilities to the department that go beyond direct project support. They also contribute to the PMO's remit of having a single set of project management standards, tools, processes, and methodologies, and they work to ensure that these best practices are being employed across all project teams.

As noted briefly above, it is important to note that in biopharma, unlike in some other industries, project managers are typically distinct from project leaders. In some industries, the terms "project manager" and "project leader" are synonymous, referring to an individual who is given decision-making authority over a budget and a set of resources to deliver an output or outcome. However, in biopharma, team leadership is usually assigned to two individuals: a project leader and a project manager. We will describe these roles more in Chapter 3.

2.3   EVOLUTION OF PROJECT MANAGEMENT IN BIOPHARMA

The biopharma industry was a relatively late adopter of the project management discipline. Considering that many "modern" project management practices were introduced in the 1950s in the fields of engineering and construction and later refined and further developed in the software and manufacturing industries in the 1980s, the introduction of project management to the biopharma industry really started to take place in the late 1990s.

During the first decade or so after its introduction, there were widely varying ideas of where Project Management fits in a biopharma company. First, the reporting line varied, with many advocates thinking the function should report directly to the CEO; some thought it fit best in the R&D unit; a few thought it should report to Marketing as a business function because many of the early project managers held MBA degrees. Second, the project management function has often been paired with other disciplines of related scope, most commonly with Portfolio Management, Alliance Management, or Business Operations. Finally, there has been a continuing organizational debate about whether the project management function should be centralized across the organization or whether project managers should report to the project leads or the disciplines they support. I'll share an opinion on these considerations later.

Regardless of organizational inconsistencies, since the early 2010s, the inclusion of project management has become a necessity rather than a luxury for biopharma companies. Typically, a company will start to look for project management support at the point of their first asset entering the clinic. More recently, companies are starting to look for project managers to join the company even as they plan their first IND.

Another area of evolution over the past few decades has been the scope of services that project managers provide. While the core project management function remains consistent (i.e., to convert strategies to action plans and execute those plans to deliver value), the ancillary services that are provided have become more critical to the business. The original project managers from the 1990s were expected to manage individual projects with basic tools such as schedules, budgets, resource plans, etc. Project managers were then relied on as the primary and central source for project information to support portfolio decisions. Owing to their central, independent role on the cross-functional teams, project managers began taking on the responsibility to drive alignment and enhance team effectiveness. More recently, project managers are being asked to support strategy realization and value maximization for the entire enterprise, not just individual projects —hence giving rise to the project management office that we'll discuss in Chapter 4.

In addition, the role of the project manager is evolving to become more specialized in dedicated areas such as Research, Development, CMC, Regulatory, and Commercial, and more recently into functions such as Safety/ Pharmacovigilance, Medical Affairs, and Clinical Pharmacology. We will describe some of these specialized roles in Section 2.4.

As mentioned previously, there has been considerable variation in how the Project Management department is connected to the organization. While companies will have different needs based on their pipeline, outsourcing strategy, size, and

geographical footprint, it is useful to think about the best practice for a "typical" mid- to large-sized company. A typical company might have multiple assets across multiple indications in one or more therapeutic areas, it will have dedicated functional support to cover the scientific and operational aspects of the business, and it will be in a competitive space with other companies, putting a premium on efficiency and speed to market. For this type of company, I feel the best organizational construct is to have a vice president (VP) of Project and Portfolio Management reporting to the head of development. I'll explain why.

First, why report to the head of development? The head of development could be a Chief Medical Officer, Chief Development Officer, Chief Scientific Officer, a President of R&D, or other title, but the key concept is that all molecule project work rolls up to this single individual. One of the key roles I've seen project managers play is in filling the gaps in the project leader's skill set (often business savvy, strategic perspective, or people skills). Since the head of development is often the person who assigns the project leader, having direct access to them helps refine the selection and coaching of the project leaders. Why VP level? The department needs to have the same access to the primary decision maker as other functions, so Director level is simply not enough. Why combine the function with portfolio management? The information flow and alignment on strategy between project and portfolio management is key to maximizing value for the company. While portfolio management is charged with identifying and selecting the mix of projects to run, project management is charged with running those projects and ensuring that the correct delivery assumptions are included in the project valuations so that maximal value can be achieved. We'll dive deeper into the interface between project and portfolio management in Chapter 5.

2.4   WHAT DO PROJECT MANAGERS DO IN BIOPHARMA?

Let's take a deeper look at what a project manager does in biopharma. Fundamentally, biopharma project managers convert complex drug development strategies to action plans and then coordinate the execution of those plans to deliver marketable drug products that bring value to the organization. To do this, biopharma project managers interface with several stakeholders across the organization, including members of a product development core team and subteams, what I call the "project operations" functions, and governing bodies. We will discuss the project manager's involvement in the project team in Chapter 3, project operations in Chapter 4, and governing bodies in Chapter 5. For now, let's describe these groups as follows:

- Project teams are responsible for delivering projects
- Project operations functions are responsible for ensuring projects are being delivered in the best possible way
- Governing bodies are responsible for selecting the projects to execute and committing the organization's resources to those projects

As mentioned previously, the application of the project management discipline has expanded beyond the original assignment to clinical development projects.
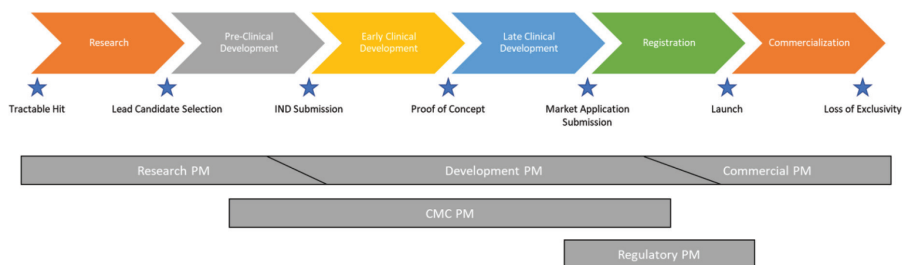
FIGURE 2.4 Project Manager roles juxtaposed with the drug development lifecycle.

Nowadays, many companies have project managers for all stages of development (i.e., preclinical, early development, late development, and commercial) and for many functional lines (e.g., CMC, Regulatory). The sections below provide a general description of the responsibilities of project managers in biopharma as well as specialized project manager roles that are commonly found in mid-sized and large companies (Figure 2.4).

2.4.1 Research Project Manager

Research project managers are focused primarily on activities within drug discovery and preclinical development that culminate in an investigational new drug (IND) application. They are typically assigned when a lead compound has been identified, and they support the project through lead compound optimization and preclinical development. After a molecule enters clinical development, the research project manager will continue to work on the asset team to coordinate any remaining nonclinical work that is needed to support clinical development and regulatory requirements.

The key responsibility of a research project manager is to build and execute a nonclinical development plan that supports IND clearance and NDA submission. While the asset is in drug discovery and preclinical research, the research project manager has sole accountability for managing the asset. When the asset enters clinical development, the research project manager interfaces with the development project manager and CMC project manager to align the nonclinical plan with other development plans (e.g., the clinical development plan, clinical pharmacology plan, and CMC plan).

2.4.2 Development Project Manager

Development project managers focus primarily on activities within early and late development that culminate in a market application submission (e.g., New Drug Application (NDA) or Biologic License Application (BLA) in the US, Market Authorization Application (MAA) in the EU). They are typically assigned just before an IND/Clinical Trial Application (CTA) is filed and while the first-in-human study is being planned. Some organizations will divide the responsibilities of development project managers even further into early development project managers who cover

activities leading up to proof of concept and late development project managers who cover activities after proof of concept that lead up to a market application submission.

A key responsibility for the development project manager is to build and execute an Asset Development Plan and Clinical Development Plan that supports a market application submission. The development project manager interfaces with research project managers, CMC project managers, and regulatory project managers to maintain alignment between plans. The development project manager also partners with the development project leader to manage the product development core team.

The generic job description for a development project manager is available in Appendix VI. The job description provides more insight into what a development project manager's responsibilities are, as well as serving as a starting point for a Director-level job description that can be used for hiring.

2.4.3 COMMERCIAL PROJECT MANAGER

Commercial project managers focus primarily on drug product launch and commercialization. They are typically assigned just before a market application is submitted, and they support the project through launch and all stages of the commercial lifecycle (i.e., growth, maturity, and decline).

The key responsibility of a commercial project manager is to create and execute a launch and commercialization plan. The commercial project manager interfaces with the development project manager and the regulatory project manager to maintain alignment between plans.

2.4.4 CMC PROJECT MANAGER

CMC project managers focus primarily on activities related to drug substance, drug product, and analytical method development. The CMC project manager also coordinates the associated quality assurance and regulatory compliance activities needed to demonstrate that the manufacturing process is controlled and reproducible. To that end, CMC project managers work with the regulatory team to develop timelines to support CMC submissions to health authorities. A CMC project manager is typically assigned during the research phase of development, and he/she supports the asset throughout its lifecycle.

During clinical development, the CMC team supports the core team by ensuring continuous supply of clinical trial material, including the manufacture, testing, packaging, and labeling of clinical trial supplies that will be sent to investigative sites. This requires close integration with the clinical supply team, who is responsible for converting study enrollment projections into drug supply–demand curves. Additionally, because most small and medium-sized biopharma companies outsource manufacturing activities to a contract development and manufacturing organization (CDMO), the CMC project manager is responsible for interfacing with and managing the flow of information with external partners, often in geographically dispersed regions (Chapter 7).

2.4.5   REGULATORY PROJECT MANAGER

Regulatory project managers partner with the regulatory lead, the development project manager, and the regulatory subteam to ensure regulatory activities are executed as planned. These regulatory activities include the following:

- Partner with the regulatory lead to development of the regulatory plan that defines the path to approval that aligns with the asset development plan and clinical development plan
- Triage, review, and QC of documents submitted to health authorities, including INDs/CTAs, NDAs/MAAs, investigator brochures, annual reports, development safety update reports (DSURs), and meeting materials. Tracking of documents submitted to health authorities across the globe and coordination of responses to health authorities' queries
- Monitoring the regulatory landscape to identify risks to and opportunities for the development plan

In addition to the broader support roles listed above, the regulatory project manager also has specific accountabilities for the planning and execution of NDA submissions. Therefore, a regulatory project manager should have expertise in the following:

- Managing cross-functional module meetings and submission team meetings.
- Creating and managing cross-functional timelines for submissions with consideration of key interdependencies.
- Standardizing the best practices for the management of regulatory submissions to ensure consistency across functions, e.g., defining the submission process, creating templates, implementing tools, and building timelines.
- Overseeing the efforts for the preparation and publishing of regulatory submissions in accordance with the submission timeline.
- Managing the timely delivery of a compliant NDA submission.

2.4.6   EMERGING ROLES FOR PROJECT MANAGERS IN DRUG DEVELOPMENT

In recent years, the trend toward more specialized project management roles has led to project managers supporting functions not listed above. For example, I have seen dedicated project managers in medical affairs, pharmacovigilance, supply chain, sales operations, and other functions.

2.5   WHO BECOMES A PROJECT MANAGER IN BIOPHARMA?

Project managers in biopharma seldom sought project management as their first career path. This is likely because there are very few academic offerings that prepare individuals for a career as a drug development project manager. Of the people

who do enter directly into project management, most have an education in business administration (e.g., MBAs), where they can use their business backgrounds while learning the drug development piece. This may be changing, as more and more universities are offering programs in life sciences, including a requisite course in project management.

Most often, project managers start their career in a different discipline in a biopharma company and, over time, gravitate to project management because their personality and work habits lend them to being effective at organizing work and coordinating teams. Project managers may come from all areas of the business, from benchtop scientists to business support. Indeed, the best project management departments I've seen have a mix of representatives with both scientific and business backgrounds because a successful project management group needs to be able to bridge both areas.

A common path to project management is when a scientist in research or CMC/technical operations wishes to move from a technical role to a business support role. These transitions are most successful for research project managers and CMC project managers, respectively, where deep technical knowledge is needed to successfully build and execute project plans. Another common route to project management is when a Clinical Trial Manager from clinical operations wishes to broaden his or her development experience by becoming a development project manager. Given that clinical trials are complex projects in and of themselves, the skills learned while managing studies is easily translated to managing broader clinical development plans and asset development plans. Based on personal experience, a candidate having project management experience in another industry is a better predictor of success than having technical experience in the biopharma industry. The common belief in the converse can be a barrier to finding great candidates.

2.6 WHAT MAKES FOR A SUCCESSFUL DEVELOPMENT PROJECT MANAGER?

Though the path to project management may differ, it is a person's personality and work habits that are most likely to make him or her effective at the essential components of the role: organizing work and coordinating teams. What are those traits and characteristics? There is no predictable formula for making a project manager successful with every project and every project team, but a few qualities that are generally recognized in good project managers may be found in Figure 2.5.

While the above characteristics are fundamental for development project managers, the competencies below really set apart a great development project manager, one that will continue to drive impact in the future of our profession. In fact, the PMI has recently updated the Talent Triangle to emphasize the evolution of the project manager role from technical experts to project professionals with multifaceted capabilities. This highlights the fact that our profession is constantly changing and evolving, and as new expectations, opportunities, and technologies arise, we need to be prepared for the future of our role (Figure 2.6).

Knowledge	Skills	Behaviors
• PM theory and practice • Scientific understanding • Business acumen	• Communication • Able to use a variety of PM tools, techniques, and methodologies • Able to identify risks in a cross-functional context • Able to synthesize and distill general strategies into actionable plans • Negotiation & Influence • Facilitation of high-stakes conversations	• Leadership • Action oriented (not passive) • Process-oriented • Organized • Clear and concise

FIGURE 2.5 Characteristics of a successful Development Project Manager, as grouped by the knowledge, skills, and behaviors a person must have to be successful in the role.
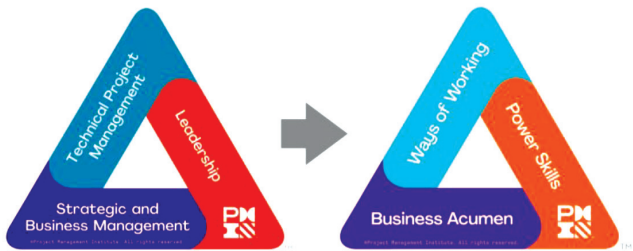

The PMI Talent Triangle® is Evolving

FIGURE 2.6 The evolution of the PMI Talent Triangle emphasizing the transition of the Project Manager's role from a tactical to strategic.

The PMI describes these capabilities as follows:

- **Ways of working**: Whether it's predictive, agile, design thinking, or new practices still to be developed, it's clear that there is more than one way that work gets done today. That's why we encourage professionals to master as many ways of working as they can – so they can apply the right technique at the right time, delivering winning results.
- **Power skills**: These interpersonal skills include collaborative leadership, communication, an innovative mindset, for-purpose orientation, and empathy. Ensuring teams have these skills allows them to maintain influence with a variety of stakeholders – a critical component for making change.
- **Business acumen**: Professionals with business acumen understand the macro- and micro-influences in their organization and industry and have the function-specific or domain-specific knowledge to make good decisions.

Professionals at all levels need to be able to cultivate effective decision making and understand how their projects align with the big picture of broader organizational strategy and global trends.

For a development project manager, the competencies described below align with the evolving PMI framework. I think of these as competencies that will "future-proof" a development project manager, meaning that they will always be in favor regardless of the changes to the profession that come in the future.

2.6.1 Collaboration of Multiple Disciplines

The future-proof development project manager will be able to coalesce a group of individuals with various expertise and experience into a focused team that delivers. To do this, the development project manager should themselves have T-shaped experience and expertise. The development project manager will have a shallow understanding of a broad range of disciplines and a deep understanding of the standard and modern project management competencies. The shallow understandings allow a development project manager to identify when there are touchpoints and dependencies between functional activities and to connect the appropriate team representatives when needed to streamline work, get ahead of potential conflicts, and avoid redundancies. The deep knowledge, skills, and behaviors in the project management discipline will continue to be valued by the project team because it relieves the rest of the team members from having to worry about such things (Figure 2.7).

The activities needed to develop a drug need coordination between many internal functional groups, such as R&D, regulatory, legal, finance, supply chain, sales, and marketing, as well as external partners. The efficiency in coordination between different functional groups is crucial.

FIGURE 2.7 The T-shaped experiences and expertise a Project Manager should have to be able to collaborate multiple disciplines effectively.

2.6.2   Coordination of Business Processes

Project teams will rely on the development project manager to navigate them through organizational business processes such as obtaining budget and resources, making decisions, addressing issues that require changes to the project plan, and maintaining an environment where the team can perform at its best. In addition to internal business processes, the development project manager must also help the team to work through dynamic external factors such as changes in regulatory, quality, and safety requirements. Therefore, integration of business processes into the execution of projects is inevitable, and seamless coordination of these business processes will enable the team to move quickly and avoid swirl.

The future-proof development project manager will know how best to maximize the business processes to keep the project moving forward. With a good PMO that provides guidance in the form of a PM Playbook or best practice knowledgebase and with access to appropriate records and systems that the development project manager can use to know when change thresholds are being hit, the development project manager is set up for success. Without these components, the development project manager will be left to his/her own resources to learn about and navigate the appropriate business processes.

2.6.3   Communication across Multiple Stakeholders

Similar to being able to collaborate with multiple disciplines, the future-proof development project manager will need to be able to communicate across a broad set of stakeholders. The key stakeholders are the project team, governing bodies, and functional area heads. Additional stakeholders come into and out of the development project manager's hegemony as the project moves through certain stages of development. There may be consultants, contractors, vendors, strategic partners, and regulators that need project information. The development project manager will need to know the right information to share with each of these stakeholders and how to craft the information into a message that the audience can understand.

To be a good communicator across the diverse set of stakeholders, the future-proof development project manager will need to be "zoomy". In a meeting with a governing body, the project manager can describe the value of the asset in the context of the development portfolio; and in the next meeting with the study management team, the project manager can discuss the implications of delayed data cleaning on database lock. The project manager's ability to zoom out and zoom in depending on the audience will always be an appreciated skill set.

2.6.4   Management of Risks and Issues in a Cross-Functional Context

The path to product approval is paved with risks and issues. Not only are there inherent risks of scientific and pharmaceutical failure, but there are also design and execution risks that can create obstacles to achieving the project goal. We describe these types of risks more in Chapter 16. Furthermore, when risks convert to issues and resolution is needed, changes to the project plan that the development project manager

has so fervently trained the project team in are inevitable. We discuss these issues more in Chapter 17. The lack of effective risk and issue management can result in delays in the project and decreased team morale.

The future-proof development project manager will be able to manage cross-functional risks and issues with agility and determination. A Risk Management Plan will help to inform the team of how risks will be identified, tracked, and responded to, but an RMP only describes on paper what needs to happen. The development project manager will also need to create an environment where the project team members feel comfortable sharing risks. The development project manager will need to know when to escalate risks for broader awareness and when and how to escalate issues for appropriate resolution.

2.7   SUMMARY

The project management discipline has become integral to drug development, and project managers are now revered as key players in managing the complex projects required to provide evidence of safe and effective drugs. The role has expanded within biopharma beyond clinical development, with project managers now supporting projects in research, CMC, commercial, regulatory, and more. The responsibilities have also expanded from the early days; now project managers use their business acumen and power skills in addition to their technical ways of working to move projects forward. As the responsibilities continue to evolve, it will be important for project managers to future-proof their skill set by being experts at collaboration across multiple disciplines, coordination of complex business processes, communication across stakeholders at multiple levels of the organization, and management of risks and issues in a cross-functional environment.