



4 Steps for Managing the Criticality and Challenges of Biopharmaceutical Projects

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The global biopharmaceutical market is expected to grow at a compound annual growth rate (CAGR) of 9.4% from 2014 to 2020, reaching \$278 billion in revenue by the end of this six-year period. Growth is being driven by numerous factors: such as aging populations in most of the Western world and an increased prevalence of chronic disease. However, likely the most important contributor to growth is biopharmaceutical drugs' superior effectiveness in treating many disease states, including treating conditions for which there were previously few effective drug treatment options available.

Given the growth of the biopharmaceutical segment, and biopharmaceuticals' ability to more precisely treat many disease states, the industry needs to become increasingly better at managing biopharmaceutical projects in order for more treatment options to become available to patient populations.

The objective of any project management pursuit is to complete the project on time, within budget and within required quality or performance parameters. Whether making an automobile, computer or pharmaceutical, project management is not easy. However, given the complexity and intense regulatory demands of the pharmaceutical industry, project management is more difficult than many other segments. As if pharmaceutical projects weren't demanding enough, biopharmaceutical project management is exceptionally challenging, requiring unique experience and expertise.

Why is biopharmaceutical project management more challenging than project management for small molecule drugs?

Chemically synthesized drugs are typically better characterized by fairly established analytical technologies and techniques spanning the complete product lifecycle. Also, analytical techniques and manufacturing processes are typically much more consistently repeatable, including at large commercial scale.

Biologics, on the other hand, have very complex production processes and are affected by a wide range of factors, including the cell system in which they are produced and inputs such as fermentation media and operating conditions. It is not easy to scale up biologics from laboratories with the quantities used for early analysis and pre-clinical testing to larger-scale batches, while maintaining product quality and batch-to-batch equivalence. Additionally, typically complex bioassays are required for batch release and stability assessment – testing that is usually more complex than the testing required for small molecule drugs.

Finally, because there is still a lot we don't fully understand about the nature, characteristics and behaviors of living cells, outcomes are less predictable.



What Does Biopharmaceutical Project Management Entail?

The question of “what is biopharmaceutical project management?” may appear to be a fairly rudimentary question, but it is an important one. A project is a temporary undertaking to achieve a defined outcome. Effective project management organizes and manages resources in a way that achieves project completion within the defined scope, quality, time and budget.

The temporary nature of a project, including well-defined beginning and end points, differs from permanent or semi-permanent ongoing processes used to create a biopharmaceutical product over and over again.

The management of projects versus the management of ongoing processes is typically quite different. Projects begin and end to enact some sort of change within a biopharmaceutical organization – new product, new production suite, creation of a new process, etc. Therefore biopharmaceutical project managers must be effective managers of discrete change, whereas ongoing process managers typically need to be skilled at maintaining operations and making subtler changes over time.



Biopharmaceutical Project Managers – Are We Asking for Unicorns?

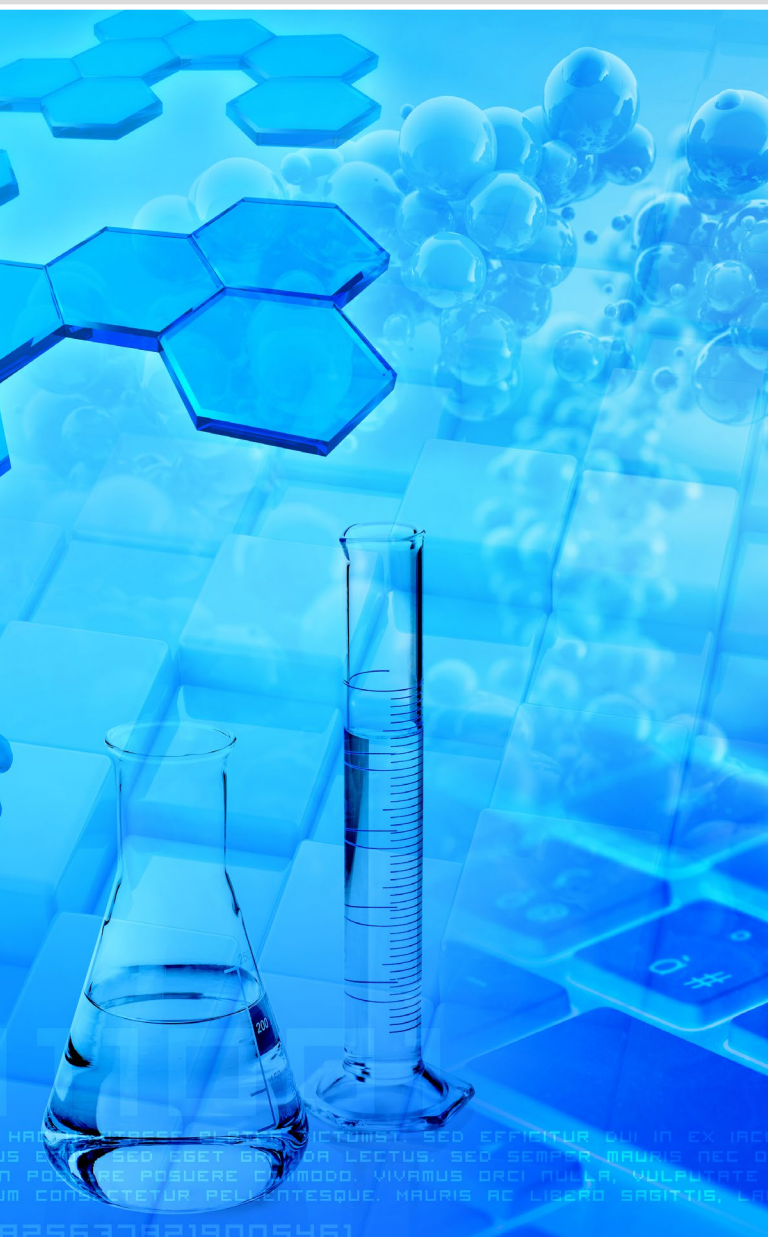
Biopharmaceutical companies often move scientists into project management roles without project management skills training. In addition to no or little project management training, promoted scientists, while highly valuable to a team or organization, often do not have the disposition required to be an effective project manager. What skills do biopharmaceutical project managers need?

- Technical and scientific understanding robust enough to lead what is typically a technically challenging undertaking
- Ability to understand the role of the project within the overall company and/or industry landscape
- Ability to translate a desired project outcome into an actionable plan that encompasses all project elements, including business objectives, schedules, budgets, resources and balancing these factors to meet the project objective
- Strong communication skills
- Interpersonal skills that allow the project manager to keep the project on track, manage conflict, manage the diverse internal and external subject matter experts (SME) the project requires and the ability to align all stakeholders to achieve the project goal
- Ability to troubleshoot and to redirect project approaches as the need arises

Biopharmaceutical project managers are asked to have: scientific and technical expertise, business understanding, ability to manage the big picture while managing many details, interpersonal skills, drive for completion, communications skills and project redirection creativity.

This assortment of skills is not common in one individual. While good biopharmaceutical project managers might not be as rare as nonexistent unicorns, they should be valued and cherished for their diverse assortment of skills and strengths. Due to the unique skills required for biopharmaceutical project management, many biopharmaceutical companies are outsourcing this role for select projects to contract organizations. Contracting often allows biopharmaceutical companies to access the skills they need for a specific project without having to expand their payroll and running the risk of having extra headcount at the conclusion of the project. Another reason biopharmaceutical companies often decide to contract project management is that a team working on a temporary objective can be difficult to manage. There is the potential of becoming mired in conflict and creating a host of behavioral problems that can often be more easily finessed by a project manager external to the organization.

How can biopharmaceutical projects be best managed, especially given the likelihood of numerous complexities and unknowns? While biopharmaceutical project management is complex, the project management process should be simply framed. The remainder of this paper offers four steps for effectively managing biopharmaceutical projects: project definition, execution planning, execution and project completion.



Step # 1 - Clearly Establish Project Definition and Impacting Constraints

Biopharmaceutical projects must be clearly defined. Every project needs to have a precisely defined goal of what will be accomplished upon successful completion of the project. Correspondingly, every project will be constrained by project scope, time and resources.

The scope of a given project is the combination of the project's final goal and the collection of deliverables that must be completed to achieve that goal. The more complex and risky a project is, the more robust the scope will likely need to be.

Time and resource constraints are a bit more straightforward. What is the project deadline — and what monetary budget, talent, equipment and other resources does the project have at its disposable?

The triad of project scope, time and resource constraints must be carefully and honestly assessed during the initial project planning stages and these constraints must ultimately be well-managed and well-balanced for successful project completion. Projects virtually never go exactly as planned; therefore, the balance of scope, time and resources usually needs to be adjusted throughout a project. However, these three elements needs to be carefully analyzed in the initial project definition phase to start the project on the best possible footing.

Step # 2 - Project Execution Planning

The most successful project planning balances the creation of a clear, concise and well-documented project execution plan (PEP) with simplicity. In other words, the PEP should clearly communicate and document all facets of the project, but be no more complex than it needs to be.

The PEP thoroughly outlines how project scope, time and resources will be balanced to achieve the project's goal. Ultimately, the PEP presents guidance for every pertinent element of the project and illustrates how project team members, sub-teams, externally contracted resources and other stakeholders will interact to achieve the successful completion of the project. Given extensive regulation from the FDA and other regulatory bodies, a strong PEP is particularly necessary for biopharmaceutical projects.

The PEP should include: milestones, needed sub-plans, project procurement/supply chain management, project risk identification and mitigation plan, project team plan, communications plan, project budget, work breakdown structure and any other elements that should be documented to assure project clarity. While the PEP should contain all of the above listed elements, project team creation, project communications plan, risk identification and mitigation planning, and resolution of issues and change management is discussed in more detail below:

Project Team and the Chain of Command

After clearly defining the project goal and assessing the constraints of project scope, time and resources, the project team must be defined. The project manager must assure the team includes the required SMEs to complete each phase of the project. Additionally, the project manager must make certain that the team's SMEs have the bandwidth the project requires.

Every member of the project management team will have specific responsibilities and tasks. Additionally, each member of the team must have the sufficient authority and resources to complete assigned tasks and responsibilities.

A project team organizational chart should be created so that all team members know the responsibilities and authority of the other members of the team. Depending on the project, the project team organizational chart might need to include sub-teams, or functional teams/ personnel outside of the core project management team. Additionally, externally contracted resources such as contract laboratories or contract manufacturing organizations integral to a project should be included within the project management team organizational chart.

Finally, the role of senior management should be defined during the project team organizational chart creation process. Inevitably, every project has challenges and areas that did not go according to plan. Therefore, a clear plan detailing when and how to escalate an issue to a supervisor, technical expert, member of the executive team or other personnel should be clearly defined.

Project Communications and Progress Tracking Plan

To assure effective communication across the project management team, the project manager should regularly assemble and share the following information with the project team:

- Scientific and technical data
- Data analysis and conclusions
- Problems or issues the project team is facing
- Adjustments to project plan based on learning and/or encountered problems
- Status of project tasks and activities
- Timeline and milestone accomplishments versus stated goals
- Costs against budget

The communications plan also defines the project planning and management tools that will be used for project communication and tracking. For example, this could be through the use of Gantt charts, checklists and other tracking tools. Although a wide variety of often complex project management tools are available, simple is often better. However, the specific tools used will in large part be determined by the size and the geographic distribution of the team.

Also, the communications plan will define if regularly scheduled status meetings or other tactics will be part of the approach for clear and concise project communications.

Project Risk Identification and Mitigation

A critical component of balancing project scope, time and resources, to assure the project objective is successfully achieved is identifying potential risks and creating a risk mitigation strategy. In short: What unique risks is this project likely to have?

Earlier stage product development projects are often riskier, therefore more time and resources might need to be assigned to the project. Use of new technologies, use of untested raw materials, development of products that will be highly sensitive are all potential risk factors that should be considered within the PEP. A risk mitigation plan should be created and ready for use in the event the defined risks become reality.

Proactive Resolution of Issues and Change Management

Inevitably, elements of a project do not go as planned or hoped, particularly with riskier projects. Therefore, a project's PEP should contain an outline of the process for managing needed change. Generally, when unanticipated problems occur, project scope, resources or timeline will need to be adjusted to keep the project on course.

When change is needed, the project manager will need to:

- Communicate the problem and the likely impact of the problem on the success of the project
- Assemble relevant facts, data and analysis
- Draft potential alternative solutions
- Recommend the best alternative
- Communicate with the project team and any stakeholders outside of the direct project team
- Assemble financial and project timeline ramifications to effectively deliver scenario and ramifications to senior management



Step #3 – Project Execution

The project manager's challenge during the execution phase is to skillfully and adaptively manage change. Even with the most skillful planning, few projects go according to the plan created during the planning phase. Therefore, the project manager must constantly re-plan the project to respond to problems, challenges and learnings. As discussed, the project manager's ongoing role is to effectively balance scope, time and resources as new situations and evidence presents itself to assure the project achieves successful completion.

Step # 4 - Project Completion

Much of the work of project completion and project closeout should be done throughout the full lifecycle of the project. The work of documentation, compilation of information needed for compliance and regulatory purposes, and report writing should be done throughout the project. Project financials needs to be reviewed and analyzed, as well as an objective analysis of the success of the project.

The last, and critically important, step in any project should be a thorough evaluation. Learnings that can be applied to future projects should be recorded. This review is best done by the primary project team and typically a group discussion is most effective. If appropriate and possible, it can be beneficial to include key stakeholders outside of the core project team.

Conclusion

Given the value of what biopharmaceuticals do and can deliver to millions upon millions of patients around the globe, the industry has the responsibility to manage projects effectively and efficiently so that more therapeutically beneficial products at affordable prices are available.

Biopharmaceutical products are structurally complex, usually unstable, and their sensitivity with manufacturing processes present many challenges. Outstanding project management is especially critical for outsourced biopharmaceutical projects, which often involve managing multiple contract organizations.

Due to the increased need for skilled project management, many biopharmaceutical companies are hiring and/or training professional project managers. Additionally, biopharmaceutical companies are opting to hire a contract project manager or project management firm so the company does not have extra project managers on payroll after a project is completed.

Life-saving biopharmaceuticals will become increasingly complex and greater in number. The only way for biopharmaceutical companies to move quickly and adaptively enough is to become very good at repeatedly launching and successfully completing projects.



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