



Progressive Project Management Focus[®] :

A STRATEGY TO LEVERAGE PROJECT MANAGEMENT TO
ACCELERATE DRUG PRODUCT DEVELOPMENT

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Never before has there been such pressure to shorten the product development lifecycle. Despite significant progress, the demand for new or improved products meeting known and newly identified needs continues to rise, creating ongoing opportunities for new product development. The cost, time, and risk associated with the product development process as well as limited product patent lives add to the pressure to condense the new product development timeframe. Historical trends of spending in excess of \$800 million and 10-plus years to develop a new drug; wasting 80% to 90% of the \$7 billion spent annually on R&D on drugs that fail to reach the market; and annually losing patent protection for \$6 billion in drugs, are driving the pharmaceutical industry to make significant improvements in its product discovery and development process.

Pharmaceutical companies, however, are not alone, as many industries have undergone similar and often-chaotic paradigm shifts. As a result, organizations often are over-committed and constantly balancing multiple and shifting priorities. Consequently, there is an enormous opportunity for project management as a profession to overlay its business discipline to all aspects of the product development lifecycle. In its simplest form, project management involves planning and executing a mix of complex tasks involving multiple people and organizations. Project management has been successfully employed in numerous organizations to manage each phase of the product development lifecycle with varying degrees of intensity to complement core scientific and technical expertise. The end result has been decreased costs, compressed development time, reduced risk of failure, and the launch of the most promising new products

THE PRODUCT DEVELOPMENT LIFECYCLE

Significant to early-stage product development and contradictory to conventional business procedures is the scientific methodology used to solve the most complex problem...the unknown. In the purest form, the scientific community employs a research loop (Figure 1) to problem solving.¹

Research is an iterative process summarized as

The Research Loop

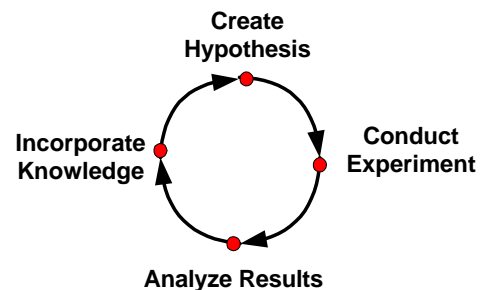


Figure 1

¹ Coleman, Jeffrey R. and Mondschein, Ellen (July 1997). Speeding the "R" of R&D Through a Deliverables Orientation. Visions Magazine [Online]. Available: <http://www.pdma.org/visions/jul97/randd.html>

hypothesize, experiment, assess data, incorporate knowledge, and repeat the iteration with the benefit of the expanded body of knowledge developed in the preceding iteration. Therefore, the end of the research loop strongly influences the direction of the next research loop. After numerous iterations, the focus of the research project may no longer be aligned with the original business objective.

In the most generic terms, the product development lifecycle represents multiple iterations of this research loop during four primary stages: exploratory, conceptual, feasibility, and development.

In a strategically aligned organization, the exploratory phase is initiated by a dictum from executive-level management that provides the organization's research leadership with general direction for the composite research program. Using a qualitative approach, research proposals that are strategically aligned with the organization's vision are prioritized by probability of success, resource requirements, and risk-adjusted return-on-investment projections. Although inevitably risky, novel platform technologies emerge from this phase that have a high potential of capitalizing on market needs and desires.

In the conceptual phase, the platform technology is broadened to meet commercial application criteria, such as robustness, speed, and size. If the platform shows strong commercial promise, it will proceed to the feasibility phase. Traditionally, the platform technology is married with existing technologies to produce a prototype for a new product or an enhancement of an existing product. It is important to note that at the transition from conceptual to feasibility, the platform technology can be applied to numerous product development paths in parallel for differing product offerings. Once a prototype has been developed and tested, only now is it ready to enter the development phase of the product development lifecycle.

In the development phase, the focus of the team is consumed by activities imminent to product launch, such as manufacturing scale-up, product safety, packaging design, supply chain development, product positioning, and market launch strategies. During this late stage of the cycle, research activities are either complete or they are on a precipitous slope as the product nears launch. While innovation can still influence the outcome, the focus clearly shifts in this phase to on-going operational elements.

Relying only upon the iterative approach of the research loop has historically not generated desired results. Moreover, simply layering project management responsibilities on an already taxed staff assumes that technically competent individuals have the time and can extend their skills to successfully manage a project. These assumptions rarely prove true. Overlaying professional project management across all phases of the product development lifecycle, however, adds overall coordination and tremendous value.

For many organizations the merits of project management are most evident in the later product development phase, where the number of cross-functional teams and the gross volume of communications and decisions necessitate the role of a project manager. However, there is vastly unrealized value in utilizing professional project management competencies in the exploratory, conceptual, and feasibility phases of the product development lifecycle to help define and focus priorities, clarify business and scientific expectations, and facilitate communications between groups. While the fundamentals of project management are relatively easy to understand, its importance lies in achieving business results.

The Project Management Institute (PMI) defines five distinct phases in the project management process: initiate, plan, execute, control, and close.² Initiation entails defining the project objective and identifying the project stakeholders. Project planning is defining and scheduling the project activities and ensuring the necessary resources are in place to complete the activities. Execution is implementing the project plan. Control focuses on systematically managing changes to objectives, plans, and schedules during execution. Lastly, closure ensures lessons learned are documented to ensure the organization is focused toward continuous improvement. Rigorous application of the project management process is highly dependent upon the project manager, who must possess project management protocol knowledge, strong business acumen, effective interpersonal and communication skills, and cross-functional team leadership experience. Organizations who have assigned the role to a professional project manager have realized the full value of schedule compression, effective resource utilization, and increased predictability of outcomes.



LEVERAGING PROJECT MANAGEMENT TO ACCELERATE PRODUCT DEVELOPMENT

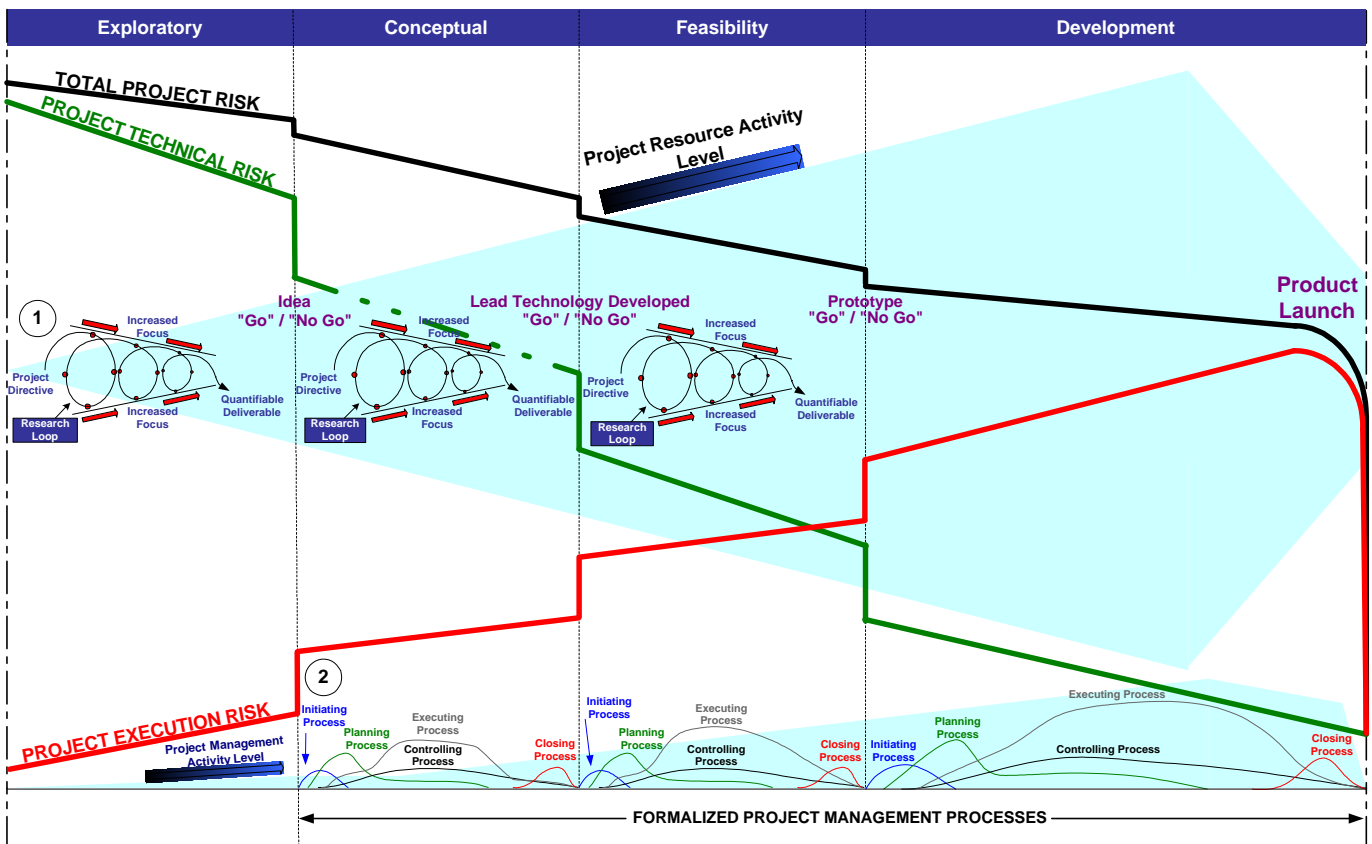
The uncertainties associated with product development are broadly summarized into two principal categories: technical risk and execution risk. Although these two components of risk added together equal a project's total risk, their magnitude is inversely proportional as the project moves through the four phases of the product development lifecycle. In the exploratory phase, technical risk accounts for the overriding majority of the project risk, due to the lack or complete absence of knowledge on how the organization will technically achieve the vision. Conversely, execution risk is minimal during this phase as project/research teams are likely to be small in numbers and co-located with a low degree of cross-functionalism. As the project transcends towards and into the development phase, the technical risk component steadily decreases as the solution becomes more tangible. However, the decrease in technical risk is

² Project Management Institute. A Guide to the Project Management Body of Knowledge (PMBOK® Guide) (2000 ed.). 2000. p.31. Newton Square, PA: PMI.

offset by an increase in execution risk as the project team grows in both numbers and functions.

The fundamental requirement for the successful deployment of project management within the product development lifecycle is to adopt a modular approach, Progressive Project Management Focus (PPMF)©. PPMF© describes a methodology where the project management process is applied to each phase of the product development lifecycle with increasing levels of intensity to mitigate project risk (see Figure 2). Each phase of product development has unique risks, challenges, and requirements dictating a discrete application of the project management process. Although how to apply the project management process at the four phases of product development may be intuitive, it is important to understand how the process affects the two components of product development risks, technical and execution.

Progressive Project Management Focus (PPMF)©



¹ Coleman, Jeffrey R. and Mondschein, Ellen (July 1997). Speeding the "R" of R&D Through a Deliverables Orientation. Visions Magazine [Online].

² Project Management Institute. A Guide to the Project Management Body of Knowledge (PMBOK® Guide) (2000 ed.). 2000. p.31. Newton Square, PA: PMI.

Figure 2

The project manager is the organizational link between the business objective and the detailed activities required to realize the objective. Using the project objective to establish a plan and schedule, although it may be flexible during early-stage development, the project manager ensures research activities remain focused to the business objective. The occurrence of a technical risk event at this stage will negatively affect speed-to-market; therefore, the plan and schedule provides a baseline to measure and control project progress and facilitate the iterative research loops to a quantifiable, project deliverable. This discipline will result in more compact and focused research loops that result in an effective research program.

As the product development lifecycle continues, technical risks decrease and project execution risks increase. The project manager becomes more focused toward project coordination and communication with multiple resources and functional disciplines. The fundamental process of aligning all resources to the project objective through project planning and execution establishes control and direction for the composite project team and the timely and on-budget delivery of a commercially viable product.



PROJECT MANAGEMENT IN PRACTICE – REAL WORLD EXAMPLES

In order to fully minimize both technical and execution risk, varying levels of project management must be applied based on the stage and complexity of the product, or technology being developed. The following are three brief examples where professional project management has made the difference in product development.

- A pharmaceutical company engaged professional project managers to supplement its scientific and technical staff on 5 critical product development projects. Across the projects, the company realized over \$12 million in accelerated profits and costs savings as well as achieved an average of 42% baseline schedule compression. These results provided a 400% return on every dollar invested in the project management resources.
- A pharmaceutical company recognized its inefficiency in selecting product candidates and effectively transitioning products from discovery to pre-clinical development. To meet the aggressive timeline the company had set for identifying the best candidate, professional project managers were engaged to coordinate the planning and interaction between the discovery team and the pre-clinical team, to define the scientific and market criteria for product candidate selection, and to define the decision making process for selection. The process and discipline of the professional project managers led the transition team to identify the highest potential product candidate, deliver an on-time recommendation to meet the product development schedule, and ensured successful transition to pre-clinical development.

- A venture capital backed start-up nanotechnology company used a professional project manager to manage efforts to prove the scientific principles and feasibility of using holographic optical trapping (HOT) technology to sort living cells. Through close collaboration with the company's executives and technical resources, research activities were planned and executed such that various scientific concepts were ultimately proven feasible. Furthermore, the risk management program and contingencies implemented by the project manager allowed for a controlled burn of the existing capital to accommodate unforeseen issues. Finally, the company, armed with significant research advancements, was able to successfully secure an additional round of venture capital funding.
- A pharmaceutical company in-licensed a late stage biological candidate to bolster its portfolio of drug treatments for rheumatoid arthritis. Faced with a very aggressive timeline to prepare new Active Pharmaceutical Ingredient (API) and Drug Product (DP) manufacturing sites, complete technology transfers, manufacture and release the requisite clinical supplies, file and obtain FDA approval of a Phase III IND amendment, and commence with Phase III clinical trials, the company engaged professional project managers to plan and coordinate the activities necessary to fulfill the intended objectives. With risks fully identified and managed, initial Phase III supplies were successfully manufactured and released, the IND amendment was filed, and the clinical program was initiated ahead of the best-case schedule.



SUMMARY

- Market pressure to compress product development timelines is a business reality.
- Project management is a skill that can facilitate timeline compression, cost savings and avoidance and risk mitigation.
- The focus and intensity of project management will vary over the course of the product development lifecycle.
- During the exploratory and conceptual phases, the project management activity level required is relatively low, and the focus is primarily on minimizing technical risk and driving convergence of the research loops to a viable deliverable.
- During the feasibility and development phases, the project management activity level steadily increases due to increased program complexity, and the focus is primarily on minimizing execution risk associated with final approval, manufacturing, and commercial launch.

About the Authors

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