Project Execution Planning: The Key to Successful Pharmaceutical Project Delivery

by Robert Garner

This article presents the importance of a Project Execution Plan (PEP) for a pharmaceutical facilities project, outlines the fundamental aspects of a PEP, and details what should be included in each section.

Every pharmaceutical project is unique and each project requires a detailed Project Execution Plan (PEP). The PEP is not a “one size fits all” document. It must be specifically tailored to meet the size and specific phases of an individual project.

While attributes that are common to all projects include safety, quality, cost, and schedule, each project combines differences in scope, scale, complexity, resources, and many other factors to achieve its goals and objectives. During the project development and delivery process, the concept and Basis of Design (BOD) phases of work are important alignment phases of project execution which help to address these attributes as well as many addressed within the PEP. The PEP communicates and documents the project “map” and the overall strategic approach for the execution of the entire project for all stakeholders. It also sets the tone for demonstrating effective leadership, project organization, progress measurement, and teamwork. A good PEP provides guidance over every applicable element of a project. Such attention to detail is particularly important for the pharmaceutical industry, which faces regulation from the U.S. Food and Drug Administration (FDA) in the form of current Good Manufacturing Practices (cGMP) regulations. A PEP is the product of good project planning and incorporates several sub-plans, such as a project procurement (or supply management) plan, project risk identification and mitigation plan, project staffing plan, construction execution plan, cost/budget management plan, project controls plan, project quality plan, and overall team alignment.

The PEP is typically completed during the early (concept, BOD, or preconstruction) phase of the project. Preconstruction is critical for the successful delivery of capital projects.

Figure 1. Key Project Execution Plan (PEP) elements.
These early phases of a project provide owners with a formal approach for developing and executing capital projects. In addition, these early phases help define the project scope, schedule and cost as early as possible to enable the most efficient use of resources and money, while reducing risks as seen in Figure 1. In order to achieve the necessary level of accuracy, project execution planning must be performed in conjunction with the project’s capital planning. Only by tying budget items, line-by-line, to construction tasks can a precise PEP be established.

A PEP should be tailored to meet the size, scope, and execution approach agreed upon for a project. For instance, a PEP that is used for a $200 million Engineering, Procurement and Construction Management (EPCM) plan should be more detailed and extensive than one for a $1 million design-only project. The key components of the plan should be the same, but the level of detail is different. Every project should have some form of PEP or alignment document that encompasses the scope and organization of the project and sets the cadence at project kickoff.

While the PEP provides guidance for the execution of the project, it usually starts with a mission statement or overall goal of the project based upon the owner’s requirements, such as scope, technology, business drivers, owner involvement, schedule, operations, project size, regulatory environment, permitting, commissioning, licensing involvement, and expectations for ROI. An example of a simple mission statement might be to deliver the new ABC manufacturing facility in a phased approach that is aligned with the Company XYZ manufacturing strategy and supports the business objectives of its supply chain. Key items to accomplish with this mission include:

• To meet Phase 1 production dates and requirements in 1Q2014 and Phase 2 in 3Q2015
• To provide the new facility and support facilities in a manner that support the production goals stated above
• To create a safe, productive, collaborative and highly motivated work culture that supports the achievement of these goals

The following discussion provides some key elements that should be covered in a PEP - Figure 2.

**Project Scope**

It is important to outline the scope of the project, as it forms the basis for the effort-hours and overall schedule required to complete the project from a design, procurement or construction perspective. It also forms the basis for the project management constraint triangle: scope, cost, and schedule. Obviously, the larger the project (defined in scope), the greater the design, construction, and procurement effort it will take to complete. The scope of work is a critical element for cost and schedule management of the project, and is the foundation of the project. Essentially, the PEP defines the “what” and “where” work will be derived.

**Project Organizational Chart**

Who is in charge? Who has the authority to allocate costs and make changes? What is the project reporting structure? How does the team fit together? This should be made clear up front and updated as required.

**Contracting Strategy and Project Delivery Model**

Is the project EPCM, design-bid-build or other? The PEP should reflect the planning of the project and state the delivery model being utilized. Many specific elements of the PEP are addressed regardless of the contracting strategy, but clearly the PEP will address these requirements from a roles and responsibilities perspective differently depending on the delivery model chosen. The key is to put these thoughts into the PEP and clearly communicate these intentions for the entire team early.

The project delivery decision should be based on a number of factors including budget, schedule, cash flow, project complexity, risk mitigation, project team composition and project goals. Essentially, a project delivery method is a configuration of roles, relationships, responsibilities, and sequences on a project.

A brief overview of some of the typical project delivery methods for pharmaceutical projects can be seen in Figure 3.
Design-Bid-Build (DBB)

DBB is a common project delivery method in the pharmaceutical industry. Owners with sufficient in-house staff contract with different entities for each phase of design and construction, and take on the responsibility of orchestrating the various team members. Each step in the execution process follows the other with minimal overlap. Under this approach, the owner functions as the overall project manager and hires external engineers, consultants, and contractors.

DBB is typically used when the project is not well-defined and there is adequate time for the design and construction phases. These projects are often competitively bid and priced as a lump sum. The competitive nature of the bidding process usually results in a competitive cost for the owner, but the quality of the subcontractors is left to the general contractor.

Under this method, all construction and performance risks are assumed by the GC. Change orders and schedule delays can occur if the owner’s intent for the scope of work is not well-defined by the architect to the contractor.

Construction Management (CM)

Under the CM method, the owner retains a firm to act as its construction management representative. There are a number of variations on this model. An architect is retained to develop a design package. The CM is retained for a fee and is responsible for managing construction while meeting goals in terms of quality, scope, cost, and schedule.

The CM representative is also responsible for estimate development, construction, subcontracts, scheduling, reporting, quality control, and cost controls. Then architects, engineers, and consultants are retained to develop a program. Multiple construction packages are developed, and bids are solicited from various trades. Under the CM method, design and construction activities overlap.

This model is well-suited for owners that lack in-house design and construction expertise or capacity. It ensures consistent oversight and careful monitoring of costs and schedule. However, this method can result in additional upfront costs and create communication challenges among the team.

Engineer-Procure-Construct (EPC)

EPC is emerging as a preferred choice of project delivery for pharmaceutical projects. Under this model, the EPC firm handles design, procurement of all equipment and construction materials, and construction services for complete delivery of the project, usually at a lump sum price. The EPC process starts with a preconstruction effort that involves some preliminary planning and engineering to define scope, schedule, and costs of the project. The EPC firm has complete responsibility for the project from start to finish.

The project schedule and project budget are known at the start. All scope, cost and schedule risks are passed to the EPC contractor. EPC project delivery offers the tightest integration of activities during the construction process through a structured and disciplined approach. In addition, communication among the design, procurement, and construction teams begins immediately.

The EPC model helps align team members for optimal project performance. EPC delivery is typically used for process or equipment-driven projects. This model reduces risks for the owner, delivers predictable results, and maximizes the effectiveness of capital planning.

The project delivery method will have an impact on the PEP. Clearly, the level of planning will be substantially different for a single source EPCM project than for a design-only PEP, so this should be covered first.

Project Contractual Arrangement

There are many collaborative methods used to properly incentivize a project. The project contractual plan should determine how the scope of work will be performed by contractors to meet the project objectives. The contract plan should address roles and responsibilities, project scope of work, contracting methods, and project milestones.

Different contractual terms have different impacts on project stakeholders. For example, is the project cost plus fee, guaranteed maximum, or lump sum? These approaches are typically negotiated. The key point is to maintain as much “skin in the game” for all parties as possible. This will ensure that the project gets proper focus from all parties until completion. Another area of focus should be the...
Project Risk Identification and Mitigation

What special risks does the project have that need to be monitored and mitigated against? It is critical to beware of potential risks and to develop mitigation strategies to ensure the cost and schedule are met. Common examples of project risk include: use of new or unproven technology, impact to existing facilities or operations, project cost, project schedule, validation of new technology or products, compliance, etc. Project risk should be defined and managed.

In a generic sense, risk can be defined as: the probability of an uncertain (unwanted) event X (times) the severity of this event.

Within a PEP, the project manager needs to identify and communicate risk in terms of both probability and severity and then needs to plan risk controls to mitigate each. Risk controls can include people, funds, time and other resources. Mitigation involves reducing the probability or severity of an event. Proper mitigation planning also can involve the utilization of a “backup” plan that is used in the event that a project risk becomes reality. The PEP should introduce a project management action log, and this log should be reviewed and updated monthly. It should visit each potential project risk and assign a status to the probability of this risk in realtime as the project goes forward. This status should be communicated to others who will be impacted or who should be informed. For more specific guidance on managing project risk on pharmaceutical projects, the reader should consult the ISPE Good Practice Guide: Project Management for Pharmaceutical Industry, Chapter 3, pages 61 to 84, as this provides a very good overview of risk management in the pharmaceutical industry.

Cost and Schedule Management

The PEP should include discussion of how costs and schedule will be managed during the design, procurement and construction phases of the project. The cost management plan should determine how costs will be estimated, reported, controlled and managed. On any project, costs are driven by a combination of scope of work, resources and productivity. This will serve as a guide for the project, starting with the original project schedule and budget through completion. This should include cost development, cash flow, milestones and other factors related to the costs and schedule of the project. Schedule management discussions should focus on how the schedule will be prepared and tracked and how milestones will be set and measured.

Procurement Strategy

Two distinct elements of this strategy are discussed below:

Package Definition — for each piece of equipment, material or construction trade, the team must develop a list of non-overlapping documents (packages) that form the basis for each purchase. This typically involves extensive planning early in a project and continues through completion. It is a planning and scheduling function and should involve project management, stakeholders, design, cost and scheduling, and procurement. Typically, this is done at the preconstruction phase. If done properly, the team will account for equipment delivery first (as this usually has the greatest impact on overall project schedule) and then phase in the various construction packages (underground, foundations, building erection, mechanical, electrical and plumbing trade packages, controls, voice/data/security, etc.) as required to complete the project. This planning is paramount to good overall execution and should be revisited continually during the execution of the project.
**Procurement Matrix** – this should be a comprehensive list of the equipment and subcontract packages that are defined above. The equipment purchasing package typically uses the equipment list as its backbone. The procurement matrix should be broken out as two documents: equipment procurement and subcontract procurement. This matrix shows the package description, package owner, sourcing strategy (competitive bid, sole source), approved (qualified) suppliers, Request for Proposal (RFP) dates, order status (out for bid, awarded, in progress), Recommendation for Award (RFA) responsibility, engineering drawing (reviews, approvals, return) responsibility, expediting responsibilities and status, milestone payments, commitment and expediting schedule and inspection (shop and Factory Acceptance Testing (FAT)) responsibilities and status. The PEP should establish the key responsibilities of this matrix and communicate them to the overall team. The PEP also establishes the overall responsibility of the procurement lead to own the matrix going forward and the obligation to hold weekly procurement meetings to continue to update this matrix as the project goes forward.

**Resource Planning**

Within the PEP, there should be a document that defines the expected participation of all team members. Using the project schedule and planning from key team members, it is best to break the project down by week and plan the participation of team members. This is typically accomplished through a large spreadsheet that shows expected durations for all design staff (broken out by discipline or role on the project), project scheduling and controls personnel, project procurement staff, preconstruction personnel, and construction personnel as required. Again, the PEP will "right size" this staffing plan based on the overall scope of the project, user group participation, project management, project engineering, design, procurement, project controls, construction, commissioning, and validation. The goal is to schedule the resources in advance and build in the steps to secure the resources. Note that this is not a Roles and Responsibilities (RACI) diagram, which serves a different purpose. The resource planning document secures the resources for expected durations and should assist project controls personnel in predicting professional services budgets. In addition, the resource planning document also should address all phases through construction and qualification. This can only be completed after the design schedule and other contracted services are awarded and properly budgeted.

**Roles and Responsibilities**

There are many different roles and responsibilities on any given project, varying with the project’s size and scope. It is important that the primary roles and responsibilities are defined early on in order to facilitate good communication among team members and promote ownership as the project moves forward. It is a good practice to include a RACI diagram to an appendix of the PEP. The RACI diagram defines who is as seen in Figure 4.

- R= Responsible (who completes the work or task)
- A= Accountable (who is ultimately accountable for the correct completion of the work or task)
- C= Consulted (whose opinion is sought during the completion of the task)
- I= Informed (who is informed or kept up to date on the status of the task or work)

**Design Plan**

After project scoping and planning, the PEP should focus on the design of the new process, facility and/or site. The following are the key elements of design that should be covered within the PEP:

- Scope of services and design deliverables – the scope is key (as discussed above), but it is important to also cover in detail exactly what deliverables are expected and agreed upon.
- CAD coordination – this is a large topic in and of itself,
and it is an important one. The following are some essential elements of CAD coordination that must be clear to the team going forward:
- CAD platform and version
- CAD standards, procedures, and conventions
- Drawing numbering standards
- CAD deliverables:
  > 2-D schematics
  > Piping and Instrumentation Diagrams (P&IDs)
  > Isometrics
  > Orthographics
- Project closeout requirements – drawing turnover requirements
- Design schedule – not just the overall schedule but dates of important reviews, meetings, and other coordination activities
- Design standards to be employed
- Review of design team’s role in the document management team
- Review of design team’s role in procurement:
  - Bid package/drawing package division
  - Pre-bid meeting attendance and responsibilities
  - Shop drawing review and approval responsibilities
- Construction support responsibilities and duration
- Estimate responsibility, accuracy and plan for the execution of the overall project estimate
- Technology or information management plan – described software and other electronic tools to be used in the execution of the project
- Health, safety, and environmental planning
- Value enhancement – this is primarily focused on value engineering. The design plan should discuss the value engineering expectations of the project as well as the manner in which ideas are documented, evaluated and incorporated into the design.

Cost Reporting – the following are recommended examples:
- Monthly (weekly)* project cost report
- An overall resource plan by month (week)*
- Detailed change order log of all change orders indicating status – approved, pending, rejected, void, or under development. This log should be kept current and reviewed during the weekly coordination meetings.
- Monthly invoice log, which will track the invoice number, the value of the invoice, submittal date and payment date.

*depends on project size and scope

Schedule/Planning – planning is one of the most important elements in every project. Overall project planning is captured and documented by project controls personnel. Once a schedule is approved, it should be baselined and included within the PEP. Any significant changes in the schedule logic, forecast, etc., will be accompanied with a written description explaining the basis for the change, forecast, etc. Any requested change to the baseline (target) schedule must be accompanied by the proper change control documentation approved by the project manager.

Schedule Status Reporting – an approach for earned value should be considered for all projects whose size warrants. Earned value is an objective project management tool for evaluating project performance and progress. The project’s approach to earned value, reporting, and frequency of reporting should be covered within the PEP.

Construction Plan
This plan covers the following:

Roles and Responsibilities – Construction Management Team
While the overall project organizational chart has already been presented, it is important in the construction arena to reiterate roles, responsibilities, and reporting requirements. The management of trade contractors requires that everyone understand their role and who has rank for making decisions and reporting status and concerns.

Construction Organizational Chart
This should be a chart reiterating the roles and responsibilities of outlined above.

Construction Quality Plan
The quality control program is a formal program that consists of inspections, examinations, and tests to ensure compliance with the design drawings, specifications, codes and standards. The program should be administered by
qualified personnel and documented in accordance with written procedures.

Quality assurance is a formal program that verifies and documents that all required tests, inspections, examinations and reviews have been performed to ensure that applicable codes, standards, project documents, and specifications have been met.

The construction management team on a project has the complete authority and responsibility to identify quality problems/concerns, investigate them to the extent deemed necessary and to initiate, recommend and/or provide solutions to those problems/concerns. In addition, it has the authority to cause any activity which is not being performed in strict accordance with the project engineering drawings and specifications, regulatory code requirements and/or the quality control/quality assurance manual to be stopped.

**Safety Program and Safety Incentive Plan**

The master safety plan communicates the requirements and culture for the safety side of the project. Safety is most important component of every project. Companies have a moral responsibility to do all that they can to ensure that every employee returns home to his or her family as safe as they were when they reported to the jobsite.

The safety plan should incorporate the following elements:

- The role (if applicable) of the safety plan for all contractors/subcontractors and the need for it to be included as a part of trade contracts issued
- Drug and alcohol test and safety orientation requirements for all personnel
- Consideration of safety awards and incentives for superior safety performance by individual subcontractor employees or crews
- Establishment of regular safety audits, inspections, and ratings of performance for each of the subcontractors
- Use of tracking programs, which will allow analysis of each subcontractor’s performance, compilation of statistics for historical use, trend analysis, and graphical communications of safety metrics
- Mandatory utilization of daily toolbox meetings and Safe Plan of Action (SPAs) by trade contractors. Contractors shall prepare SPAs for each unique activity and thoroughly review the SPAs prior to the start of performing that activity.
- A near-miss reporting program. A near miss is an event that did not cause injury or property damage, but had the potential to do so. An example is tripping without getting hurt. The goal is to communicate that near misses should be reported immediately in order to prevent a similar incident from causing an injury.
- An unsafe conditions reporting program. All unsafe conditions should be corrected immediately and reported to project management. Permitting requirements for the following activities:
  > Construction
  > Hot work
  > Excavation
  > Roof access
  > Crane
  > Scaffold
  > Line breaking
  > Potable water connection
  > Safety reporting for total construction hours worked, and the number of near misses, first aids, recordable, and lost time incidents

**Site Logistics Plan**

A site plan drawing should be created that shows directions to the site, proper locations for craft parking, material laydown, dumpster locations, shelter and muster locations, restroom and water locations, etc.

**Commissioning and Validation Plan**

Sometimes termed the Validation Master Plan (VMP) or commissioning plan, this plan should be referred to within the PEP, but should not be the primary focus. Proper planning and input should be given to the definition of turnover systems, and enough engineering and design should be complete to provide a solid basis for system turnover decisions. Initial activities include a planning session with owner’s site representatives to ensure an appropriate system definition and turnover sequence that facilitates a smooth transition into the owner’s care, custody and control.

**New Collaborations between Manufacturers and Construction Firms**

The PEP should be completed as early as possible. For complex projects, such as pharmaceutical facilities, there needs to be complete alignment between the earliest capital planning stage and actual, on-the-ground construction processes. Outdated workflows – in which parties are brought on-board even in late stage construction and where alignment is sought as the project unfolds – are no longer viable. Successful firms are developing a more comprehensive system, tying their construction services in with a process which integrates overall project planning, design, procurement and construction to create cost-effective capital solutions. Firms which assemble an inter-disciplinary team in-house can provide solutions at a project’s earliest stages, and are therefore able to provide their clients with a guaranteed project cost from the outset.

Front-end planning, as a series of structured processes, is receiving much industry attention because it provides owners with a formal approach for developing and executing their capital projects, which require long-term investment...
to develop, build and maintain. Capital project delivery processes and front-end planning have been extensively studied by the Construction Industry Institute (CII). CII is a consortium of more than a hundred leading owner, engineering-contractor, and supplier firms from both the public and private arenas, and its mission is to improve the cost effectiveness and sustainability of the capital facility project life cycle. CII research has shown the critical importance of effective front-end loading to increase project predictability in terms of cost, schedule, and performance metrics. The process conclusively fixes the project scope while capturing design, construction, and operating requirements.

The Total Project Delivery Toolkit
CII has developed a scope readiness tool, the Project Definition Rating Index (PRDI), which is a weighted scoring system that evaluates all aspects of a capital project. The PRDI was developed based on research of more than 25,000 completed capital projects, and it improves the front end planning process and aligns team members’ and owner’s expectations.

PRDI documents define the key elements of an industrial facility project and provide a rating system for those elements. After the preconstruction team assigns a rating to each of the elements on the checklist, a final score is generated. This score indicates, at a glance, the overall risk associated with a project; during the CII validation process, projects scoring less than 200 (out of 1000 total points) were found to be, according to the CII, “significantly more successful than those that scored greater than 200.”

Project Delivery: One Firm’s Experience
Using PRDI as a springboard, O’Neal, an integrated design and construction firm, has developed a preconstruction approach that is driven by their proprietary Capital Appropriation Process (CAP). The CAP process can be an assessment tool that can effectively determine cost, scope and schedule for an investment. It provides owners with a thorough front-end assessment of their proposed project and identifies areas in which there is a specific risk to success, especially from a design and cost standpoint as seen in Figure 5.

O’Neal’s CAP focuses on project development and delivery models that exhibit the following characteristics:

- Every potential project is viewed as an opportunity for savings.
- Capital is directed toward the areas that best benefit the organization’s overall goals.
- Stakeholders are included in the front-end loading process at the appropriate times.
- Each step in the capital process is connected to and builds on the previous step.

Figure 5. Project development and delivery for cGMP facilities.
• Long-term requirements are considered at the front-end of a project.
• “Gates” or review processes, occur throughout front-end loading. Projects must meet owner-established criteria at the beginning of the project in order to move forward.

O’Neal has successfully used the CAP and PDRI processes and tools for pharmaceutical, biotech, and other projects, including solid dose manufacturing, aseptic and sterile fill operations, vaccine production, medical device manufacturing, warehousing, packaging and BSL labs.

Proper planning is critical to successful projects in the pharmaceutical industry. The PEP process is instrumental in ensuring effective team communication and interaction. The PEP communicates and documents “the map” for the execution of the entire project, providing guidance over all elements of the project. By setting the tone for effective project leadership, project organization, progress measurement and teamwork, the PEP is a critical tool for successful project delivery. It is important that the project manager issue the PEP early and then take time to review and update the document monthly as the project proceeds to ensure that all of the proper planning is occurring at all phases of project execution.

References

About the Author
Robert Garner is in Project Management for O’Neal, Inc. He has a BS in chemical engineering from North Carolina State University and has more than 28 years of experience in capital project management, process engineering, process controls engineering, and production management experience. His primary expertise is in biotech/pharmaceutical process engineering, fill/finish, and other sterile manufacturing projects. He can be contacted by phone: +1-919-840-9500 or by email: rgarner@onealinc.com.

O’Neal, Inc., 3000 RDU Center Dr., Suite 200, Morrisville, North Carolina 27560, USA.