The Chemical Engineer

Purity in delivery

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Purity in delivery

Wael Allan, Bill Flemming, and **Philip Southerland** explain how integrated "pure" construction management can create real value

CHOOSING the right delivery method for a capital project is a fundamental and crucial decision in project management. Companies have to balance quality and speed of delivery with an increasing pressure to cut the price of capital projects.

Nowhere is this more apparent than in the pharmaceuticals industry. Historically, pharmaceutical companies have been among the most conservative when choosing a capital project delivery method because of the stringent regulatory environment in which they operate, and they have focused on quality and schedule as the main criteria for delivery of their capital projects.

Today, the pressure to increase shareholder value while controlling or even reducing drug prices, combined with the recent poor productivity in R&D and the end of many blockbuster patents, have altered the fundamental business practices of this industry. Companies are increasingly focusing on reducing the price of capital projects. We believe that implementing a 'pure' construction management project delivery method – in which a construction manager is focused on meeting cost, schedule and quality goals without self-performing any engineering or construction – can achieve this goal.

selecting a project delivery method

The increased emphasis on reducing the price of capital projects, and the associated impact on fees, has driven some of the most capable engineering and construction contractors out of the pharmaceutical and life sciences market. In many cases, this has resulted in considerable delays and compromises in quality. At the same time, natural disasters and strong demand have driven up the cost of many building materials.

These factors have complicated the decision-making process for owners selecting a method for design and construction of capital project. Over the years, alternative delivery methods have been developed to address weaknesses in the traditional design-bid-build method, among these, construction management (CM) as agent or at risk, and design-build, including engineering procurement construction management (EPCM). Of all the alternatives, the authors believe the most successful approach for reducing cost, accelerating schedule and ensuring that the project meets the owner's quality standards is a pure CM project delivery method incorporating integrated construction, commissioning and qualification (see Figures 1 and 2).

Figure 2 shows the range where clients/owners are directed during pre-construction – in between the quality limits. Theoretically, if an owner pays more, they should get higher quality. That is generally true, but there is a point where the owner can over-spend. That point is where for example the maintenance costs of an initially high priced complicated system are so exorbitant that the client/owner would have been better off with a simpler system. Conversely, if the owner buys mediocre products at low price, they will pay dearly for maintenance and replacement. The aim is to buy the system with the best, proven overall lifecycle.

avoiding conflict of interest

Construction management evolved as a professional discipline distinct from design and construction in the early 1960s. Since then, increasing regulatory requirements, litigation and other risks created a need for an independent professional to be an advocate for the owner and to bridge the gap between the owner, the designer and the contractor. In the pharmaceutical industry, a construction manager who is fully aware of the regulatory and documentation compliance requirements can add great value to clients' projects.

In many ways, the construction manager and general contractor (GC) are similar, especially with respect to their management responsibilities during the construction phase of a project. However, unlike the GC, the construction manager performs a host of important pre-construction services. In addition, a GC typically will self-perform some of the work, such as civil construction, in addition to performing construction management. There is an inherent conflict of interest in this arrangement. By contrast, the CM firm will not self-perform any of the physical labour, enabling it to remain objective.

In fact, a pure CM model ensures that management of subcontractors,

cash flow, quality and change order management are achieved with no conflict of interest. Thus the business drivers of the CM and owner are aligned, unlike a project delivery approach in which the business driver is the sale of man-hours.

addressing owners' critical issues

A CM method can add more value and reduce the risk to the owner whenever the owner is addressing important issues common to biopharmaceutical projects. Timing is often critical, with many projects on an accelerated schedule. Many projects also require considerable flexibility. For example, fast-track projects typically are not fully defined by the owner and designer prior to the start of construction. In other cases, end-users have considerable influence on the outcome. Either way, there is potential for substantial change during the detailed design and construction phases of the project.

Many owners also require pre-construction services to help with planning so they can meet their objectives with respect to quality, safety, and balance of cost, scope and schedule. Involving a professional CM during pre-construction can help make a project smooth and trouble-free, resulting in a facility that meets these strategic business goals. Complex projects may also require expert design process management. Finally, most pharmaceutical projects are subject to financial constraints with respect to type of contract, risk and other issues.

On projects affected by these issues, the construction manager can add value by representing the owner in the following areas:

- optimal release and use of funds throughout the project;
- optimal project/programme scheduling options;
- enhanced control of scope;
- optimum use of other firms' talents and resources;
- avoidance of delays, changes, disputes and cost overruns;
- optimum flexibility in contracting and procurement;
- assurance that the project is built to specification; and
- effective site logistics and installation sequencing planning.

successful contracting structures

A number of CM contracting formats have evolved which enable owners and contractors to either shift or share the risk of a project or to increase the speed of delivery. The most obvious definition of risk pertains to meeting the cost objectives of the project. But projects also entail performance risk, that is, the ability to complete the project on time and at the level of quality as agreed between the owner and CM.

It is important to distinguish between CM 'at risk' and CM 'agency'. CM at risk is a delivery method that entails a commitment by the construction manager to deliver the project at or below a specific price – the guaranteed maximum price (GMP). The CM acts as consultant to the owner in the development and design phases, and as the equivalent of a GC during the construction phase, holding individual construction contracts for subcontractors. In CM agency, the CM acts as the owner's principal agent to advise on or manage the process from project conception to completion.

The key difference between these two forms is that the CM at risk is a distinct delivery method due to its responsibility for construction performance. Agency CM, on the other hand, is a distinct set of consultancy services that can be applied to any delivery method. The agency CM is assuming little financial risk and may be receiving no incentive for meeting schedule, cost, or quality parameters (see Figure 3).

Shifting risk to the CM creates the potential for an adversarial relationship between owner and CM *unless* the base compensation, provision for liquidated damages, and performance incentives are truly commensurate with the construction manager's level of risk. Unfortunately, in today's cost-conscious environment, many pharmaceutical companies pressure CMs to accept 'low-ball' fees. But, in shifting the risk to the CM, the owner must select a construction manager with the capacity, expertise in the pharmaceutical industry, and local knowledge to deliver a successful project on time, within budget and at the expected level of quality. That sort of expertise is only sustainable when the price is equitable.

While the industry standard has been the lump sum, fixed price or reimbursable contract structure, pharmaceutical industry leaders have begun to recognise that for some projects, the GMP contract offers a better solution. Essentially a hybrid structure – a reimbursable contract with a not-to-exceed amount – the GMP balances the advantages to the owner of the lump sum contract while recognizing the risk inherent in most large pharmaceutical projects.

Contracts based on a fair base compensation with performance incentives have been most successful in generating good results and high levels of satisfaction for both parties when there is a system and methodology in place to ensure that quality is not simply an "inspection" function of the project.

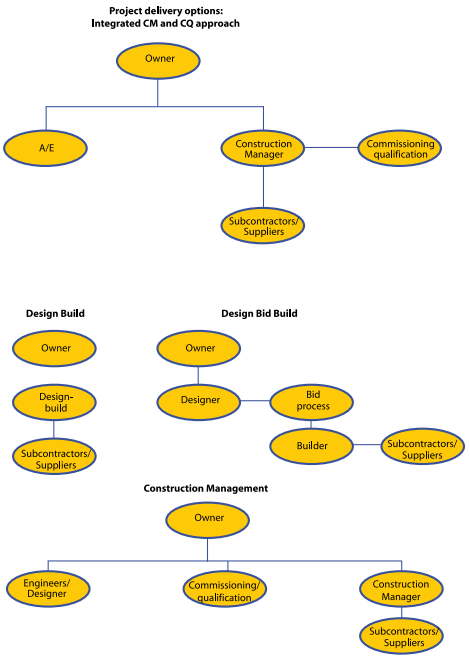

Figure 1: Project delivery methods

pre-construction services save time and money

One of the most important phases to the success of a pharmaceutical project is the pre-construction phase. Involving the CM at this phase is the best way to save money and keep a project on schedule. In the pre-construction phase, the CM typically performs the following services:

- estimating;
- constructability reviews and value engineering/management;
- develops project schedule;
- plans for equipment and subcontract procurement;
- initiates project management systems;
- develops site logistics plan;
- establishes site-specific safety and quality plans;
- develops project execution plans and project procedures manual;
- develops integrated commissioning & qualification plan;
- develops clean build plan; and
- develops modularisation strategy.

Accurate estimating is the key to understanding

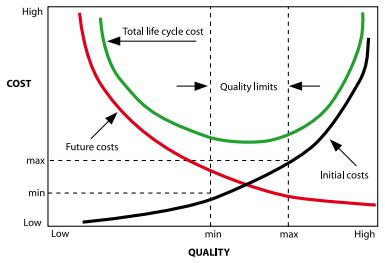

Figure 2: Correlation between quality and cost

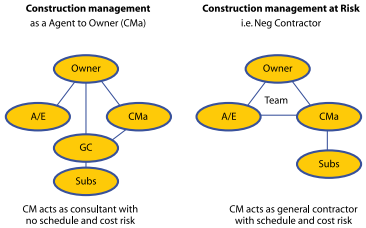

Figure 3: CM as agent and at risk

and managing costs. The construction manager normally provides detailed estimates as the design progresses. Typically at a minimum, these will include a conceptual design estimate or cost model, detailed design estimate and, later in the process, a construction documents estimate. The development of a detailed cost model is a key deliverable needed in the early pre-construction phase. Here the

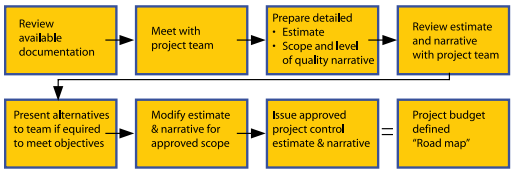

Figure 4: Budgeting process

CM will start by thoroughly reviewing the available design documentation, preliminary equipment arrangements and site issues. After this review, the construction manager will meet with the owner and design team to review interpretations of the documentation

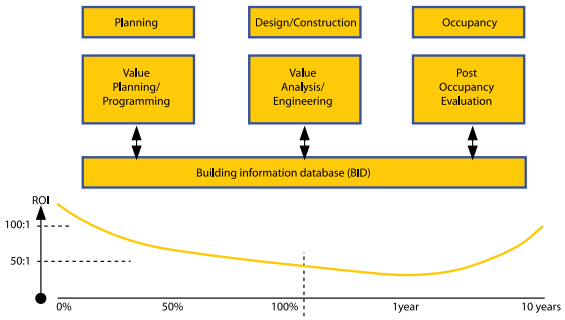

Figure 5: Process and benefit of value management

and design detailing yet to come. These meetings are held to research the true scope of the project and ensure that all requirements are accounted for in the budget (see Figure 4).

Constructability reviews and value

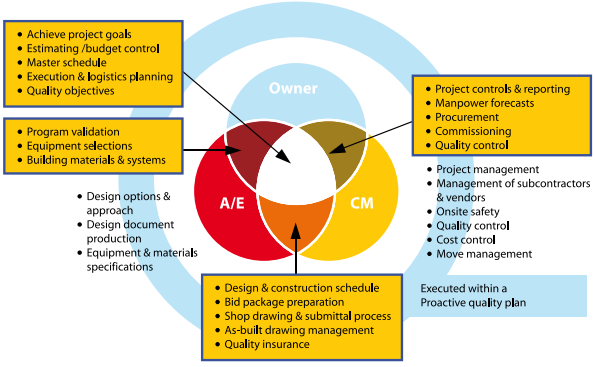

Figure 6: Project team roles and how they must interact as one

engineering seek maximum value for money. The CM views constructability and value engineering as two complementary areas in which project value can be maximised. This approach – rather than traditional cost-cutting practices – seeks to find the point in the cost curve with maximum value. For example, systems that facilitate future changes in a communications systems network may not necessarily have the lowest first cost, but their future value (ie lifecycle cost) in terms of expansion and technology upgrade capabilities are well worth exploring for implementation, as Figure 5 illustrates.

In addition, Figure 6 shows how the project execution plan and procedures manual are the strategic blueprint providing a single agreed-upon set of procedures for the project team.

a pragmatic approach to procurement

While engineers can talk technically to equipment vendors, CM firms shift the emphasis from technical perfection to cost and expedited delivery. Thus a primary objective in the procurement phase of any project is to ensure optimum value in the purchasing of equipment and services, provide information vital to the design team, and ensure that equipment and subcontractors meet the construction schedule and quality. Procurement must also support the needs of commissioning and qualification. In order to do this the construction manager needs to identify an execution strategy that will allow portions of the design and construction documents to be issued early, enabling construction to commence as early as possible. Design and construction document packages are produced in a way that enables an early start for construction and supports the overall time frame for the project.

Thus the purchasing/procurement strategy for any pharmaceutical project requires the ability and experience of a CM. As the scope of the project and the type of materials are defined, the construction manager will develop a strategy that will clearly define the type, quantity and timing of the bid packages required from the design firm. Although the primary goal of the purchasing plan is to ensure that the necessary labour and materials are available for construction, a corollary benefit is that it provides the design firm with a clear definition of the timing and scope of specific design deliverables.

construction, commissioning and qualification

The CM performs a host of essential services during the construction and post-construction phases of any pharmaceutical project. Functioning as the GC, the construction manager will coordinate project mobilisation by conducting pre-construction conferences with trade subcontractors to review the various requirements and procedures necessary for the orderly execution of the work. Quality of installation, including mobilisation, safety, security, invoicing, claims, scheduling, inspection and quality control, documentation, coordination, submittal and approval and project closeout must all be agreed.

Using the site-specific quality management plan, the CM will establish and monitor conformance with quality objectives, sample and mockup requirements, testing and acceptance procedures, and documentation of the specific inspection requirements of building code officials, the owner and the construction manager. Field auditing of critical systems will also be conducted as per the construction qualification programme.

During the construction phase, the CM will maintain and update the detailed project schedule, which will incorporate the activities, relationships and required milestone dates for the work of all trades. The CM will also initiate appropriate schedule updating procedures and reporting formats to plan the work activities of trade subcontractors and monitor completion status. Depending on the contractual end point, the schedule must be integrated to encompass commissioning and qualification activities at a detailed enough level to ensure compliance.

integration yields results

Overall, the most successful approach for reducing cost, accelerating schedule and ensuring that the project meets the owner's quality standards is a pure CM project delivery method incorporating integrated construction, commissioning and qualification.

This is a process and methodology through which the construction manager integrates quality assurance at every phase of the project. A quality plan is agreed with the owner at the outset and on-going auditing will confirm that the work is right the first time.

For projects in the pharmaceutical industry, which is subject to regulatory compliance, the importance of

qualifying the construction can not be overemphasised. This construction qualification process is essential to construction in the same way as design qualification is important to the design/engineering phase. The extension of design qualification into construction is pivotal to the success of a pharmaceutical project and will result in cost and time savings.

Often problems encountered in qualification are due to incomplete commissioning and lack of integration between design and construction. Properly planned and executed commissioning eliminates many downstream problems and can generate much of the data required for qualification and plant delivery. Focusing on the project quality programme, an experienced CM will aim to achieve regulatory compliance and reduce cost and time to market through a number of critical steps:

- risk assessment and criticality analysis;
- Construction audits at approved for construction (AFC) stage, and during field activities (based on the risk criticality analysis);
- Turn over package (TOP) definition and organisation;
- Establishment of appropriate field procedures;
- Training of key personnel and contractor staff;
- Control and traceability of field changes; and
- Good practice construction forms specific to biopharma projects.

Properly-documented commissioning can be leveraged into qualification by systems, and by completing the process in phases, the CM can allow for early production and manufacturing. This approach is effective on fast-track projects and when commissioning and qualification are integrated with construction management, fast-tracking and qualification/validation are not mutually exclusive objectives.

documentation is critical

High-quality documentation is essential to achieve regulatory compliance and it should be an integral part of the construction planning, implementation and commissioning process. The CM's goal is not only to build a facility on time and within budget, with systems that perform to specifications – it is also to develop a TOP that is well organised, meets the owner's unique needs and expectations, and provides the proper level of documentation quality. Effective management of the construction and commissioning documentation process will ensure the resulting documentation can be leveraged into the qualification process, reducing time to market.

When companies come under pressure to minimise capital expenditure, it can be tempting to focus on price as the primary driver when selecting professionals to design and execute projects. Unfortunately, this exclusive focus on price has often resulted in delays and quality compromises. But achieving good value for money need not compromise quality or time to market. In fact, implementing a pure CM project delivery method, incorporating an integrated construction, commissioning and qualification can enable pharmaceutical companies to achieve all of their objectives: optimum cost, accelerated schedule and high quality. **tce**

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