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Collaborative Approaches Streamline Capital Project Delivery

By Carl Bergsten

In this regular column I intend to examine the current issues impacting the overall pharmaceutical and biotechnology process industries. A number of forces, including ongoing globalization, new product development, continuous advances in technology, and government regulation and deregulation, have consistently impacted the industry in recent years.

The responses to these forces by industry are not new, but the intensity and speed of the responses are growing significantly, with firms scrambling to:

- Boost research and development (R&D) effectiveness;
- Continue to build a seamless global organization;
- Leverage supply chain synergies;
- Manage regulatory compliance;
- Streamline manufacturing;
- Achieve scale; and,
- Improve capital project delivery.

For this inaugural column, I will consider the principal issues impacting improvement of the capital project delivery process. Because all the response issues are interrelated, however, future columns will examine them as well.

Costs under scrutiny

Capital projects are an increasingly important part of the pharmaceutical industry's overall cost structure, which is coming under increased pressure as a whole. Manufacturing costs, of which capital costs are but a part, generally make up 18 percent to 20 percent of a pharmaceutical company's operating costs.

Ten or 15 years ago, this percentage was approximately half of what it is now. Increased cost pressures from the public, insurance companies, competition (including rapid introduction of "me too" products), reimportation ("gray" markets) and governments have led to greater cost scrutiny. This heightened focus on cost has increased manufacturing's share of total costs because manufacturing costs tend to be less variable than other cost components.

One part of manufacturing cost optimization is ensuring capital expenditures are as efficient as possible. By improving the project delivery process, plants can optimize capital expenditures, enhance asset utilization and meet time-to-market demands.

Time-saving strategies

Those of us who design, build, validate and/or operate pharmaceutical and biotechnology facilities are familiar with many of the strategies currently being employed to improve the capital project delivery process. The first challenge within the manufacturer's organization is to reduce the time between specific product development milestones and a fully operational plant, while optimizing manufacturing and capital costs. Early inclusion of manufacturing and capital project experts in multi-disciplined project teams is a tactic pharmaceutical companies have learned from other industries.

Beyond this basic business process change, more specific project-level strategies can be implemented, including design-build-validate; project execution; multi-purpose/multi-product plant design; standardization of equipment, systems and facility designs; modularization; and full integration of project and regulatory compliance activities.

Each of these has its time and place for implementation, and much of the "low-hanging fruit" is already gone. For instance, multi-product/multi-purpose plant design is the norm — it is now rare for companies to build a "greenfield" plant dedicated to a single product.

Although our industry traditionally has executed projects with separate design, construction management and validation support firms, most significant new projects now at least consider grouping several — if not all — of

these activities under a single service provider. As an alternative, many owners combine multiple service providers in a single team, using incentives to promote teamwork.

These approaches can improve execution efficiency and product quality while simultaneously reducing the number of individual entities the owner needs to manage. This last point is increasingly important as owner capital project organizations continue to be reduced in size.

Validation and regulatory compliance typically are now considered at the beginning of a capital project. Tremendous schedule savings have been realized through the integration of validation with design, construction and commissioning. This integration enables the owner to have a licensed, validated plant in the shortest possible time.

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The industry has been wrestling with implementation of standard processing building blocks (e.g., piping and instrumentation diagram modules and standard process trains) for years. However, these efforts have had limited success because of the challenges involved in balancing standardization with advances in technology and the need to retrofit existing facilities.

One current and significant trend is toward modularization of facility design and construction. Although this takes a wide variety of forms, it generally involves off-site construction, systems integration and checkout, including early validation activities, followed by module breakdown and transport to the plant site for reassembly.

This execution strategy frequently is driven by a desire to compress the overall schedule because it allows construction to be accomplished in a shop environment. Also, it facilitates the completion of many different activities at the same time instead of in a traditional sequential mode. This project execution strategy likely will see increasing use as operating companies and service providers both become more proficient at capitalizing on modularization's advantages.

Early involvement needed

Manufacturing and capital project costs will continue to come under increased scrutiny. The professionals employed in pharmaceutical and biotechnology plants are in a position to add significant value to the pharmaceutical/biotech industry and, ultimately, the end-user customer.

These professionals must tap into the creativity needed to identify new opportunities that would improve the capital project process and overcome obstacles to successful implementation. For example, by incorporating product life-cycle planning into the facility design — and by getting design, construction and validation service providers involved early in the design phase — plant personnel can positively impact costs.

Owners and outsourcing service providers need to bring together the technical expertise, creativity and business acumen required to balance the competing demands placed on our organizations and our industry.

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