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PREFERRED PROVIDERS
Finding the Right Partner
Project Management

Case Studies in Pharmaceutical Project Management

A Technical Forum

Moderated by Patricia Van Arnum

Effective project management is an invaluable competency in a successful outsourcing relationship.

Project management underpins successful relationships between contract technology and service providers and their sponsor companies. As pharmaceutical companies increase their level of outsourcing, it becomes increasingly important for contract technology and service providers to provide not only the technical capabilities needed to execute a given project, but the management skills to deliver a project on time, to specifications, and with the necessary communication to prevent or mitigate project delays. To illustrate the importance of project management in outsourcing, several industry members provided case studies on how to coordinate, organize, and implement a successful project.

Blow/fill/seal manufacturing

Norman Weichbrodt, strategic account manager at Catalent Pharma Solutions

Catalent Pharma Solutions is a provider of drug and biologic development services, delivery technologies, and supply solutions. Effective project management is the cornerstone of being a complete provider of services ranging from development of new products to technical transfer of existing products. Building the proper project team and employing the correct methodology for handling a complex project is the foundation on which success is achieved.

In July 2010, Catalent was approached by a major pharmaceutical customer to transfer an ophthalmic product approved for sale in Europe to Catalent’s blow/fill/seal (BFS) manufacturing site in Woodstock, Illinois. The successful technical transfer of the manufacturing process for this product would potentially lead, following FDA approval of the product already made in the European facility, to approval of the drug for manufacture and sale in the United States.

Project scope. The actual scope of this project was much larger for the Woodstock facility than a simple technical transfer. The project required the following:

- A complete renovation of a formulation and filling suite, including a new separate air-handling system
The project team consisted of a project manager from NPD, an engineering project manager, a development scientist, a validation specialist, a technical writer, and various contract resources as required. A strategic account manager, a technical writer, and the quality-assurance product specialist worked with the NPD project manager to manage the change-control process for the project and to complete all the required documentation, including material specifications, standard operating procedures, and manufacturing batch records. The NPD Project manager also provided oversight of the analytical method transfer, development of secondary packaging materials, and the documentation of project activities.

**Technology transfer.** The technology-transfer process was initiated by creating a comparability document that detailed every aspect of the manufacturing process. The process used in the European manufacture was listed step by step in the document with Catalent’s suggestions and capabilities side by side. A final agreement for each step was included and served as the approved path forward. The specifications for in-process testing at each stage of the formulation as well as finished-product specifications were included in the document. The formulation process required bulk sterilization of a multicomponent polymer base with a relatively tight viscosity range. Two APIs were combined in a second part of the formulation and transferred to the polymer solution by sterile filtration. Of course, the entire formulation skid required steam sterilization of the product path through the BFS machine and maintenance of the sterile boundaries for the product during the entire filling process. Electronic documentation of all temperatures, times, and controls for each process step also were also required.

**Communication.** The NPD project manager and the strategic account manager facilitated weekly calls with the original equipment manufacturers of the formulation and BFS equipment as well as construction meetings during that phase of the project. Weekly calls were held with the customer representatives who were in liaison with the project team. A standard methodology was used to ensure that the meetings had a structured agenda and minutes issued for review in a timely fashion. A joint Project Steering Committee was formed, which was comprised of customer senior leadership members, Woodstock site leadership members, and Catalent business-development members.

Project Steering Committee meetings were held every three weeks during the course of the project. A formal presentation was made at each meeting to discuss progress toward major milestones in the project plan. Strategic decisions were discussed and developed through the Project Steering Committee meetings, and the decisions were ultimately made by the joint project team. This management design reduced the cycle time for critical decision-making between the customer and Catalent.
An example of such decision making was approval of a change to the SAT/FAT strategy originally planned for the formulation skid. The formulation skid is a fully automated two-tank system with over 100 control and process valves that are actuated in approximately 20 sequences. When the software development lagged behind the construction of the hardware, the opportunity arose to do a mechanical FAT, ship the formulation skid to the Woodstock site, complete the installation and mechanical troubleshooting of the skid and wait for the software to complete the qualification as a SAT. This decision saved as much as six weeks in the project schedule and enabled Catalent to meet the customer’s timeline for stability and process-validation manufacturing. It also resulted in a formulation system that is part of a robust technical transfer process from the customer through the NPD group to Catalent’s commercial manufacturing team.

**Execution.** To date, all of the engineering, stability, and process-validation batches have met the in-process and final-product test specifications. With nine batches produced, there have been no out-of-specification results for bulk or final product. In addition, no human error deviations have occurred in the formulation and filling of these batches.

Figures 1–3 (Catalent) show the facility upgrade and project equipment after installation.

In summary, Catalent did not employ new or groundbreaking methodology for this project. However, supplying the proper structure and resources for a project team is the crucial first step in meeting a customer’s timeline and supplying the customer with quality product, reliably supplied.