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FACILITIES START UP

Fast-Tracking Facilities Start-up

Rapidly turning investment into revenue

The vaccines division of a major pharmaceutical manufacturer set aggressive timelines for establishing new production capability and winning U.S. licensure. Because the division lacked sufficient facilities start-up expertise, technical project leaders, and technical resources, the project had been stalled for three years. But after turning to Tunnell for assistance, the company met – and exceeded – its ambitious goals.

The Result:

Ahead-of-schedule FDA approval of production lines, enabling the division to improve revenue and profitability by getting to market on time with a key seasonal product.

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The project employed a unique, single-source approach to using external resources.

After three years of slow progress completing validation and start-up at a formulation and filling facility, the vaccines division faced two challenges.

- First, the stalled project had undermined the confidence of the organization.
- Second, the site lacked sufficient expertise and technical resources to meet Corporate's aggressive timeline for completion of this major $200 million-plus effort.

Facing what was in essence a turnaround, the project director concluded that not only were there insufficient technical resources to execute the plan but also not enough experienced project and technical managers to provide the needed leadership. He also determined that the standard practice of contracting technical resources from a variety of sources was not going to get the job done.

Recognizing the need for a unique approach, he decided to supplement the internal staff with external resources and project management expertise that would be hired and managed by a single outside firm, Tunnell Consulting.

Working with Tunnell, the project director established clear principles for using the external resources:

- The project would be run as a single organization with internal and external resources integrated into a single team.
- The most qualified person, regardless of source, would lead technical teams within the project.
- The project would include, as a major objective, the transfer of knowledge from experienced external resources to internal personnel.

In just eight weeks, more than 40 Tunnell resources were onboarded and integrated with internal personnel. Tunnell's senior subject matter experts provided project management, regulatory and quality guidance, process expertise, and badly needed technical resources in all areas of facilities start-up.

The team's collective objective was to deliver and achieve U.S. licensure of a formulation and fill facility encompassing:

- Two syringe lines
- One vial line
- Formulation and buffer preparation capability for multiple products

The joint internal-external team was organized into sub-teams designed to address the entire range of complex tasks associated with facilities start-up. Major tasks and issues included:

- Process development
- Process validation
- Cleaning and sterilization process development
- Cleaning validation
- Environmental monitoring process qualification
- Regulatory submission strategies
- Procedure and report generation
- Quality oversight and system design
- PAI inspection preparation and hosting
- Development of structured training process and documentation

In addition, an advance plan for shifting from a project to an operational focus was put in place to smooth the transition to production. As operational problems were identified, such as a WFI rouging problem, Tunnell subject matter experts led problem-solving teams to identify root causes and implement solutions.

The results have exceeded expectations.

With Tunnell's expertise in facilities start-up, the vaccines division rapidly removed obstacles to line approval and ensured the move into a modern, compliant facility ahead of schedule. As a result, when the opportunity arose to supply the US Government with a large order of pandemic vaccine the company was able to seize it.

Working with Tunnell, the division:

- Won FDA approval for the first syringe line 9 months sooner than the company had anticipated
- Used a CBE-30 filing, underpinned by a comparability protocol approach developed by Tunnell, to get the second syringe line registered on schedule

... an advance plan for shifting from a project to an operational focus was put in place to smooth the transition to production.

- Got on a fast track toward approval of the vial line four months ahead of schedule.
- Developed a simplified approach to accelerate the transfer of products to this new facility.
- Got to market on schedule, thus improving revenues and profitability for a key seasonal product.

In addition, the single-source, single-team approach, combined with Tunnell's subject matter expertise and project management experience, achieved the knowledge transfer the client sought. Over the course of the project more than 80 external resources from Tunnell were involved in the project. But the single-team approach eliminated the "us vs. them" mindset that often impedes knowledge transfer in the use of outside personnel.

Initially, the gap in internal resources required external leadership in several areas but, as soon as possible, internal personnel were partnered with those leaders in order to combine the external person's industry experience with the internal leader's knowledge of company practices. As a result, all leadership positions were filled by internal personnel prior to the achievement of the first major milestone.

Knowledge transfer rapidly became knowledge sharing. With the development of collaborative working relationships, learning became a two-way street with all parties benefiting from the experience of their colleagues and, most importantly, maximizing the team's capability to achieve the project objectives.

For resources-constrained organizations, the approach offers a solution for the rapid completion of major technical projects

In today's cost-sensitive environment, most pharmaceutical manufacturing organizations are not staffed to manage and execute significant capital, compliance or efficiency projects. Even in segments of the industry that are growing, high-level, qualified resources for these projects may not be internally available.

Although the single-source contracted services model is common in the construction, engineering and maintenance services industries, it has found only limited use in the pharmaceutical industry – being usually confined to technical support for validation services, laboratory support, or quality remediation in response to external audits. But as the experience of this vaccine manufacturer demonstrates, the comprehensive application of this approach offers a cost-effective, efficient means of putting facilities start-up and other major technical projects on the fast track to completion

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For over 60 years, Tunnell has provided both expert talent and consulting services to clients including Biopharmas, CDMOs, the US Government, incubators, investors and NGOs. We have experience across multiple platforms – including large molecule, vaccines, cell and gene therapy and small molecule – and our subject matter expertise focuses on regulatory, quality, GxP, pre-clinical/clinical, supply chain, manufacturing, CMC and product launch. To learn more, visit us online at http://www.tunnellconsulting.com.

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