

COST REDUCTION



Performance Transformation for a Leading Vaccine Maker

Making 'right-first-time' a way of life
in a critical production facility

A leading vaccine maker was plagued by deviations that were disrupting supply of the product, driving up costs, and impeding the company's ability to compete in international markets. To resolve the recurring problems once and for all, company leaders turned to Tunnell and its site-wide Performance Transformation methodology designed not just to fix processes but to change behavior.

The Result:

Dramatically fewer deviations, increased throughput, reduced per-unit costs, greater ability to ensure a timely supply of product, and – most importantly – a deeply rooted right-first-time culture.

Tunnell diagnosed a host of problems impeding performance.

The vaccine maker had built up a backlog of several thousand deviations at one of its key facilities. Despite the company's best efforts, they had been unable to uncover the root causes of these recurring compliance problems. The business consequences were manifold: the production facility could not meet the high demand for the product. The site could not attract additional volume because per-unit costs were too high. The high per-unit cost also hampered the company's ability to compete in international markets, where margins were significantly thinner.

Determined to get at the root causes of the problems, senior leaders turned to Tunnell for assistance. Through a comprehensive assessment of the site's operations – including Quality Control, Quality Assurance, manufacturing, maintenance, engineering, site services, and more – we uncovered numerous process and people issues that were adversely affecting performance. We found that the site's performance problems were compounded by the heavy use of temporary labor with high turnover and a poor record of compliance. Various functions at the site worked in silos. The many remediation projects were not integrated and produced few lasting results. Most importantly, genuine performance transformation was hampered by the stiff resistance to change often found in long-lived organizations with deeply ingrained ways of doing things.

Tunnell's Performance Transformation methodology systematically and holistically addressed critical issues.

Based on our initial assessment, we determined that achieving the necessary step-wise improvement – cross-functionally, operationally, and financially – would require a site-wide, holistic approach. We launched a site-wide right-first-time Performance Transformation project designed to:

- Establish an efficient platform to make vaccines accessible as soon as possible by reducing overall cycle times and improving the flexibility of site operations
- Improve the competitiveness of the industrial platform to attract additional volume and stimulate the development of the site by reducing operating costs and better allocating resources
- Improve collaboration and integration among all site functions
- Improve regulatory compliance by addressing root causes of deviations
- Improve labor utilization and provide project prioritization
- Establish a transformational change program that would alter behavior and mitigate risk by creating a culture of right-first-time execution

The project was structured in three successive waves designed to achieve lasting change.

Changing deeply rooted behaviors and imparting new ways of doing things cannot be accomplished overnight. To make sure that change was driven deeply into the organization and the people who comprise it, we structured the project in three successive waves of 6-9 months each. Through this structure and our proven methodology for holistic Performance Transformation, we were able to:

- Transfer skills and knowledge to the client organization
- Create buy-in and build momentum for right-first-time performance
- Change deeply rooted behaviors impeding performance
- Develop a cadre of internal leaders to sustain the changes

Changing deeply rooted behaviors and imparting new ways of doing things cannot be accomplished overnight.

Our proven methodology effectively addressed the chief impediment to performance transformation – resistance to change.

When new ways of working push people out of their comfort zones, resistance naturally occurs. Such resistance can be particularly strong among long-tenured mid-level managers who persist in sub-optimal behavior because “we have always done it this way.” Turf battles can also arise, and transformation projects can be seen as headcount reduction in disguise.

Such resistance must be convincingly overcome. For example, getting at root causes takes more time than firefighting and quick fixes, and many managers protested that they were already overburdened with projects. But by helping them prioritize their projects, we were able to uncover hidden capacity in the people as well as hidden capacity in the plant.

Further, highly visual boards vividly tracked key performance indicators on a daily, weekly, and monthly basis. The increasing improvement recorded on the visual boards as new practices took root – including a steady drop in deviations – won over even the most resistant participants. The project also attained all-important critical mass with more than half of the site’s 1600 personnel taking part in the transformation. And through newly skilled in-house change leaders the organization genuinely owned that transformation.

Our holistic approach addressed critical processes across multiple functions.

Lasting Performance Transformation requires coordinated improvement across functions and in people processes, financial processes, and operational and technical processes. Some of those many functions – and just a few of the processes we addressed within each over the course of the transformation – include the following:

- Human Resources: change execution and communication, organizational effectiveness, and training

- Quality: laboratory effectiveness, sample management, GMP document flow, and deviation and CAPA management
- Manufacturing operations: labor utilization, operations system management, and packaging
- Materials management: supply chain execution, demand management, and distribution
- Site services: energy efficiency, engineering effectiveness, and maintenance
- IT systems: SAP effectiveness and information systems prioritization

Because these many projects were executed, coordinated, and integrated under a common framework, they not only produced significant improvement in individual processes but also mutually reinforced each other, multiplying benefits and coalescing in a right-first-time culture.

The project yielded significant business and operational benefits.

Tunnell’s combination of deep industry knowledge, proven methodology, and ability to initiate organization-wide behavior change enabled the client to:

- Achieve cost savings greater than 5:1 return on investment (ROI), exceeding the initial target established in the assessment
- Reduce cycle time for change controls by 55 percent
- Reduce review time for batch records from 33 days to 14 days; reduce number of reviews from two to one; save 950 labor hours per year
- Reduce EM error correction requests by 57 percent and EM-related deviations by 48 percent
- Reduce investigation cycle times for deviations by 16 percent

”

... getting at root causes takes more time than firefighting and quick fixes, and many managers protested that they were already overburdened with projects.

But by helping them prioritize their projects, we were able to uncover hidden capacity . . .

In addition, our approach entrenched a new operating model using visual management and Focused Factory Support Team (FFST) concepts designed to support Operations by providing technical and regulatory guidance on the shop floor to resolve things gone wrong and drive improvements.

The company is now equipped to sustain right-first-time performance far into the future.

During the course of the project, Tunnell's team continually transferred knowledge to the client's team about technical operations, process improvement, and

project management. In addition, we helped develop 12 'coaches' – in-house leaders capable of sustaining the right-first-time culture and operations that emerged from the project. Further, 24 managers who helped lead individual work streams acquired the skills to manage such projects in the future. And personnel throughout the organization adopted a right-first-time mindset, internalizing its principles and learning how to apply it in unforeseen circumstances. Though harder to quantify, these organizational and behavioral benefits will continue to pay dividends for the company for many years to come.



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>.

1235 Westlakes Drive, Suite 280
Berwyn, PA 19312

t: +1 (610) 337-0820

tunnellconsulting.com