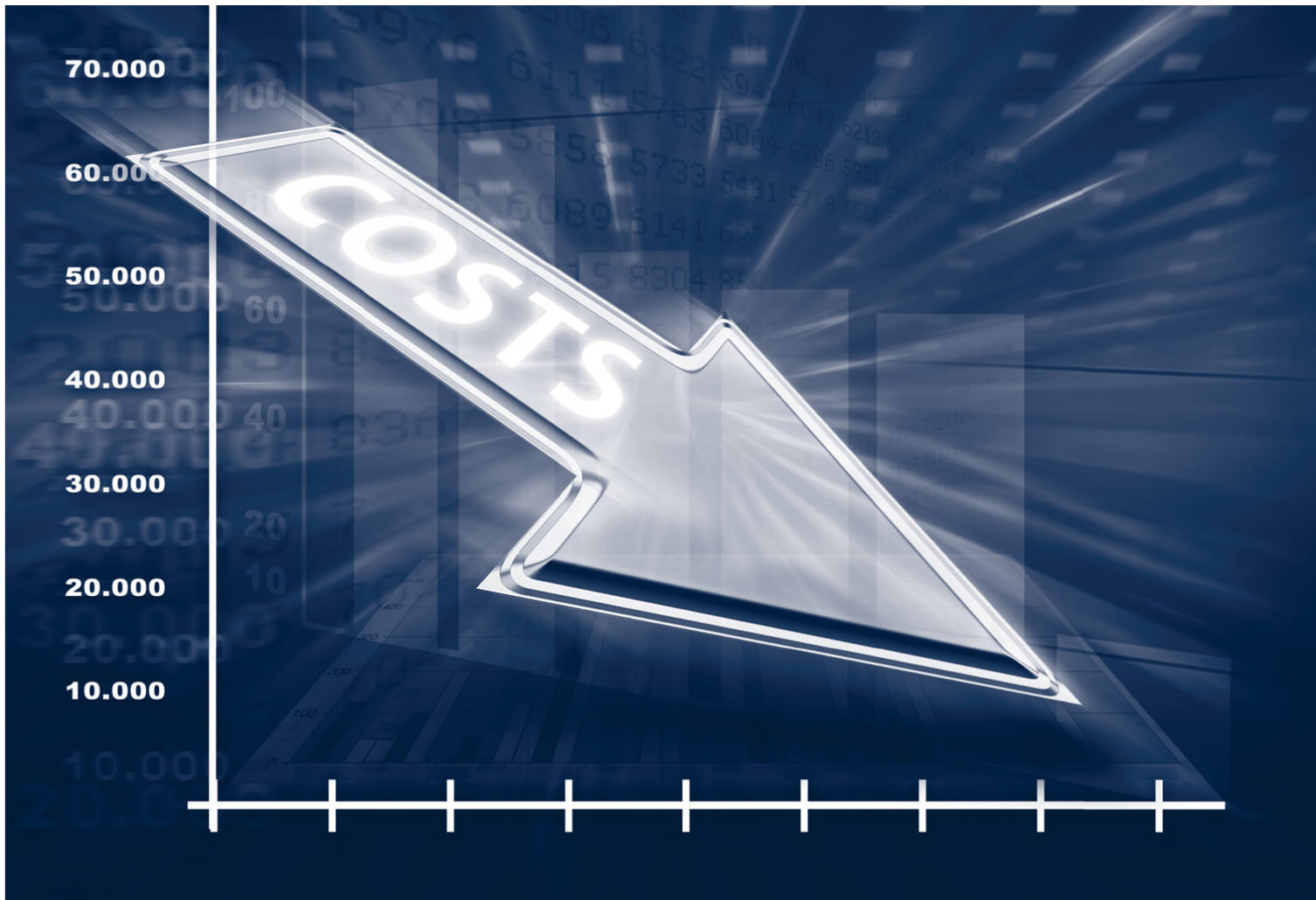


COST REDUCTION



Getting Up to Speed and Staying There

Lean Lab improvement that lasts

In order to maintain competitiveness, a global manufacturer of brand and generic drugs needed to cut per-unit costs by 20%. To achieve that ambitious goal they intended to make their operations faster and leaner. That included making the laboratory more responsive and shrinking its throughput time with no compromise in quality or safety.

The Result:

Most observers agree that a Lean approach to lab operations can support such improvements and the cost savings they bring. But sustaining such improvements is another story.

Tunnell brought a comprehensive understanding of Lean Lab principles – and a proven method for making them stick.

In a sector where speed-to-market and cost-competitiveness are decisive for success, the manufacturer targeted three key areas for improvement: Manufacturing, Quality Assurance, and the QC Laboratories. Working with Tunnell, the company wanted to design and implement Lean systems in each area that together would achieve the 20% cost-reduction goal.

For more than a decade, experts have elaborated the operating principles required to create a Lean Lab:

- Identify how the Lab creates value and reduces non-value-adding activities
- Map and improve the entire value stream, not just parts of it (which only creates bottlenecks elsewhere)
- Reduce waste
- Level the laboratory's load and mix of samples
- Create a system that "pulls" samples rapidly through the Lab based on market and customer priorities and on a first-in-first-out (FIFO) basis
- Measure performance and keep it on track.

However, creating a Lean Lab presents some unique challenges. Lean has long been practiced in manufacturing and is relatively well understood there, but its application – as opposed to the elaboration of its principles – has lagged in laboratory operations. In part, that's because lab work differs greatly from manufacturing, although Lean works for any type of process.

An even greater obstacle lies in the inability of many organizations to sustain improvements in the lab or, indeed, in almost any area of operations. Experience has shown that when personnel encounter unfamiliar problems or exceptions they will revert to their old ways of working. Improvements begin to fade and efficiency deteriorates. To these critical challenges, Tunnell brought proven methods for establishing a Lean Lab and an approach to implementation that ensures sustainability.

Because piecemeal approaches to change permit people to slip back into their old comfort zone, Tunnell's approach typically entails transformation – going "all in" is critical for making the changes stick.

For the company-wide improvement project, we created a team that included representatives from manufacturing, QA/QC, packaging, and planning & scheduling. Each representative then led sub-teams in his or her area to help design, implement, and maintain the new way of working. As a result, client personnel owned the new way of working: internalizing its principles and learning how to apply it in unforeseen circumstances.

This transfer of knowledge was achieved in three distinct phases. In the first phase, Tunnell team members collaborated with the client teams on designing improvements, training them in Lean techniques, and coaching them through the early stages of implementation.

We then acted as mentors to client team leaders, who then acted as coaches to their teams. Finally, as the transfer was completed, we acted as a sounding board, ultimately leaving the client with a sustainable Lean operation and a capability in continuous improvement.

Client-led teams designed efficient "Lean Lanes" for the testing of a complex array of products.

The company's large number and variety of products – solids, liquids, nasal sprays, capsules, and tablets – created significant complexity in the queuing, coordinating, and conducting of tests. Prior to the improvement project, lab throughput time – the elapsed time between the arrival of a test sample in the lab and the completion of its testing – stood at 15 days. Working with Tunnell, the company established a goal of 30% reduction in throughput time within three months, and greater reductions over the long term. In order to realize the full potential of cost savings, it was also imperative to increase right-first-time results and achieve increased utilization of personnel rather than simply speed up lab operations by throwing more money and people at the problem.

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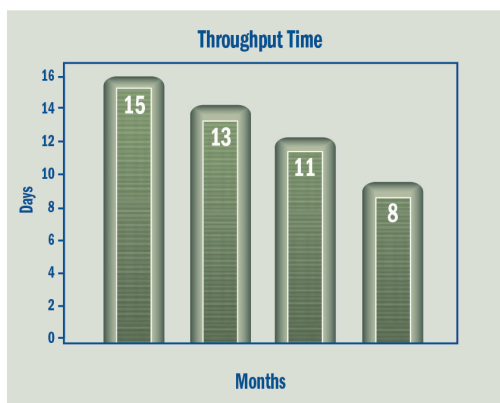
The lab team first designed a process that would reduce time for testing and increase the utilization of instruments and people. The team also determined the optimal frequency and number of lots to be tested. They also designed the optimal flow of test samples through the lab, including the equipment on which they would be tested and personnel who would test them, and allocated the samples to appropriate test lanes.

To keep all shifts on the same page, it was also determined that lots for testing would be selected on the basis of first in/first out.

To design testing lanes for the products in the company's solids family, for example, the team analyzed a complex set of data that included all of the factors that could affect the speed and productivity of the lab. They were then able to design the optimal testing lanes for the products. Similar analysis and design was undertaken for the five other product groups.

Once the director of the lab had selected the analysts for testing lanes, they were trained by the team in Lean techniques, and the new way of working commenced. Also, key performance indicators were identified and visual management tools were implemented in order to maintain open communication and feedback.

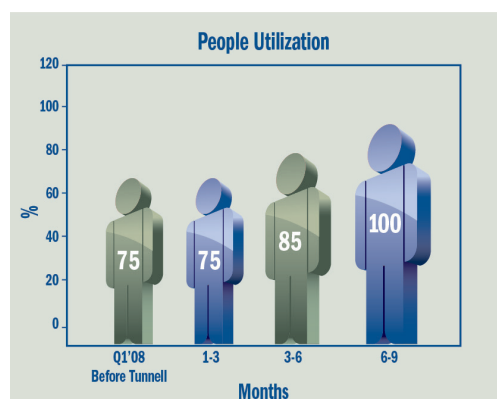
The lab achieved significant improvement in all key measures of its performance – meeting and exceeding project goals.



With Tunnell acting as coach in the initial three months and as mentor and

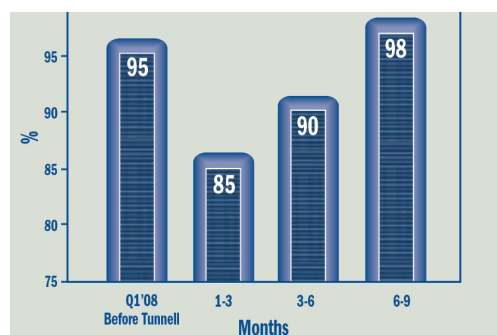
sounding board thereafter, the client teams became increasingly adept at continuous improvement, achieving some striking results:

Throughput time for the solids group dropped from 15 days to just 8 days, an improvement of 46%, which far exceeded the target of 30% and is likely to drop to as few as 6 days within a year of implementation.



People utilization – defined as the percentage of time that personnel spend in value-adding activities – climbed from 75% to 90%. Within the solids group, the percentage of cross-trained personnel – that is, those who are trained to perform all tests as well as the review step – rose to 100% within two months of implementation, an increase of 42%.

The percentage of right-first-time testing climbed from 95% to 98%, thereby reducing laboratory investigations and decreasing laboratory throughput time.



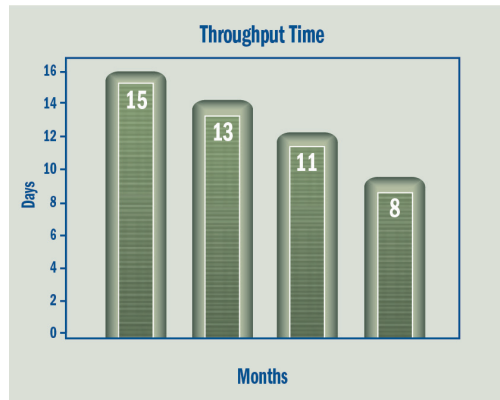
The number of samples released per week rose from 14 to 15, and the number of stability samples tested and approved shot up from 5 to 15 per week. The overall number of samples released from the lab increased from 20 to 30 per week.

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As the accompanying “Right First Time” and “Lots Released” charts indicate, there is a slight dip in these metrics in the beginning as the team learns the new way of working. However, as these figures quickly and steadily improve the team gains confidence and commitment.

Meanwhile, they gain additional confidence from the uninterrupted rise in throughput time and people utilization.



With the new way of working thoroughly embedded in the laboratory and the newly acquired ability of lab personnel to create continuous improvement, the organization should continue to see even more gains in speed and productivity and further reductions in costs – the indispensable components of successful competition in today’s demanding life sciences environment.

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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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