

THE CLIENT

A maker of active pharmaceutical ingredients, serving customers in the U.S. and Europe.



CHALLENGE:

LARGE-MARGIN WORKFLOWS, HIGH-VOLUME CLIENTS

With more than 35 years of experience, our client boasted advanced research-driven operational workflows and an extensive client portfolio. But after the organization's largest customer left the marketplace, they faced a devastating decrease in earnings before interest, taxes, depreciation, and amortization (EBITDA).

Facing this steep drop off in EBITDA, our client realized they needed help in cutting cost and optimizing their operations at their facility in the Midwest, and so they reconnected with us. It had been more than a decade since we collaborated on a small-scale initiative aimed

at establishing actionable batch-production metrics. However, this time around this API producer faced a significantly larger issue.

While the company had seen significant growth since our initial collaboration in 2005, this expansion was a product of multiple acquisitions and consistent work from large-margin, high-volume clients. These strategies led to success in the short-term but threatened to put the firm in a vulnerable position if any of those linchpin clients ended their partnerships. And that's exactly what happened, leaving the niche pharmaceutical firm with lab and production operations tailored to a slew of large jobs that no longer existed.







Solution No. 1: Reduce batch and cycle times to increase yield

Despite its successes, the company had room to improve its capacity and production planning processes. Having grown so quickly, it had not yet fully reviewed past performance and set up future performance targets. This underperformance on the shop floor led to high batch and cycle times and depressed yield.

We worked with the company's engineering and laboratory teams to optimize production, developing with them in a Gantt chart format the steps in the batch cycle. We paid particular attention to critical to quality (CTQ) steps, interactions and targets, then created visual aids so operators could compare actual figures to actionable targets in real time, determine root cause issues and address them. The improvements in performance were then used as input for the next campaign, in order to build in continuous improvement.

Solution No. 2: Cut maintenance costs by installing an effective maintenance management operating system

Before its top client left, the API producer had outsourced its maintenance. It paid external technicians to address problems that in-house staff, with help from some minor process improvements, could tackle themselves.

Our improvement team showed the organization that it didn't need third-party specialists, so long as it was willing to adhere to best practices for utilizing their current computerized maintenance management system (CMMS). Eventually its production teams could effectively harness internal expertise. We also collaborated with human resources to beef up the maintenance planner role, which had been scaled back. Thanks to our improvement specialists, the company retrained the employee in this position and gave him the strategies and tools he needed to effectively oversee preventive and reactive work orders. A number of internal technicians participated in new instructional initiatives as well, cultivating the technical competencies required to tackle work that had once been outsourced.

Solution No. 3: Decrease the direct and indirect costs of production

Like most businesses in the pharmaceutical space, our client had significant sourcing needs and worked with multiple third-parties to ensure it had the expensive base ingredients needed for production. Again, this was not a big concern in the past, as



the company's large margins afforded it the power to purchase raw materials notwithstanding the cost. But times changed.

We helped the company implement a strategic sourcing plan that not only accounted for price and availability but also took into consideration vendor location. Because the company operated globally, it needed a global method for acquiring resources that met its requirements for cost and quality.

Solution No. 4: Reduce labto-production times

In addition to addressing operations on the shop floor, our improvement team tackled the back-end laboratory workflows that preceded production. The client's laboratory had quality assurance and quality control groups. (Q.C. focused on product development, and Q.A. ensured that finished products met internal and external quality standards.) While functional, neither executed in a streamlined fashion, leading to significant slowdowns. Production teams often fell behind schedule because of its slow sample approval or research and development processes.

To speed things up, we introduced simple but effective capacity planning and scheduling tools. They accelerated laboratory workflows and were flexible enough to accommodate the creative time that scientists needed to produce pharmaceuticals.

Solution No. 5: Implement a holistic strategy

With new methodologies in place on the shop floor and in the laboratory, our improvement team configured an overarching operating system that gave operational stakeholders and business leaders a top-down view of the new processes in place. It also helped them better understand how the disparate workflows functioned in concert.



CONCLUSION

The 24-week collaboration helped the API producer develop and implement new production and planning processes, ultimately freeing up capacity that could then be filled by new customers, flowing quickly through the RFP process with improved coordination from the lab.



The annualized savings certainly speak to the immediate success of the initiative, but smaller developments may have an even more significant impact as the company moves forward. For example, contributors in all departments, from maintenance to research and development, embraced the improved workflows and tools. This internal

acceptance demonstrated how the people driving the business could handle change, a revelation that bodes well for an organization that operates within such a volatile market. In fact, the client has already moved forward with us on another project that may further extend its long-term viability.

Organizations navigating the Life Sciences industry can achieve similar results by collaborating with our improvement specialists. Connect with us today to learn more about our work and how our expert consultants can improve your operations and facilitate growth within your business.





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