



Planning for profits

Getting organizational design right in biologicals

A major global pharmaceutical manufacturer projected that a recently acquired manufacturing site for biologicals production and packaging would never become profitable under existing start-up plans. But they were reluctant to resort to a CMO located far from the product's largest market. So the company chose Tunnell to determine if the costbase at the site could be sufficiently reduced to justify putting the plant into commercial operation.

The Result:

A combination of process improvements and a projected headcount reduction of 30% that would save \$10 million annually, reduce cost of goods sold by \$13.5 million, and put the plant solidly in the black.

Tunnell uncovered more than 150 improvement opportunities right away. Because high costs can result from the interplay of many factors, any site-wide cost reduction effort must begin with a comprehensive understanding of all aspects of operations – core manufacturing, the overall operating system, and human capital. Tunnell therefore devoted the first two weeks of what proved to be only a six-week project to walking through the site’s entire production process from the warehouse to manufacturing, quality assurance, and packaging. Our subject matter experts observed processes and their interplay and interviewed key personnel at every stage. Based on this work, we undertook step-mapping and roles and responsibility analysis of the largest functions in the operation and uncovered more than 150 opportunities for process improvements. These opportunities were distilled into 12 high-impact changes designed to realize significant cost savings.

We quickly determined the key factor that would inflate costs.

During the walk-through a critical theme emerged in the area of human capital – over-staffing. Through observation and by eliciting the views of personnel about what would be needed to maintain the successful operation of various processes, the Tunnell team recognized a familiar pattern. In many life sciences organizations, staffing is often based on having the maximum possible number of technical staff to avert or correct problems. This worst-case-scenario approach to staffing is expensive. Because it assumes that failure is inevitable, it also undermines

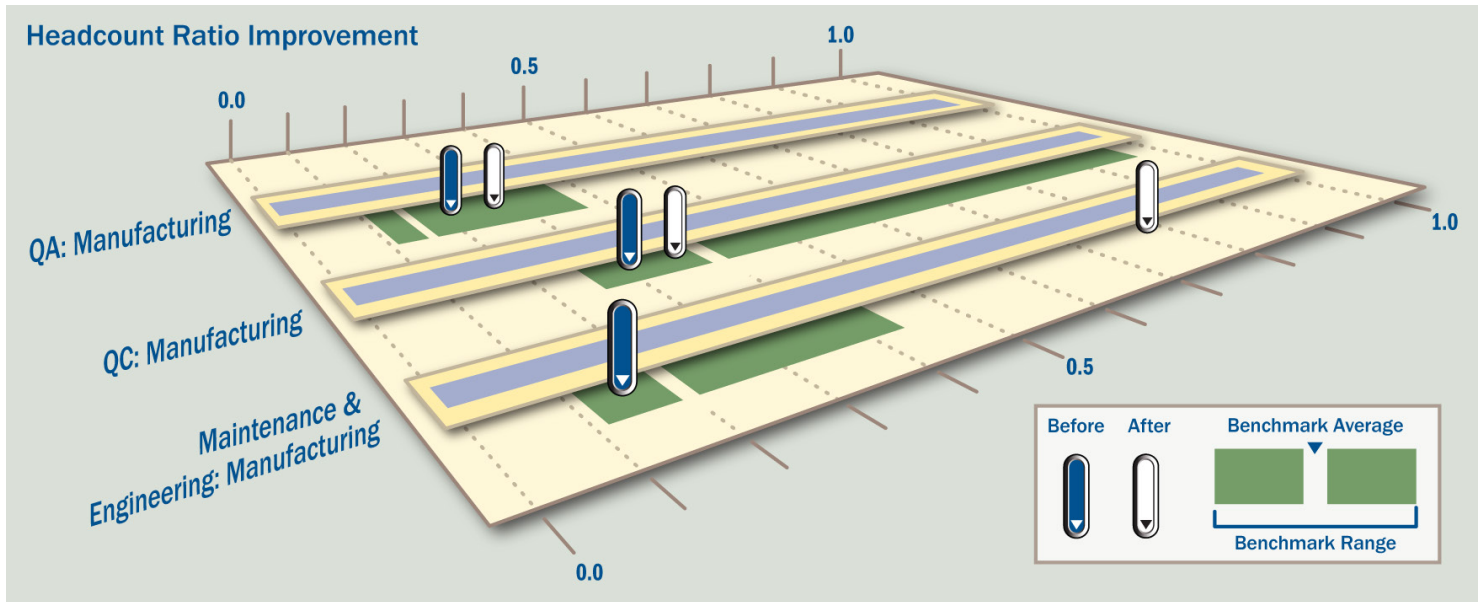
the incentive to correct the root causes of problems and optimize processes. Such overstaffing often results when management decisions are made by technical people. Their first concern may be to cover every possible technical base rather than to carefully balance technical considerations with business needs in order to achieve optimal – not maximum – staffing.

Staffing at the biologics site stood at approximately 150. The site’s plan to get to full commercial operation anticipated a headcount of 330. Tunnell benchmarked this level of staffing against the industry and against a very similar biologics company. The analysis found that the site’s projected headcount far exceeded the numbers in technical services in the industry at large and at the similar company. Tunnell’s team also interviewed the company’s technical services group at locations in other countries to further understand the intra-company justification for significantly more staff than the industry average. The subsequent analysis demonstrated that aside from depreciation, which of course they couldn’t control, the largest single contributor to the site’s cost challenge was overstaffing.

A new design profitably reshaped the organization and ensured the right behaviors.

Tunnell then partnered closely with management at the site to reshape the organization through value streaming, an approach to organizational design that enables the deployment of the right resources at the right scale.

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In addition, the previously identified process improvements that were organizational in nature were incorporated.

Because human capital is far more than a matter of numbers or an org chart, care was taken to ensure the right behavior in managers. In our experience, no matter how efficient the organizational design, the operation will build waste back into the operation within a year. Therefore the technical, regulatory, and business competencies required of managers to ensure profitable operation were built into job specifications, the performance review process, and the reward structure.

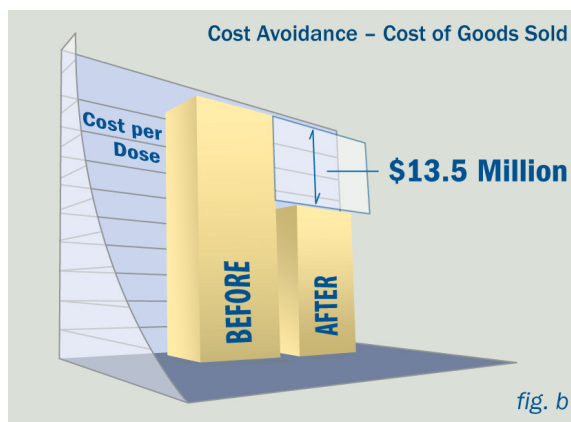
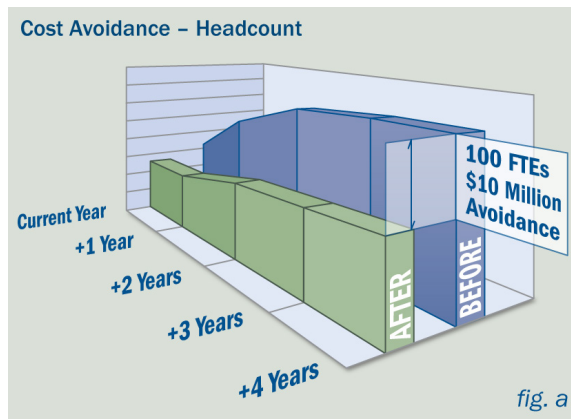
In addition, Tunnell spearheaded the development of a management assessment tool to capture the current state of business acumen in the organization, enabling the company to determine its needs for external talent and internal development. And a career track was established for technical people who were unable or uninterested in managing people but needed a clear path upward.

At the conclusion of the project, Tunnell presented several choices of organizational design and the projected cost savings each would generate. The company adopted the design that would bring the most savings while best fitting with other corporate objectives. The new design, instead of requiring 330 people, required only 225. And, like all of the options, the design would, in combination with the process improvements, facilitate sustained, profitable operation of the site.

The project enabled the company to make good on its investment in the site.

By building the organization on actual requirements, not worst-case-scenarios and risk avoidance, the company put itself in position to realize significant business benefits:

- The projected process improvements and headcount reduction of 30% would save \$10 million annually and reduce cost of goods sold (COGS) by \$13.5 million. (figures a and b)



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Tunnell’s highly competent and resourceful professionals helped us design an organizational structure that will enable us to achieve and sustain profitable operations. Working collaboratively, they brought us to see new possibilities and to create a flexible and competitive organizational design that would also reinforce the behavior and values we need for success.

– Site Head

- The client also estimated that by not closing the plant and going with a CMO they avoided more than \$50 million dollars in severance package costs, agreement termination fees, and associated plant closure expenses.
- The reduction in the cost-base allowed the company to keep the manufacture of the product in-house instead of sending it to a CMO, giving the company more control over manufacturing.
- The cost reduction also enabled the company to keep production in the largest market for the product.

In addition, because the company undertook the cost reduction effort before going commercial, they were spared the pain of uprooting an existing organization. Further, they enjoyed more options for designing the organization and the ability to lay the right foundation for the culture at the start.

It is never too late, however, to undertake cost reduction, and companies that do so, whether before or after they are in commercial operation, will outstrip their competitors at a time when there is little room for error in business performance.



Founded in 1962 and serving emerging and start up companies as well as many of the world's leading life sciences firms, Tunnell Consulting integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific credentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve.

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