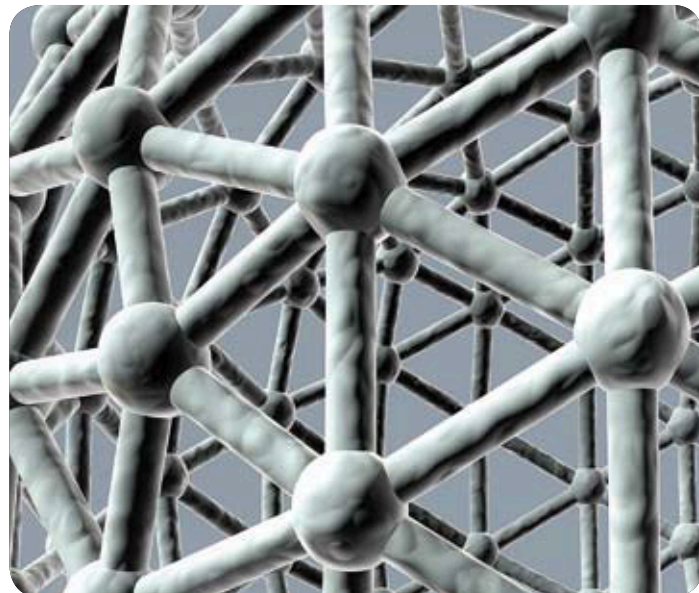


The challenges of a changing landscape

B *Biotechnology companies contend with unique circumstances, yet share many of the problems of broad industry. Benchmarking can be a tool to focus on the real key issues*

A quarter of a century after the launch of the first biotechnology drug, the global biotechnology industry finds itself split. Many startups and middle-aged companies remain unable to realize their long-anticipated aims and are steadily losing money. But the more successful companies are being acquired by Big Pharma to fill a dry pipeline and bolster their otherwise loss-making operations. In both cases, these biotech companies are finding that margin maximization and cost reduction are moving ever higher up the agenda. Indeed, this rapidly maturing industry, which has historically focused much of its effort on volume growth, is now facing operational challenges as severe as those faced by more case-hardened sectors. One tool these companies are using to develop a response to the changing environment is benchmarking. Using a combination of metric benchmarking and process benchmarking, they are find-



ing out not only the extent to which they need to be better to compete, but also the specific operational practices that need to change for them to achieve better results. Tefen's recent bio-benchmark study, with six of the biggest names in the sector, was designed to reveal an overview of their operations from the inside. The study's aim was to

identify the main levers that influenced each participant's results, and to guide them toward necessary changes. In doing so the benchmarking study uncovered the trends and challenges facing the industry, and the ways companies are coping with them. As a young industry, biotech companies have been used to focusing their efforts on

by Pete Caldwell and Mark Oliver

2007 Bio-Benchmark Participants

- GlaxoSmithKline Biologicals
- ImClone Systems
- Johnson & Johnson Global Biologics Supply Chain
- Merck Serono
- Novartis
- Wyeth Biotech

filling the market with their eagerly anticipated product. Today, demand remains strong in certain areas but generally the market has slowed and in some areas, become saturated. The emergence of competition has led to excess capacity and severe price erosion, and these companies have had to adapt their operational strategies accordingly.

Senior executives in biotech find themselves dealing with challenges typically faced by more mature businesses. They find they must switch focus from creating capacity to improving productivity: the operation is required to be faster yet cheaper.

The changing landscape is making itself felt in a number of key areas. In light of reduced prices, costs have become too high. Overhead recovery needs to improve. Also, because of worsening forecast reliability and the growing extent of product variety needed to supply new markets, flexibility needs to improve and lead-times need to be reduced, both in manufacturing and development. And as the focus shifts from growth to cost reduction, the balance of talent at all levels needs to tip away from scientific and project management skills to operational leadership skills. It's one thing to list the needed improvements and another to execute them. The benchmark study found typical obstacles,

Diagnostic benchmarking – the best of two worlds

Many different types of benchmarking tools exist, each with advantages and disadvantages. It is generally accepted that 'metric benchmarking' studies can provide companies with a view on how they perform in terms of outcomes, such as cost, lead-time, delivery reliability, cash-flow, inventory, risk, and so on. However, the criticism of such studies is that the comparison companies are often not equivalent, that the lack of depth leaves the companies with more questions than answers, and that the experience provides little - or worse, inaccurate - direction on how to improve. At the other end of the scale lies the in-depth 'process-benchmarking' studies, typically not led by a prescriptive benchmarking tool or questionnaire, but customized to focus on specific, detailed activities. The main advantage of such studies are that, so long as the scope of study is narrow enough, the argument of incomparability is removed (for example, within the scope of a warehouse operation, a manufacturing company can usefully benchmark itself against a best-in-class supermarket). However, these studies are notoriously expensive, narrow in scope, and difficult to recruit benchmark partners. The optimum would seem to be something in between - a sector-specific diagnostic-benchmarking study, led by a structured questionnaire, facilitated by an assessor, focused on identifying the key results-based metrics (cost, service, lead-time, quality and so on), but crucially, also focused on identifying the enabling practices that led to the results. Such a study would seem to incorporate the best elements of metric-benchmarking and process-benchmarking studies.



including general protraction of management and production processes, even compared with the sluggish pace of bureaucracy in the pharmaceutical industry. Product release can take 60 days compared with 7 to 20 days for the best companies. Deviations take 35 to 40 days on average to clear, while the best companies managed this in 10 to 15 days. And changes in procedure take on average 10 to 15 weeks to be approved. Another obstacle is that cost reduction efforts are slow to impact. Despite rising cost pressure, little time, typically 2% to 10%, is spent in driving cost reduction opportunities and in 2007 operational costs were reduced by only 4% to 5%. Plant utilization is running at an average of 70% to 80%,

which is poor for a capital-intensive process industry. Inconsistency of internal processes causes waste. The benchmark study found that biotech manufacturing averages 15 non-conformances per batch compared with one to two at the best sites, and all deviations require investigation. The majority do not affect product quality but still, some 5% of batches are found to be out of specification and have to be discarded. Biotech companies also have to cope with raw material supplies not growing in line with demand. Risks to the entire supply chain are intensifying as more companies vie over the same suppliers. Companies may wait more than half a year for raw materials and the entire industry is too depen-

dent on single sources for key materials, putting delivery at risk and impairing flexibility. As the industry matures, brilliance in R&D isn't enough. The companies need excellent business management skills at all levels, yet there is a lack of managerial talent and the churn rate is high. Biotech companies typically lose 10% of their staff each year. How do they prevail against these odds? The companies showing the best benchmark results were ones that took an active approach, that understand profit to depend on operational excellence, and took steps.

One "secret", the study showed, was to forge tight working relationships between production, R&D and industrialization, which accelerated the R&D process. Cross-functional teamwork helps resolve deviations speedily. Some companies even started linking remuneration to speed of product-flow and decision-making.

Another crucial element is to work more closely with raw material suppliers, while in parallel diversifying sources to reduce supply risks. Within production, investment in new technologies is working to increase yields and processes are being reengineered to reduce variation and decrease the minor non-conformances. Multi-skilling and job rotation

programs can be instituted to increase motivation and retention, while improving the match between skills and business needs. Personal development and succession-planning processes are gaining in prominence, as is working with external local academic institutions. Employee needs are being addressed for the sake of retention. Flexibility is the word, including through offering part-time options. In parallel, maturing biotech firms are learning to outsource noncore activities such as packaging, to improve overhead recovery and reduce variable cost.

The proof of the pudding

Benchmarking proved itself to be a valuable tool in highlighting key issues and solutions in biotechnology in general, though the lessons have broad application to industry as a whole. Diagnostic benchmarking is relatively inexpensive and delivers proportionately high benefits, so long as both performance metrics and enabling practices are evaluated, and as long as the output is heeded.

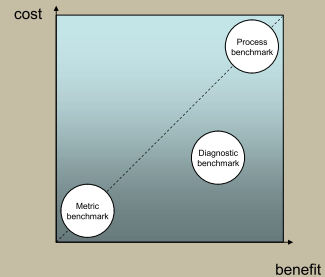
The study portrays the picture of an industry traversing through its lifecycle. We see the shift in emphasis through the embryonic and growth phases into the shakeout phase. The effect of competition has forced many companies to focus on their poor

operational performance. Operational Excellence has ceased to be an ephemeral fad, but a source of real competitive advantage. Companies lagging in performance excellence are facing ever greater external pressure. The majority of biotech companies face similar external pressures – intensifying competition, excess capacity, talent constraints. The diagnostic study showed their common issues: how to accelerate development, increase productivity, reduce manufacturing lead-times, manage costs and how to recruit and retain the right staff.

Many prove to be tackling the issues in the same way. Most are trying to improve margins by improving productivity – achieving the same output with fewer people. They are trying to speed up manufacturing and product development by simplifying management processes. They are working more tightly with suppliers to ensure reliable supply. They are reorganizing themselves around value-streams to attain better line-of-sight to their customers; and they are redoubling their efforts to retain and develop staff.

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Tefen's BioBenchmark study incorporated this theory within its structure as follows: for each operational business outcome examined (for example, operational lead-time, delivery performance, etc), key levers were identified (for example, level of multiskilling, level of dual-sourced suppliers, etc). Tefen's knowledge of operational excellence within the fields of Manufacturing and Quality was drawn on to design this hypothesis. When the study had been designed, each operational business outcome was driven by 5-10 key enabling practices or processes, each of which was investigated and scored at each site. Where performance-results were relatively poor, comparisons against the Participant's peers could then be made, focusing on the relevant enabling practices. This structural link between enablers and results was crucial for the BioBenchmark study as it took place over 16 very diverse biotech operations, ranging from brand new to 50 years old, from 200 employees to 3,000.

