

# BioBenchmark<sup>SM</sup> Biopharmaceutical Operations Benchmarking Study

## EXECUTIVE SUMMARY

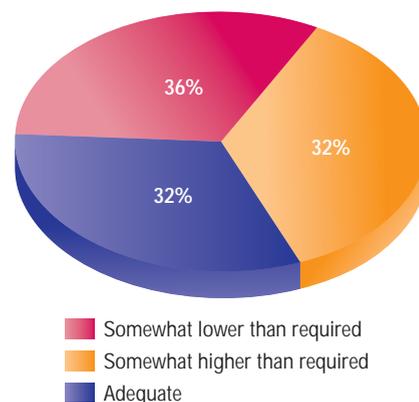
**A**s part of the BioBenchmark Study, key executives were asked a series of questions to gain a better understanding of the overall trends in the industry, as well as to identify the biggest challenges facing biopharmaceutical companies today. The questions were designed for respondents at the vice president level and above in the participating benchmark companies.

### OVERALL IMPRESSIONS

Generally, the concerns of biopharmaceutical company executives are more focused on pipeline and product issues rather than on capacity shortages. Many companies in the survey recently invested significantly in building new plants. As a result, meeting capacity is not of primary concern. Good research and a strong product portfolio to fill this capacity are critical, and the general impression is that manufacturing and quality operations will do what is needed to meet the product demands. Focus will truly move to the operations side when these areas negatively impact

supply, either through manufacturing issues or regulatory enforcement. Cases like Immunex, a company that forecasted poorly and forfeited hundreds of millions of dollars in revenue due to capacity shortfalls, are rare. The opposite seems to be true for most biopharmaceutical companies – there appears to be plenty of capacity, so the challenge is in finding ways to fill it.

In 5 to 10 Years,  
Capacity in Biotech Industry Will Be:



## DATA ANALYSIS AND RESULTS

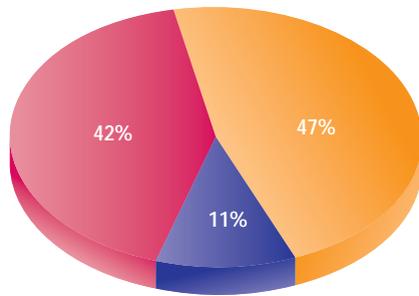
### Capacity

The first part of the survey focused on the future of the industry with respect to manufacturing capacity.

With the significant amount of production capacity coming online over the next few years and improvements in yields being a focus of development, many recent industry articles reflect the belief that there will be excess biopharmaceutical production capacity in the industry. Most industry executives agree that in five to ten years, there will be adequate or excess capacity, with only one-third believing there will not be enough to meet market needs.

Relying on the contract manufacturing organization (CMO) for the majority of manufacturing has been a popular strategy for years in many other industries. Companies usually choose this path for cost advantage, maintaining focus on core competencies, or supplementing a process with technology they cannot replicate internally. Even in biopharmaceuticals, many companies use third-party providers for fill-and-finish operations. However, due to the proprietary nature of

**In the Long-Term Vision of the Industry, Outsourcing Manufacturing to Contract Companies:**



- Will remain appropriate in most cases, but not significant avenue
- Will be minor avenue for leading companies and used primarily by smaller companies
- Will become the main strategic avenue for most companies

the biopharmaceutical bulk production process and the regulatory aspect of the business, most executives agree that, except for small companies who cannot afford the risks of developing in-house capacity, most companies with marketed products will build capacity to meet their upstream production needs.

The same is true for laboratory operations. Contract and reference laboratories have existed for years, offering significant testing capabilities to the marketplace. But 70% of the surveyed executives feel that most laboratory testing should remain in-

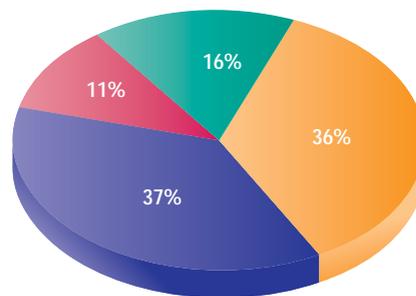
house because of the criticality of laboratory performance on release turnaround time. However, the use of contract laboratories will still be common for certain types of testing that are very expensive or rarely performed.

Executive opinions are divided on the industry's building manufacturing capability outside of North America or Europe. All agree that the availability of qualified, biopharmaceutical-savvy individuals is key to making this a viable option. Singapore leads the list of potential locations, with India and China also making the list. The latter two countries currently have biopharmaceutical manufacturing capabilities, producing products that include counterfeit growth hormones and Epogen®. Considering more traditional geographical manufacturing areas, 25% of the respondents felt that Ireland and Puerto Rico are developing strong biopharmaceutical capabilities and are likely to become prime locations for bulk production, not just fill and finish operations.

**Automation**

Automation has been the Holy Grail of manufacturing for many years. Visibility, error reduction, and trending would be faster and more efficient with the implementation of electronic manufacturing and laboratory records. However, most executives, jaded by previous automation failures and understanding the regulatory difficulty in getting such systems working, view converting to a "paperless" operation as a long-term endeavor. None of the interviewed executives seemed willing to be the first to go significantly paperless, preferring to

**How Big of a Role Does IT Play in Helping the Organization Achieve Its Objectives?**



- Plays a minor role, but should/will increase in importance in the future
- Plays a critical role; key to operational efficiency
- Plays a minor role
- Plays a medium role; recognize IT is necessary but not solution to everything

see a proven system in another biopharmaceutical company before venturing forward.

Overall, information technology has yet to penetrate the industry in a way that makes it an essential tool for running the business. Seventy-three percent of the executives agreed that it is necessary to the operation, with only 36% believing it plays a significant role in driving overall improvement and success. This is contrary to most other advanced industries, where highly automated production equipment and manufacturing lines provide significant information and input towards process improvement.

### Staffing

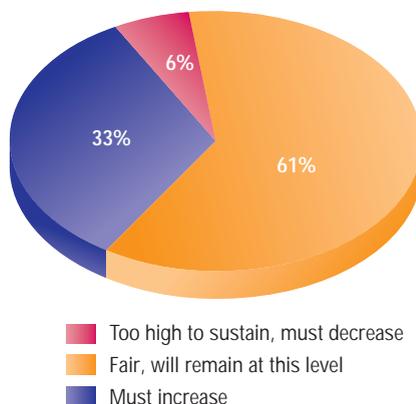
Although salaries in biopharmaceuticals need to be high to attract talent, 61% of the executives agreed the rate of pay is fair, and salaries will not drop significantly as more qualified individuals enter the workforce.

Even with high salaries, companies see turnover as a major issue, especially in the biopharmaceutical clusters such as San Francisco, Boston, and North Carolina. When executives were asked to list key factors to employee retention, they ranked the items in the following order:

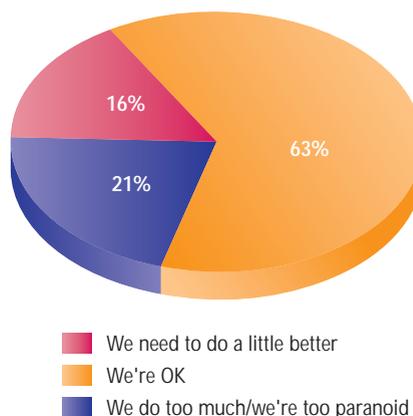
1. Interesting/challenging job
2. Career development path/options
3. Salary and benefits
4. Organizational culture/management philosophy

Regardless of how the executives answered the turnover survey questions, the conversation always led to discussions of the high salaries and benefits offered by other companies to attract their employ-

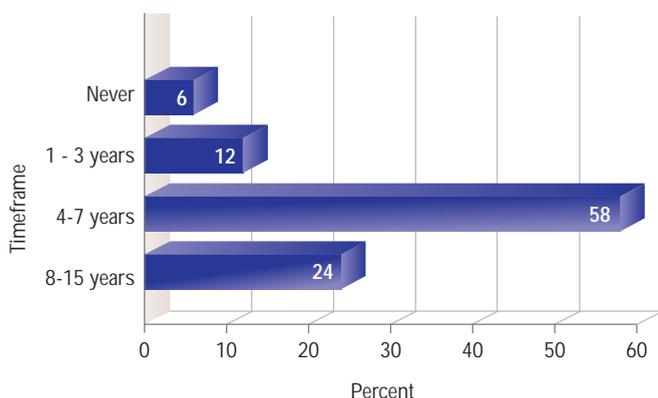
**Salaries in the Industry (Excluding Upper Management) Are:**



**What Do You Think About Your Compliance and Quality Assurance?**



**When Do You Expect Approval of the First Biogeneric Drug?**

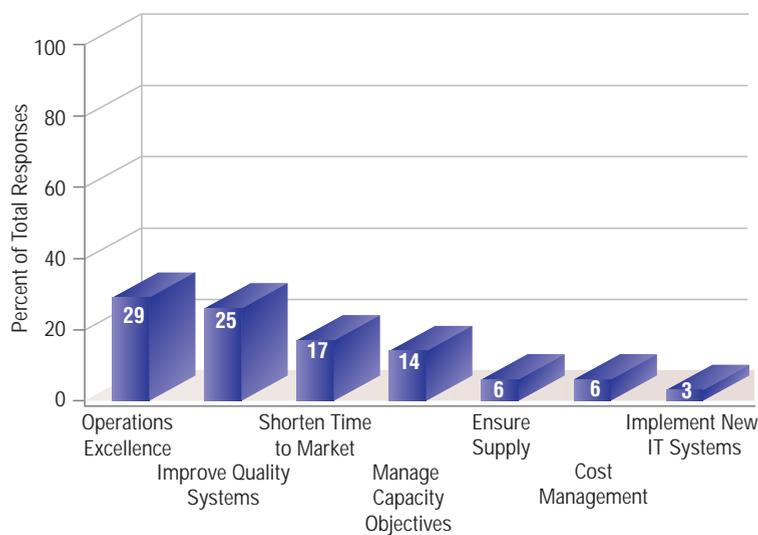


## Executive Rankings of Industry Leaders

Area	Rank #1	Rank #2	Rank #3
Research and Development	Genentec	Amgen	Wyeth Biopharma
Manufacturing Technology	Genentec	Amgen	BI
Operational Excellence	Amgen	Genentec	BI
Sales/Marketing	Amgen	Genentec	Centocor; Genzyme
Management Team	Amgen	Genentec	Chiron
Best Company to Work for	Amgen	Genentec	Biogen
Most Desirable to Partner with	BI	Genentec	Biogen
Quality	Amgen	Genentec	Biogen

\* BI = Boehringer Ingelheim

### What Are Your Critical Operational Objectives for the Next 2-3 Years?



ees away from their organizations. To combat this, executives are improving their hiring packages to remain competitive, and they offer training in retention tools to mid-management. Some companies have even modified their existing production shift structures to attract local talent from other plants.

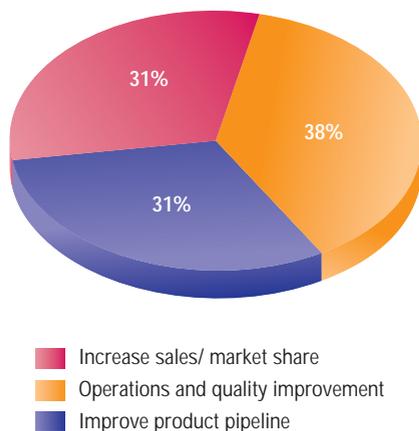
Part of a retention program includes offering rewards for good performance. The survey indicated that 41% of the executives offer monetary compensation as a reward; 21% provide non-monetary awards, such as awards or specific recognition; 17% offer stocks/options; 10% prefer to give gifts; and 10% offer "intangibles." All felt that recognizing good performance was critical to employee satisfaction, with multiple, non-monetary methods available for achieving the desired results.

### Generic Competition

If the surveyed executives are accurate in their perception of the U.S. Food & Drug Administration's (FDA) direction, true generic competition will enter this market within the next four to seven years – most likely with human insulin, in Europe. With the approval of biologics will come the need for more efficient, effective operations to minimize their impact on profitability. Additionally, cycle time will become crucial to capitalizing on early exclusivity and capturing market share.

Due to the complex nature of biopharmaceutical drug production, the executives surveyed also believe that competition will come from existing biopharmaceutical companies with excess capacity, not from dedicated generic companies that currently exist in the traditional, small-molecule pharmaceutical arena.

### What are your Overall Company Objectives for the Next 2-3 Years?



### Industry Leadership

Executives were asked to identify the industry leaders in eight key categories. Amgen and Genentech are widely felt by other executives to be the leaders in most of the categories. Boehringer Ingelheim (BI) has clearly gained the respect of many industry executives, ranking high in a number of categories – even with little public relations influence. It should be noted that in many cases, biopharmaceutical executives had very little knowledge of other companies besides those for whom they previously worked or those reported most often in the news. This potentially explains the companies chosen above. Additionally, biopharmaceutical divisions within large pharmaceutical companies are typically less known than the independent biopharmaceutical companies.

### Company Objectives

Executives were asked to identify the overall company or biopharmaceutical divisional objectives. The pipeline, sales, and operations improvement were almost evenly divided as major priorities. Filling capacity will be vital to the success of the company in light of the number of new plants currently coming online.

Operations improvement activities were key priorities in 38% of the executive responses. Most companies in the study currently are involved in reengineering their quality systems as a result of meeting regulatory requirements or an overall desire for higher efficiency.

### Quality

Most executives felt they were doing well with respect to quality and described their relationship with the FDA as good-to-excellent. Some execu-

tives of large pharmaceutical operations expressed that other divisions' reputation with the FDA had an impact on their own, for better or for worse. Many executives were still uncertain about how enforcement moving from CBER to CDER will affect their performance in future quality audits.

### Internal Evaluation

Executives had the opportunity to identify what they felt were their company's main strengths and weaknesses.

For their main strengths as an organization, executives highlighted people and teamwork as key drivers of success. Due to the nature of the product and the complexity of the processes (R&D, manufacturing, and quality), the existence of motivated, skilled employees plays the biggest role in the success of the organization. Another perceived strength is having large or expanded facilities, since they increase a company's ability to ramp significantly if necessary.

Company weaknesses were identified as poor efficiency and a reliance on paper systems. Additionally, biopharmaceutical organizations that are divisions within large pharmaceutical organizations see an added layer of bureaucracy in much of the decision making within their operations, which impacts their ability to change rapidly or release product in a timely fashion.

When executives were asked about the level of accuracy in their capacity and labor planning processes, most felt that with respect to the plant capacity, they had an accurate understanding of capacity to a level of +/- 10%. Staffing requirements, however, were only accurate to about +/- 20%. The dramatic increase in headcount is a result of the rapid growth many of these companies have experienced. During this time, effort was not invested to adequately model labor requirements, resulting in a poor understanding of the true company needs.

The final question of the study asked executives on which company-wide operations excellence practices they were currently focusing. Eighty-four percent of companies did not have a formal system for driving ongoing improvement, while 16% of the executives mentioned the existence of Lean/Six Sigma type programs. Any improvement activities currently underway in the remaining biopharmaceutical companies were focused on a specific business process and driven by the individual operating groups, not a centralized organization. However, many executives commented that they expect the creation of a centralized process improvement function will become a reality within the next few years.