

BIOPROCESSING

Survey Assesses Biopharmaceutical Manufacturing Capacity Growth

The "3rd Annual Survey of Biopharmaceutical Manufacturing Capacity and Production" reports production capacity for biopharmaceutical manufacturing will expand by 48% over the next five years for mammalian and microbial production systems. The study includes responses from 187 biopharmaceutical developers and CMOs from 23 countries.

The report, produced by BioPlan Associates and coauthored by Howard Levine of BioProcess Technology Consultants, provides details and comparisons of production by biotherapeutic developers and contract manufacturing organizations (CMOs).

The industry's current five-year projection of production capacity expansion is now significantly lower than in 2003, where the five-year projection indicated capacity would expand 69% by 2008.

"With the recent capacity crunch behind us, the decrease in perceived capacity utilization is partly a reflection of continued industry expansion. There have been a number of recent CMO facility expansions. Much of this new capacity may not be fully utilized," says Eric Langer, president and managing partner at BioPlan Associates.

Another significant factor now starting to

affect demand on capacity is that biopharmaceutical developers are seeing results from efficiency-based R&D aimed at producing greater yields.

"This has two effects," notes Langer. "It can open existing capacity for organizations like CMOs, and it can reduce the requirements for additional capacity for producers who can expand into the extra capacity generated by the efficiencies."

Additionally, the failure of a few large-volume, late-stage products, along with continued improvements in expression levels and yield, may be reducing capacity utilization.

But is the current level of industry capacity healthy? Capacity utilization for all biomanufacturers using mammalian cell culture systems is currently 68.8%. Capacity utilization for microbial fermentation is 60.5%. As a comparison, the U.S. Federal Reserve Statistical Release showed that capacity utilization for all U.S. industries in July 2005 was 79.7%. This suggests that the pendulum has swung to the side of excess capacity.

Nearly 40% of the respondents to the survey indicated a critical issue impacting production capacity expansion over the next five years will be the lack of trained and experienced production

staff. This factor scored as the highest concern. Contract manufacturers are feeling the pinch more acutely, with 43% citing lack of trained and experienced staff as a major problem.

"While all industries experience periodic shortages of trained operations and production staff, biopharmaceutical manufacturers are more consistently concerned about the impact of available workers, and about training new staff. To overcome the projected lack of trained staff, the industry is turning to both internal and external trainers," says Langer.

"However, because much of the training is specific to a given technology or process, many times manufacturers will use their existing production staff and managers to act as trainers. This, in itself, can impact productivity. So when newly trained employees are lured away to higher paying jobs, the cost of replacing them can be significantly higher than it is for other, less technical fields.

"The answer, then, is likely to be more of an overall HR issue. Even if more employees are trained, the issue of employee retention will need to be addressed. There's also the question of whether we are training the right employees.

"Someone with a masters in biotechnology from Johns Hopkins University may enter the

workforce as a high-level technician, but will that person be retainable? The training may need to begin in technical high schools, or at similar stages."

Today, companies are using in-house training for employees in areas such as cGMP biopharmaceutical production (77%), fermentation processes (66%), cell culture techniques (65%), and process validation (64%).

External organizations are typically used for training in areas such as management training (35%), FDA regulatory compliance (32%), analytical methods (24%) and others.

"There is a lot of training going on out there—in fact, 34% of companies put every one of their biomanufacturing employees through some kind of training during the previous 12 months. Only 4% trained none of their employees," according to Langer.

In addition to staffing problems, the report found that for CMO respondents, lack of financing for production expansion (indicated by 52% of CMO respondents) is expected to be a major factor. Key areas to address to avoid capacity constraints included: optimizing cell culture systems to increase upstream performance (noted by 54.2% of respondents) and improving downstream purification performance (43.8%).