

International Competitiveness of Biopharmaceutical Manufacturing Hit by Technical Staffing Shortages

Biomanufacturers Attempt to Manage Their Competitiveness Through Training and Staffing

By Eric S. Langer, MSB

A lack of trained and experienced technical and production staff will have an impact on more than half of the world's biopharmaceutical developers and contract manufacturers in the next five years, and impact their ability to meet demand according to a survey¹ of 100 international biopharmaceutical manufacturers and contract manufacturing organizations.

How manufacturers plan to deal with the potential opportunities, bottlenecks, and production requirements was part of a major study on biopharmaceutical large-scale production, for the American Society for Microbiology. In its annual survey of biopharmaceutical manufacturers, BioPlan Associates, Inc. of Gaithersburg, MD quantitatively assessed industry capacity and analyzed potential industry bottlenecks that may develop over the next five years. The results provided information and insights on current capacity, capacity utilization, projected future capacity needs, reasons for production bottlenecks, and how these bottlenecks might be resolved.

Current Situation

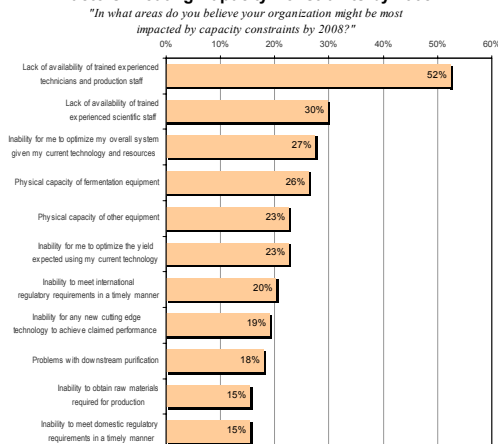
As biopharmaceutical manufacturing matures, the factors creating constraints become more predictable and manageable. The lack of trained and experienced technical and production staff over the next five years is one factor that the industry predicts will create production bottlenecks.

Other factors creating capacity constraints were distant runners-up. Following lack of availability of trained technicians, an insufficient number of experienced scientific staff was the second most likely factor to create capacity constraints in 2008 (indicated by 30% of respondents). Notably, physical plant capacity was indicated by only 23% of respondents, suggesting that manufacturers felt that the

long-term outlook for capacity based on physical equipment was adequate.

52% of respondents see technical staff training as a key area that needs to be dealt with today.

Factors Creating Capacity Constraints by 2008



Adi Mohanty, Vice President, Manufacturing at Transkaryotic Therapies, Inc, Cambridge, MA, believes that staffing issues tend to be a continuous concern for companies, "During our most recent expansion, we knew how and when the plants would come on-line, but we had no idea initially how we would staff it, which was a major concern," he said. "We were ultimately able to meet the needs, and train the staff. But getting there wasn't easy."

Dealing with Staffing Shortages

Across the board, manufacturers agree that there is an immediate need to address the availability of trained technical staff. In fact, 52% of respondents see technical staff training as a key area that needs to be dealt with today. There were other short-term areas that manufacturers felt needed to be tackled today as well: Aside from trained staff, three out of five manufacturers indicated that "Optimizing cell culture systems to increase overall performance," was important and nearly the same number indicated that "Improving downstream purification

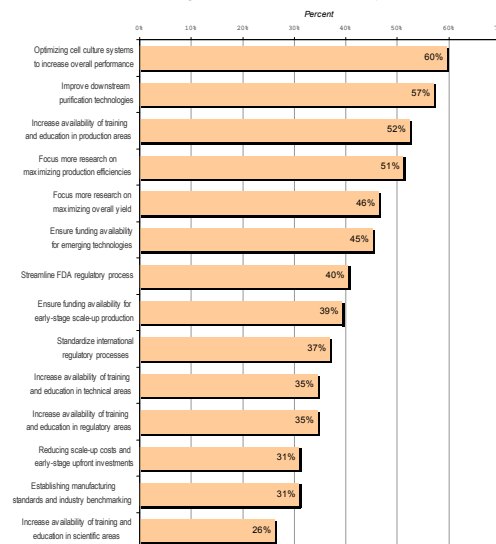
technologies" topped their list of bottlenecks. (See Graph).

The training required to get a technical staff person to a point where he or she can take a 'lead' position can take between 12-18 months. Some larger pharmaceuticals intentionally hire "green" technical staff to avoid bringing in people with work habits that are incompatible with their production philosophies and methods. Smaller biotechnology companies often do not have the luxury of time required to establish that level of expertise in-house. This can cause a dilemma between the need to maintain in-house control and retain institutional knowledge, and increasing a company's value developed through a well-trained workforce, and the need to meet investors' demands for rapid commercialization.

There is little consensus on how to deal with staff shortages. Some companies assume the problem will be resolved through market forces. Others are

Key Areas to Address to Avoid Capacity Constraints

"If this industry is to avoid significant capacity constraints, what are the most important areas that need to be addressed today?"



developing strategic programs to manage the problem directly.

"The lack of availability of trained experienced technicians and production staff is a concern that can be handled by carefully managing your growth rate," according to Dr. Marco Cacciuttolo, VP

¹ Advances in Large Scale Biopharmaceutical Manufacturing and Scale-Up Production. Second Annual Survey of Industry Capacity, BioPlan Associates, Inc. Gaithersburg, MD November 2003.

Technical Operations at Medarex in Bloomsbury, NJ. “Three years ago, capacity constraints were the critical issues. Today, the problem on the horizon is availability of production and quality unit staff. Organizations need to be responsible for planning their growth rate and preparing for future capacity requirements.”

Cacciuttolo says that this includes selecting key personnel within the organization to train future staff, and maintaining the corporate know-how. “Talented individuals are naturally attracted by successful companies. Success feeds on itself and managing the growth of an organization is a full time job of each responsible manager...Companies not dealing with their staffing problems today, could end up with a big problem five years from now.”

Growth may also include the use of a contract manufacturing organization, which will need to be managed by capable individuals in the areas of production, quality control, and quality assurance, concedes Cacciuttolo.

The Problem

More than half of the biopharmaceutical manufacturers surveyed felt that a shortage of trained, experienced production staff was going to be a major problem. Part of the reason for this is that many manufacturers consider training to be something beyond their control. Most have had little experience with it, and often that experience has not been satisfactory. In addition, because there has been relatively little concerted effort to develop production workforce training, many plant operators are unaware of the options currently available.

A typical scenario occurs when a company’s senior management informs its operations staff that a new product is finished in R&D. The organization’s operations staff is asked to ramp up and take on a new process rapidly. Operations needs to get the plant and equipment ready, and the people trained. This will involve adding new hires to run the process. Senior managers often set

aggressive time schedules, based on financial considerations. The costs associated with renovation, build-out, engineering, and new processes, are established. Often, however, managers neglect to factor in, or underestimate the costs associated with readying the workforce to step up and take on the new process.

Internal Training

Managers commonly expect that existing staff will be able to readily train new staff on new processes. However this leads to problems. Facility managers, often busy specifying equipment, working with vendors, negotiating with engineering, and ensuring that utilities are available, are now expected to train new staff on old equipment, and existing staff on new equipment.

“It’s an overload situation. And it happens frequently,” says Ed Sybert, Director, Biotechnology Program, University of Maryland. “The impact is that something has got to slip. People in this industry tend to be very dedicated. They will start working 70-80 hour weeks, and they burn out. Either the quality goes, or the people go. Neither is acceptable. The workforce will do the best they can, but can’t keep up. Mistakes are made because of pressures.”

“It falls to the already-overloaded staff to do the training. These people may not...be particularly interested in sharing their internal knowledge or experience with newer, younger staff...Sharing this information may not be to the older staff’s personal interest.” *Ed Sybert, Director Biotechnology Program, University of Maryland*

Sybert contends that even when new people are hired, in order to contribute, they still need to be trained. This task invariably falls to the already-overloaded production staff who may not want to do it, , may be inadequate at it, or not particularly interested in sharing their internal knowledge or experience with

newer, younger staff that are seen as cheaper.

Impact on Industry Competitiveness

Longer learning curves result from hiring production staff that lack real-world experience. This gap between applied learning and fundamental basic science knowledge results in higher staffing expenditures, and higher turnover rates, which is an emerging global competitiveness issue. The large learning curve in getting a plant to full capacity results in longer start-up windows, and higher staffing and training costs. Some in the industry believe that this will have an immediate impact on our domestic biomanufacturing industry’s ability to compete internationally. The US domestic industry may be out-pricing itself compared to other countries.

What’s Needed

A number of options are being proposed to deal with the shortage of trained staff. These include more industry-academic partnership, establishment of local and regional training programs, and creating effective, internal mentoring programs.

Many in the industry feel that there are not enough technical level, 2-year, associate degree programs designed to effectively prepare people for the job market. Companies are sometimes forced to hire people that are under-trained, or over-trained. Either situation is not acceptable: the under-trained, high school level people require too much time to get up to speed, and the over-trained, BS or masters level people often become bored, and staff turnover and morale suffer.

Transkaryotic Therapy’s Mohanty states, "At the supervisory level, universities focus heavily on pure research, not the applied programs that companies like TKT need. Most people with PhD's don't want to work a shift on Sunday nights. But that’s the nature of this business. What’s needed is for the top-notch traditional universities to offer biotechnology programs that will generate graduates with excellent applied and technical skills at the masters level.

We've approached universities on this very issue. The answer we've heard is that universities find it not to be cost-effective. Universities often don't seem to focus on this type of masters program. For our purposes at TKT, an individual with a basic chemical engineering undergraduate, and a masters in biotechnology from a reputable university would be our ideal candidate."

According to Mohanty, a 2-year AA degree would be sufficient for technical positions. A Masters degree would be ideal for a supervisor, plant manager, process engineer, area manager, purification, fill/finish, or fermentation manager.

Working with local universities is an important step

To maintain a competitive workforce, many believe that this industry will need to start working more closely with local community colleges and top-notch universities. Industry-academic partnerships are necessary. While this is beginning in some regions, many manufacturers feel that it will be a necessary step to ensure an adequate supply of well-trained production workers and supervisory staff.

Transkaryotic's Mohanty also practices what he preaches, "I ran a 2-year programs myself. Students going through this 2-year, very hands-on learning program, were ready to work in the plant after 2 weeks, rather than several months on the job. That amounts to a huge savings. At the managerial level, you could conceivably shave years off the learning curve through a master's program. This industry would be much more efficient, and we would be creating a domestic competitive advantage, if community colleges, local colleges, technical schools were generating the technical people we need, and the universities were preparing masters level staff for managerial roles."

Meeting Training Needs

Ed Sybert, Director of the University of Maryland's Biotechnology Industry Program, runs one such university-level program. He is responsible for developing

and delivering industry-appropriate training in biopharmaceutical production. This is targeted at the plant or production operator and technicians.

"In biopharmaceutical manufacturing the workforce generally needs to have appropriate training in three areas: 1) GMP regulations 2) Equipment being operated, and 3) Production and manufacturing processes being run," says Sybert. The training is generally unique to the particular company, plant, and process that is being run. This requires at least some level of customized training."

Customization

There are relatively few training companies or organizations that provide the customized, proprietary training that most biopharmaceutical manufacturers require. When it is available, it tends to be costly. The format for training is part of the issue. Generally, there are few areas where a company's workforce needs to be trained as a group. As such, most training tends to be an individualized activity.

Of the three areas of training mentioned by Sybert, 'regulations and GMP,' is the one that is most often available 'off-the-shelf.' This, of course, is due to the nature of GMP training. An added benefit to outsourcing is that external experts tend to stay up-to-date on regulations, and are often more effective at conveying the information than in-house staff.

The second area, 'equipment training,' can in some instances be developed off-the-shelf. However, a certain level of customization will likely be needed to ensure the training is relevant to the application.

The third area, 'production and manufacturing process,' requires extensive customization. Although some processes, such as inoculating a bioreactor, can be delivered in a non-customized setting, most require extensive customization, to ensure they are relevant to the application.

According to Sybert, "Developing a training program around a company's manufacturing process is a challenge.

First, unless the company sees training as an on-going commitment, they will not have in-house trainers. Second, even if there are in-house trainers many tend to be generalists, with broad experience in a number of areas, QA, QC, or HR staff. Many will not have the hands-on experience in the process itself."

Sybert believes that effective process training requires both extensive knowledge of the process, and the ability to effectively communicate this information, "Some people that are extremely good at running a process, may not be good at articulating it. Just picking your top fermentation guy to do a training program doesn't guarantee you will get the message across."

In-House Mentoring Programs

The solution may be in the development of professionally established in-house mentoring programs. The final step for getting a new hire, having good basic process or GMP training, up-to-speed is to set them up in a professionally developed mentoring program. In this, the trainee is paired with an experienced technician: someone with both process expertise, and communication ability. Part of the program should include testing of post-training comprehension. This process ensures that new members of the team are properly paired, and are able to learn the right ways to perform in-house processes.

Conclusions

Biopharmaceutical companies and contract manufacturers recognize that as new products move through the development pipeline, it will take more than physical capacity to meet the demands for production. Companies will hire new staff, and demand that their new hires have as much experience as possible. By definition, these people are likely to come from other companies. At present, experienced technicians are not being delivered from colleges or universities. While this is changing, some feel that much more partnering between industry and academia needs to be done.

In order to be effective, manufacturers often agree that training will need to be done at the local level. Training tends to require

local fixes. Sending staff out of the area for extended training is not an option for many companies. In addition, regional needs tend to be unique, and often require unique approaches. Local training can keep logistical issues and travel costs down.

In addition, manufacturers sponsoring customized programs have demanded that they own the proprietary content. To accomplish this, companies tend to hire near-by consultants to prepare and regularly deliver proprietary, customized course materials. Customization is costly, but most larger companies recognize the alternatives associated with an under-trained staff are unacceptable. Custom training can run \$250/hour. The time required to develop a program depends on

the process, elements, depth, and level of the people being taught. Prices of \$50,000 or more for a customized, proprietary program are not unusual. Many smaller biopharmaceutical companies are not ready to invest in this level of training. To keep costs rational, biopharmaceuticals should build a comprehensive program that takes advantage of the off-the-shelf programs for as many of the elements as possible (GMP, basic equipment processes, etc) and then balance the need for the more costly, customized, work-for-hire.

In the end, the demand for training is not going away. As the industry grows, by its nature, and by regulation, we will see increasingly more programs. Many of these will be regionally created, especially

in regions where there is a critical mass of manufacturers. To meet the need, many more industry-academic partnerships are likely, as well.

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