

Benchmarking Biotech

by Michael Kamarck

Manufacturing matters in biotech. That's not something most of us were contemplating even a few years ago. But today several factors are pushing manufacturing issues more and more to the forefront.

Why? In part because the industry is reaching a new phase. A few years ago we were primarily research-driven and concentrated on getting molecules into the clinic. Today we're concentrated on how to get medicines into the patient. More and more we're becoming an industry with marketed products.

Interestingly, that fact alone isn't enough to make manufacturing a central concern of senior management. Look at the small-molecule pharmaceutical industry. They've been involved with manufacturing for decades, but only in the past few years has manufacturing become an issue that could make the difference between success and failure.

Supply-Chain Management

One reason that manufacturing has started to matter more is increased regulatory scrutiny. Problems with your plant can interrupt your entire supply chain. In addition, because of cost pressures and regulatory requirements, manufacturing is suddenly on senior management's radar screen.

If that is true for the small-molecule world, you can imagine how true it will be on the biotech side, where the cost of manufacturing makes up a much greater portion of the cost of goods — 15% or 20%, compared with 5% or 15% in small-molecule products.

And so our focus is moving to manufacturing. But how do you focus on something that, as an industry, you have never actively managed? That is the situation we face in biotech: We've had few products in the market that required a supply-chain management function. Our processes are sufficiently different that we can't hire people from other industries to say, "That's how we do it, that's the percentage of costs we spend on quality, that's what we spend on maintenance." We're starting without any reference point to show us what a supply-chain structure and metrics should look like. The only thing we have is a gut feeling that cost may be out of control.

Surveying the Industry

For many industries, such reference points come in the form of well-established benchmarking studies that establish industry averages, identify best practices, and help point out trends. These studies are invaluable in improving the manufacturing process.



Michael Kamarck is senior vice president at Wyeth BioPharma, 500 Arcola Road, Collegeville, PA 19426, 484.865.6289, kamarcm@wyeth.com, www.wyeth.com.



A major benchmarking study for the biotech industry is nearing completion. The study was designed and is being conducted by Tefen, an operations consulting firm, under the auspices of the Biotech/Pharmaceutical Operations Excellence

Consortium, a group of 30 pharmaceutical companies and contract manufacturers. Thirteen member companies with substantial biotech operations are participating, including Abgenix, Amgen, Bayer, Biogen, Chiron, DSM, Genentech, Genzyme, IDEC, Lonza, and Wyeth.

At the heart of the study is a 900-item questionnaire covering manufacturing, facilities, supply-chain planning, quality assurance, and quality control. Under each main heading is a host of questions covering staffing, processes, deviation and change management, throughput, and cycle time. The focus is on quantitative information — equipment up time, release time, cycle time, and so forth. The study also looks at procedures: Who does what in the plant? Are maintenance and quality personnel embedded in plant floor teams? What resources are dedicated to in-process testing? What support systems exist? Does the plant have a LIM system? Does it have electronic batch records? Are there investigator pools to deal with excursions, or are they within the purview of each lab supervisor?

Providing Perspective

The study should provide an invaluable look at how biotech companies function and what they are capable of. Most important, the data will be independent and based on industry averages. That is important for every segment of biotech.

Larger companies can compare their performance with the industry as a whole and with industry leaders, identifying specific, achievable goals for improvement.

For biotech operations embedded within small-molecule companies and companies partnering with traditional pharma, the study will provide backup for discussions of metrics and timelines. That can be crucial: Biotech production is so different from small-molecule production that mismatched expectations can sometimes scuttle potential partnerships.

The study should also provide a road map for small companies designing their own systems. It should be especially valuable in creating a sense of realism. Too often, when I talk with fledgling companies, I hear overly optimistic plans. The objective data in the benchmark study, if taken seriously, will help provide some necessary perspective.

And of course, just going through the benchmarking study can be an important educational tool. In my own company, it has been especially useful in getting all departments to think of their work in terms of costs and cycle time.

Interviews with the participating companies are in their final stages and data should be available in another four to six weeks. Results from the public portion of the benchmarking data will be published in the September issue of *BioPharm International*. **BPI**