



Outsourcing Outlook

Jim Miller

Although much of the pharmaceutical outsourcing industry has enjoyed a robust past 18 months, contract manufacturers of small-molecule actives and intermediates are having a bad time. That segment of the industry continues to be plagued by soft demand and a large amount of excess capacity. As a result, the mood at the recent Informex trade show in New Orleans was pretty gloomy.

Commercial-scale pharmaceutical chemical manufacturers have been hit hard by product cancellations and Big Pharma mergers, which often have resulted in sponsors doing more work in-house. Unfortunately, in expectation of a major boost in demand, chemical manufacturers have just completed a round of capacity expansions.

At Informex, one chemical executive complained that just five years ago sponsors and analysts were issuing dire warnings of capacity shortages resulting from swelling product pipelines. The chemical manufacturers responded with a capital-investment binge, only to find that the expected demand has not materialized.

Overcapacity usually means brutal price competition, and the current situation is no exception. Major pharmaceutical companies, with their buying power and procurement sophistication, are particularly adept at squeezing the last penny out of the price. "Big Pharma has pricing mod-

els that can tell suppliers just where their bid is too high," one industry representative said. Several observers also noted that sponsors are becoming more open to doing business with manufacturers in China for early-stage intermediates and starting materials. Chinese sources offer significantly lower costs, and their GMP compliance has been improving.

In the current market, small- to mid-sized sponsors are in the driver's seat. Major pharmaceutical chemical producers are being forced to work with smaller companies a lot more than they used to, even though they perceive them as high risk because of their small pipelines and lack of expertise and experience.

The major producers also are having to scramble to offer kilo- and pilot-scale development and manufacturing services, which are in high demand by both Big and Small Pharma. Research and development operations at most of the commercial-scale chemical manufacturers are scattered among their commercial manufacturing sites, and few have dedicated development centers to compete with companies such as Pharm-Eco, Irix, or Seres. Also, companies built to pursue multiyear, multimillion-dollar commercial supply contracts don't like dealing with \$100,000 clinical trial material deals.

Biomanufacturing capacity

Hard times in the chemical business have had a direct effect on the willingness of the major active pharmaceutical ingredient manufacturers — who now control the contract biomanufacturing business — to invest in biomanufacturing capacity. "The industry doesn't want a repeat of the current [chemical market] situation in the biotech segment," one chemical industry executive said at Informex. The situations are quite similar, he noted, in the way that there is much hue and cry at the moment about the demand for biomanufacturing capacity, just as there was about

chemical capacity five years ago. The industry does not want to get stuck again with a lot of underused capacity if the demand doesn't actually materialize.

A recent report by US Bancorp Piper Jaffray ("The Road Ahead for Biologic Manufacturing," Minneapolis, MN, 22 January 2002) suggests that the biomanufacturing contractors have been wise to move slowly. The report says that more than enough capacity is under construction or is planned for construction to meet the industry's needs in the next five years. Most of that capacity is being built by major biotech sponsors, including **Immunex** (Seattle, WA), **Amgen** (Thousand Oaks, CA), **Genentech** (South San Francisco, CA), and **Biogen** (Cambridge, MA), with **Boehringer-Ingelheim** (Ridgefield, CT) as the only contractor with capacity in excess of 100,000 L. The report also suggests that in the next five years some sponsors will be active sellers of excess manufacturing capacity.

The greatest short-capacity problems in the industry recently have been in cell culture, where the take-off of large-volume monoclonal antibody products caught the industry by surprise. Contractors also have been concerned that the low yields of tank-based cell culture make it vulnerable to replacement by other technologies. However, capacity in microbial fermentation also has become tight in the past year or so.

One contract manufacturer that finally has decided to make a move is **Avecia** (Manchester, UK), which has announced a plan to build 40,000 L of microbial fermentation capacity at its Billingham, United Kingdom, site. The \$100 million investment will be completed in two stages: two 5000-L fermenters and associated harvesting and purification suites will come on-line in 2003, and two 15,000-L fermenters and purification streams will begin operation in 2005. **PT**

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