

Pharma Company Investment in Parenteral Manufacturing Capacity Picking Up

Jim Miller



Jim Miller is president of PharmSource Information Services, Inc., and publisher of *Bio/Pharmaceutical Outsourcing Report*, tel. 703.914.1203, fax 703.914.1205, jim.miller@pharmsource.com, www.pharmsource.com.

After a several-year lull, pharmaceutical companies are ramping up their capital spending in parenteral manufacturing. That investment in in-house capacity comes at a time when contract parenteral manufacturers are completing their own major investment programs.

The decision to outsource is often referred to as a “make or buy” decision, with *make* meaning to perform the function in house and *buy* meaning to source the function from a contract service provider. Often, the choice to *make* requires a decision to *buy* the manufacturing and test equipment needed to do the work internally. Equipment sales, therefore, provide some insight into the demand for contract services.

We recently talked with business development executives from several manufacturers of parenteral manufacturing equipment for their insights into investment trends in that market segment. Demand for parenteral manufacturing capacity is expected to boom because of the many biopharmaceuticals and small molecule cancer drugs in the pipeline. This should be reflected in demand for parenteral manufacturing equipment.

Manufacturing equipment suppliers report that after several years of slow sales, their market has been growing again. Bob Briggs, director of sales and marketing at **Cozzoli Machine Company** (Somerset, NJ), www.cozzoli.com), a manufacturer of filling equipment, says that “inquiries are up exponentially” this year. Tom Kelly, account manager at **Hull** (Warminster, PA), www.hullcompany.com), which makes freeze dryers, says orders have been on the upswing in the past one or two years after a slowdown in the late 1990s and early part of this decade. Because the delivery cycle from order to delivery is 18 months, and installation and vali-

ation can take another 6–12 months, equipment ordered will affect available capacity in 2–3 years’ time.

The big driver of demand seems to be replacing aging equipment more than building new capacity. “Companies have been nursing some equipment along, so there is a pent-up need,” says Briggs. Because it traditionally has had the most capacity, Big Pharma has been the major driver of replacement spending.

To the extent that Big Pharma has been investing in new facilities, those plants have been in offshore locations offering either favorable tax treatment or lower costs, according to the people we talked to. Ireland and Puerto Rico are two countries benefiting from this offshore trend. Some small companies have been investing in new facilities for clinical or commercial production, but it appears that most small pharma and biopharma companies are going the route of contract manufacturing. In fact, the equipment manufacturers report that contract manufacturers have been their fastest-growing customer segment.

In addition to the overall market tendencies, the equipment manufacturing executives noted several other manufacturing trends:

Impact of PAT. The Food and Drug Administration’s process analytical technology (PAT) initiative is expected to require some modification of equipment, but not wholesale replacement. Drug manufacturers will retrofit equipment with more controls and monitoring instruments wherever possible. Of course, new equipment already will be outfitted with advanced production data-capture and process-control capabilities.

High-potency compounds. The growing number of compounds with microgram and nanogram dosing is likely to have a significant effect on equipment demand, according to Jack Lysfjord, vice-president of consulting at **Valicare**, a division of **Bosch Packaging** (Minneapolis, MN), www.boschpackaging.com). “The increased potency of products creates exposure issues for operators, and problems like the need



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to prevent the material from getting on the outside of the package," says Lysfjord.

Lysfjord says the growth in high-potency compounds will lead to greater demand for barrier isolation equipment. Demand for isolator technology in the fill-finish areas has grown slowly. "Companies are not jumping in with both feet," Lysfjord observes. He esti-

mates that isolators account for about 10% of fill lines currently, but expects that percentage to grow in coming years.

Prefilled syringes. Filling-equipment manufacturers have seen a slight upswing in demand for syringe filling equipment in recent years, but report a substantial increase in 2004.

The developments in the parenteral manufacturing equipment market sug-

gest that contract parenteral manufacturers are not facing any major shift in market sentiment away from outsourcing. That's good news, because contract parenteral manufacturers have been making substantial investments in capacity in recent years. Nevertheless, equipment investment trends do raise some interesting issues for contractors:

- Now that they have started buying equipment again, will Big Pharma companies continue to outsource older products manufactured on older lines, or will they keep them in house on refurbished lines? Older products outsourced from Big Pharma have been an important part of the demand for contract manufacturing in recent years.
- Can domestic US and European contract manufacturers remain competitive with in-house facilities located in tax- and cost-advantaged countries? Pharmaceutical chemical manufacturers have been facing this issue for years, and the industry has expected that it would be only a matter of time before dose manufacturers would have to deal with it as well.
- How will contractors deal with the opportunity in high potency compounds? The high-containment segment represents a special problem for contract manufacturers. Lysfjord notes that barrier-isolation equipment still does not lend itself well to multiproduct environments, because cleanup between batches can be a long and time-consuming process. Contract manufacturers may have to find alternative solutions to meet this expanding market. **PT**

FYI

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Abstracts should be 3-4 pages long and focus on nasal and pulmonary pharmaceutical research. The deadline is 7 January 2005. For more information, contact Respiratory Drug Delivery, tel. 804.827.1490, fax 804.828.8277, info@rddonline.com, or visit www.rddonline.com.