

Contract Manufacturers Getting Squeezed

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Too many players and threats to the main customer base challenge European dose manufacturers.

Clients are always asking us for more information about the European market for contract manufacturing. They seem to think they are missing out on business opportunities by not participating more fully in that marketplace.

Well, they should probably feel lucky that they don't have more European exposure. European contract manufacturers are getting squeezed by adverse developments on the supply and demand sides of their market, and they have no obvious means of escaping their problems. Surviving the next several years will take a combination of managerial ingenuity, a strong balance sheet, and some luck.

The problems for European contract manufacturers begin with the erosion of their core customer base by competition from generic drugs manufactured in Eastern Europe and Asia. According to contract manufacturers we talked with at December's CPhI trade show in Brussels, the increasing flow of generic drugs from the lower-cost countries is already hurting their business. Generics have been a mainstay of contract manufacturers in Europe, where the pricing of generic drugs has been sufficient to provide contract manufacturers with a decent profit margin. In the United States, by contrast, contract manufacturers generally avoid generics because the prices are so low.

The volume provided by generics has made up for the relative scarcity of opportunities in the European market for contract manufacturing of branded drugs. Major pharmaceutical companies have not had to outsource much of their production, because they already have too much European capacity. Early-stage pharmaceutical and biopharmaceutical companies in Europe have presented few opportunities because they are chronically under-funded.

These demand-side problems are being compounded by the constant entry of new players into the European market. The parade of new contenders, and relative infrequency of exits, is a re-

sult of European laws and regulations that complicate the closing of manufacturing facilities. The resulting incessant growth in the number of contract manufacturers means that capacity is growing even though the market is not.

Prominent among the new entrants we saw at CPhI were several major pharmaceutical companies seeking to sell surplus capacity. **The Roche Group** has gone so far as to establish a new subsidiary to house its contract manufacturing services, which it calls **Cenexi** (www.cenexi.com). The business is headquartered outside of Paris and offers manufacturing for tablets, liquids, and sterile injectables.

Similarly, **Boehringer-Ingelheim** (Ingelheim, Germany, www.boehringer-ingelheim.com) is promoting its capabilities at its facility in Reggello, Italy. Marketed as the Instituto De Angeli, the facility has capabilities for solid dose and liquid products. Finally, **Novartis** (Basel, Switzerland, www.novartis.com) has begun offering contract manufacturing of injectable products, including lyophilization, at its facility in Stein, Switzerland.

The steady influx of new contract manufacturers in the face of declining demand is creating a supply-demand imbalance that will hurt the entire industry. The situation could last for years because of the barriers to closing down unprofitable operations.

The situation could be especially difficult for the major dedicated contract manufacturers, including **Patheon** (Toronto, Canada, www.patheon.com), **NextPharma** (London, UK, www.nextpharma.com), and **Haupt** (Berlin, Germany, www.haupt-pharma.de), whose businesses are focused solely on outsourcing. With their survival on the line, those companies are pursuing a variety of strategies to improve their competitive advantage, including restructuring operations, emphasizing development services, and gaining FDA compliance (few European dose manufacturing facilities are FDA-compliant). Some companies have turned to contract manufacturing of health and beauty aids, with some success.

Another strategic move that some Western European contract manufacturers are considering is



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the acquisition of operations in Eastern Europe. The executives of these companies realize that the compelling cost advantages of the Eastern European countries will require them to move east if they are to keep up with their client base.

Federa facility nearing completion

One European manufacturer preparing to meet the market challenge head-on is injectables manufacturer **Federa** (Brussels, Belgium, www.federa.be), which is owned by **Cardinal Health, Inc.** (Dublin, Ohio, www.cardinal.com). Federa is putting the finishing touches on a new, state-of-the-art manufacturing facility outside of Brussels, which will replace its existing Brussels facility. The new facility will be ready for validation in the second quarter of 2005 and ready to manufacture for clients in the fourth quarter.

The new Federa operation will focus exclusively on filling prefilled syringes. Prefilled syringes represent a growing, value-added market opportunity in Europe and especially in North America. The

facility incorporates barrier technology for Class 100 areas to safeguard sterility. It also uses sterile, clean, and ready-to-fill (SCF) technology in its packaging lines, which reduces processing steps and labor requirements. Also, the new facility will be FDA-compliant, so it can supply both the European and US markets.

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Federa can fill 120 million syringes annually at its new site, and has packaging capability for 60 million syringes (it will use other Cardinal Health packaging facilities for overflow capacity). It can han-

dle components from any of the three major prefilled syringe suppliers (Becton-Dickinson, Schott, and Buender Glas). Its equipment matches that of Cardinal Health's other new prefilled syringe facility in Puerto Rico. **PT**

FYI

Call for posters

Excipientfest (Gurabo, Puerto Rico, www.excipientfest.com) has issued a call for posters for Excipientfest 2005, which will be held 19–20 April 2005 in San Juan, Puerto Rico.

Posters should focus on topics related to excipient technology or drug applications and should be structured under these headings: title; author(s)/company/institution; purpose; methods; results; and conclusions. Abstracts must be 300 words or less and fit with in one 8.5 x 11-in. page.

Poster topics and abstracts should be submitted to rosa@excipientfest.com or fax 787.746.8000 by 7 March 2005.

For more information, contact tel. 787.746.5080; info@excipientfest.com, or visit www.excipientfest.com.

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