Straight to the Point, Part 1

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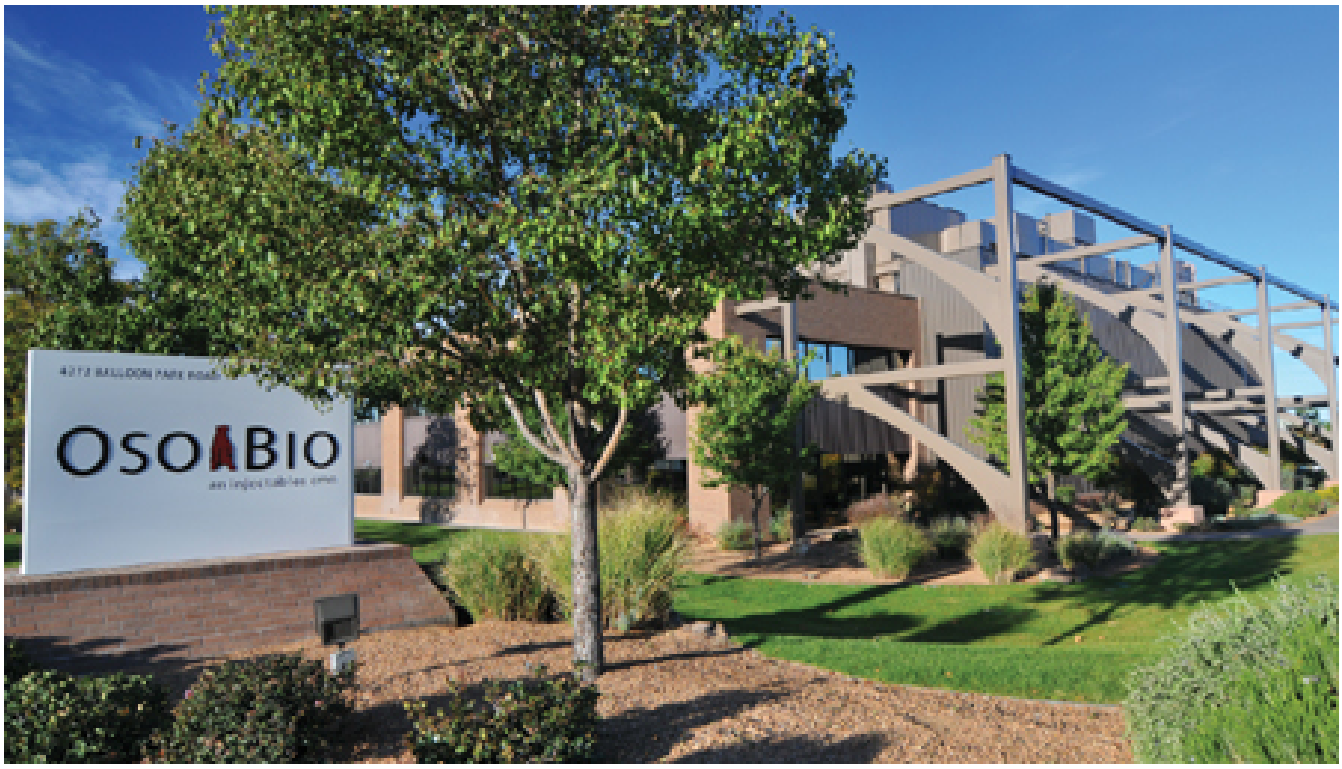

In the wide and varied world of pharmaceutical contract manufacturing there is an ongoing debate about what type of company you should look for when you need a contract manufacturing company. Some experts point to the benefits of working with a generalist-type company — a jack of all trades — that can supply a wide array of services. Others point to the benefits of working with companies that are specialists — those that concentrate their efforts and expertise to do one thing and to do that one thing better than anyone else.

When it comes to injectables — that company is OsoBio.

Indeed, as you drive up to OsoBio's main facility in Albuquerque, New Mexico its plain to see where their area of concentration and expertise lie, because right on the sign under the company's name it says it all: Osobio — an Injectables CMO.

The OsoBio Story

As with many CMO and CSO firms today, OsoBio's road to its present incarnation is a story of past companies, mergers, acquisitions, upgrades and then a concerted focus on providing the best injectables manufacturing service possible.

"We specialize in sterile manufacturing, liquid, liquid suspensions and lyophilized

formulations," says the company's President, Milton Boyer.

"The business has been here for about 30 years under different names," says Boyer, "and I think we have commercialized about 250 to 260 products and that spans about every therapeutic category."

Indeed, the company's past reads like a who's who of the pharmaceutical industry. The operation dates back to 1980 when it was built by Summa Medical. It was purchased by Erbamont in 1988 and renamed Adria SP as the primary product that was manufactured was Adriamycin — a sterile product — which started the site's sterile manufacturing legacy. In 1993 the company was acquired by Pharmacia, which became Pharmacia Upjohn in 1995. In 1997 a management buyout was done and the company was renamed SP Pharma — a clinical scale CMO. In 2001, SP Pharma became a part of Cardinal Health's PTS division — a large network of CMOs. "The key part about the Cardinal acquisition was that they made sizable investments in the site to bring it to a commercial scale facility," says Boyer.

A few years later in 2007, Cardinal PTS was spun off becoming Catalent, and the next year a group of private investors bought the site and in May 2008, OsoBio became a reality.

According to Boyer, OsoBio has retained the best parts of the previous owners, helping the company attract big pharmaceutical clients.

"We have returned the company to a nimble entrepreneurial company while still having the best IT systems and quality systems available," says Boyer." We use the investments that have been put in."

Current Capabilities and Facilities

OsoBio's campus in Albuquerque features four buildings: a manufacturing facility, an administrative building which also houses engineering and maintenance, and metrology and validation functions; a lab building which features a QC area and the company's IT group and the warehouse and packaging facility which also houses the company's Sterile University.

OsoBio's manufacturing facility features two compounding/formulation areas encompassing three Grade A aseptic filling suites with vial filling capacities from 2 cc to 100 cc. There are four lyophilizers with a total of 1230 square feet of capacity. The plant can handle all types of sterile liquids, suspensions and lyophilized formulations aseptically filled and/or terminally sterilized.

"We are set up to do commercial scale production," says Boyer, "but we can also do clinical scale. Anything from early Phase II to commercial scale products can be accommodated."

The company can also process potent and cytotoxic compounds. "Using the appropriate assessment tools, we have been able to process SafeBridge 4 and 5 products in a multi-use facility," notes Boyer.

In the packaging, inspection and warehousing facility the company boasts approximately 139,000 square feet of total warehouse space and with 7,000 square feet of 2 to 8-degree cold storage and 10,000 square feet of ambient storage. There is also DEA compliant storage available.

In the company's inspection, labeling and packaging facilities technologies available include 2 semi-automatic and 3 manual inspection stations; two labeling machines, and 3 cartoners.

When asked about the need for multiple inspections of glass vials, Boyer points out that glass quality is a big issue when you are processing injectables. "There are two primary types of vials - molded vials and tubing vials - with molded vials having a generally higher defect rate. We routinely perform a 100 percent inspection of incoming glass and have seen rejection rates as high as 40 percent. For high value products, glass quality is a key issue and pre-inspection is a crucial component of the manufacturing process."

Speaking to the valuable contributions equipment vendors make to the overall success of his company Boyer says, "It is extremely important especially in the design and set up of equipment for factory acceptance – we need their expertise for proper operation of equipment. In many cases we choose the same vendor to have continuity and familiarity with equipment."

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