

## Making Devices for Others

By VITA REED

Computer companies do it all the time: outsource production of their hardware to contract manufacturers that can do it faster, better and cheaper.

Now outsourcing is gaining ground in the medical device industry, and a handful of players in Orange County—a nerve center for the invention and development of biomedical products—are getting in on the action.

"There used to be a trend toward outsourcing in the medical products industry," said William Goolsbee, chief executive of Santa Ana-based Horizon Medical Inc., a contract device manufacturer.

"It's no longer a trend. It's a reality."

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Workers at Santa Ana's Horizon Medical: 210 employees and growing

NOTE: Life Science Outsourcing, Inc. was formerly Medical Device manufacturing & Ventures, Inc.

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In the past year, Horizon has hired 60 new workers for a total of 210 employees and expects to expand to around 300 in coming months. Earlier this year, the company consolidated operations into a new 60,000-square-foot facility.

Medical device outsourcing isn't new—Horizon itself has been around for 13 years. And the segment hasn't grown as fast as the contract electronics manufacturing industry, in part because of the heavy regulation medical device makers face.

But big names such as Johnson & Johnson, Medtronic Inc. and Abbott Laboratories are turning to outsourcing for the same reason computer makers do: the cost savings.

"This is a highly regulated industry. The technology is more complex. The cost is ever-increasing," said Barry Kazemi, chief executive of Medical Device Manufacturing and Ventures Inc., a 30-employee contract producer in Brea.

Outsourcing device production is based on the premise that individuals and companies that invent medical devices may not have the time, financial resources or expertise to make them. For bigger companies, outsourcing of existing products frees up resources for new product development and production.

Outside influences are also leading small device makers toward outsourcing, according to Kazemi: "The venture capital companies are pushing the medical device makers to go out and find a contract manufacturer."

But defining a medical device outsourcing company can be tricky. Companies such as Horizon and Medical Device Manufacturing do everything from designing prototypes up to full-scale production, while scores of others have carved niches somewhere in between.

Among the larger U.S. contract device manufacturers are Avail Medical Products of Fort Worth, Texas, MedTech Group Inc. of South Plainfield, N.J., and Zevex International Inc. of Salt Lake City, which does work for Irvine-based Allergan Inc.

Smaller contract producers include TriVirix International Inc. of Chapel Hill, N.C., Ethox Corp. of Buffalo, N.Y., and Michigan Instruments Inc. of Grand Rapids, Mich. Some contract electronics manufacturers, including Santa Ana-based Express Manufacturing Inc., also do some medical device work.

Then there are the engineering, design and consulting companies that do contract work for medical device makers, including Aubrey Group Inc. of Irvine. Patton Design Inc., also of Irvine, has done product designs for Allergan, Tustin-based Toshiba America Medical Systems Inc. and Aliso Viejo-based Medstone International Inc. Others players include SeaMED Corp., a Redmond, Wash.-based unit of Plexus Corp., and Fallbrook Engineering Inc. of Valley Center, Calif.

Vytas Pazemenas, Aubrey's president, said his company concentrates on cardiology devices, such as blood pump controllers and patient monitors. About 75% of the company's clients are startup companies, he said.

All sizes of device makers outsource, said

Russ Joseph, an industry executive who oversaw work with contract manufacturers while at Sorin Biomedical Inc. in Irvine before it closed late last year. Smaller operations contract out because they don't want to tie up their money in manufacturing, while big companies outsource because they may have many projects going at once, he said.

With single-use medical devices, Horizon's Goolsbee said his own customers often are his biggest rivals. While declining to name Horizon's clients, he said half of the company's business comes from top industry names, with a third from mid-size companies and another third from startups.

"Our real focus is on the top 120 medical products companies in the U.S.," Goolsbee said.

Among the devices and products developed and made by Horizon are bone screws, custom intravenous infusion sets, thin-film dressings, electrosurgery grounding pads and leads, and in-vitro diagnostic products.

Goolsbee estimated his company could do \$30 million to \$40 million in sales this year. He puts the total market for final finished outsourced products at around \$300 million annually.

"This can be a far bigger business," Goolsbee said.

Biomedical outsourcing is growing in part because the contract industry is becoming more sophisticated and focused, executives said. And customers' expectations are higher.

"We specialize only in manufacturing—not R&D, sales or distribution," said Kazemi of Medical Device Manufacturing & Ventures. "We can deliver on time and within a budget."



Medical Device Manufacturing's VP Jim Reimers, CEO Barry Kazemi, production workers in Brea



Kazemi's 3-year-old company makes catheters, implantable devices and electromedical and fiber-optic instruments. The company also sterilizes and packages

products and does assembly work such as ultrasonic cleaning and welding.

Medical Device Manufacturing & Ventures has around 75 clients, Kazemi said.

"We really like the startups," he said. "They appreciate the work that we do."

In Garden Grove, BBI Source Scientific, a unit of West Bridgewater, Mass.-based Boston Biomedica Inc., specializes in contract diagnostic testing and product development. BBI Source Scientific has about 100 employees in OC, according to sales and marketing director Randy Johnson.

The need to get products to market quickly is fueling contract manufacturing's acceptance, Johnson said. "Because you have rapid market change, you have to move quickly," he said. "Twenty years ago, when I was with Abbott, we did everything ourselves."

Some manufacturers include a bit of medical device-related work in their overall portfolio, such as Viking Rubber Products Inc. Viking, which specializes in precision, custom-molded parts, makes seals, diaphragms and check valves for medical devices, said company President Dave Wykoff.

Wykoff attributes growth of medical device contract manufacturing to "so many ideas," he said. "Southern California is a hotbed of startups."

Viking employs about 70 people in Brea and another 20 in Mexico. Its medical-related work is all done locally. Wykoff said Viking began courting medical device makers for outsourcing work several years ago.

Around \$2.5 million of Viking's \$6 million in projected sales this year will come from medical products, Wykoff said. He noted that the company is continuing its push into devices. ■