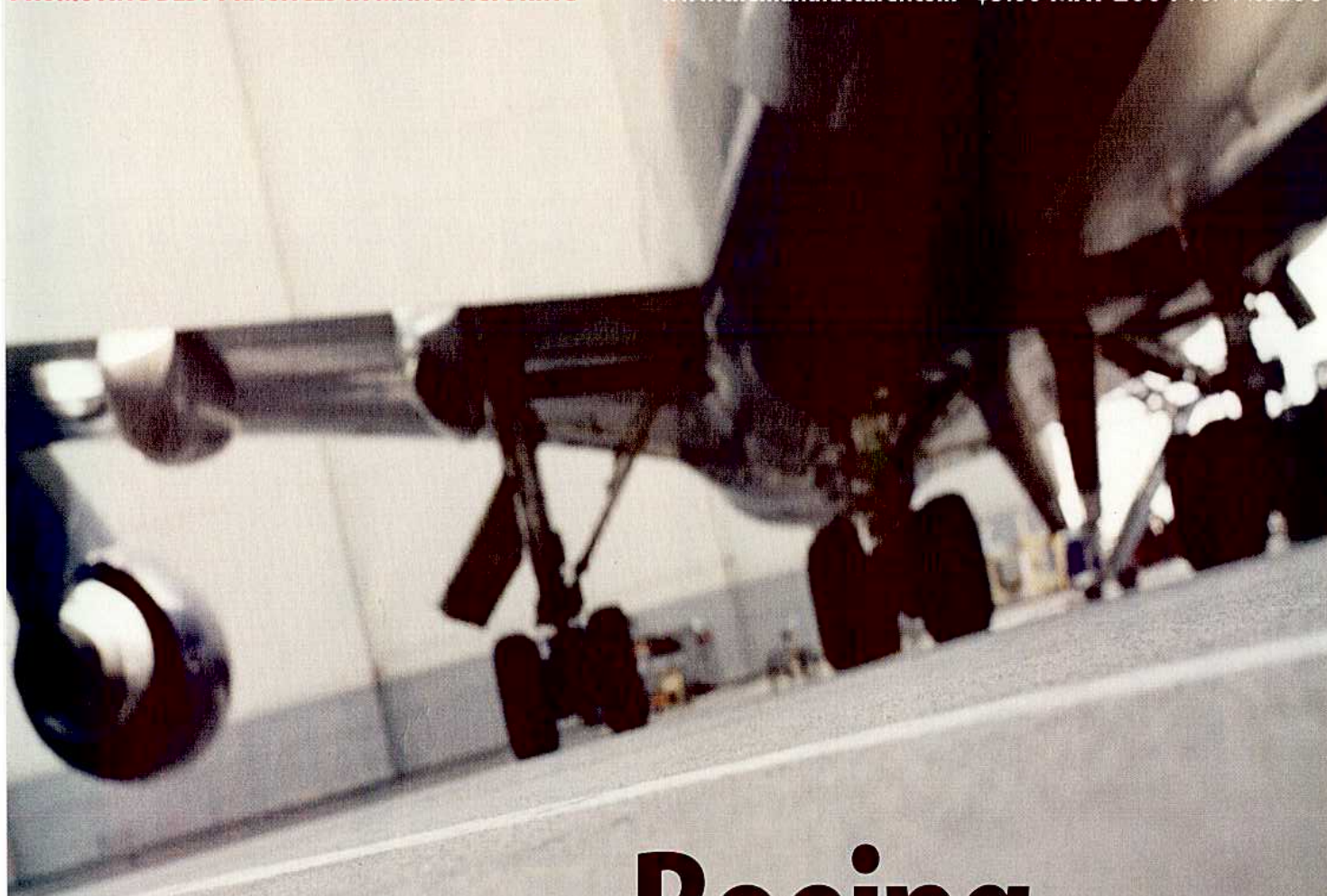


# THE MANUFACTURER

PROMOTING BEST PRACTICES IN MANUFACTURING

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## Boeing *takes off*

### Interview

The Hayes Company's Glen Waisner on IT essentials

### Back to school

Top university programs for executive education

What the 7E7 deal means for manufacturing

**PLUS: SHOP FLOOR ENTERPRISE MANAGEMENT, TOP FORKLIFT TRUCKS**

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# Manufacturing in action

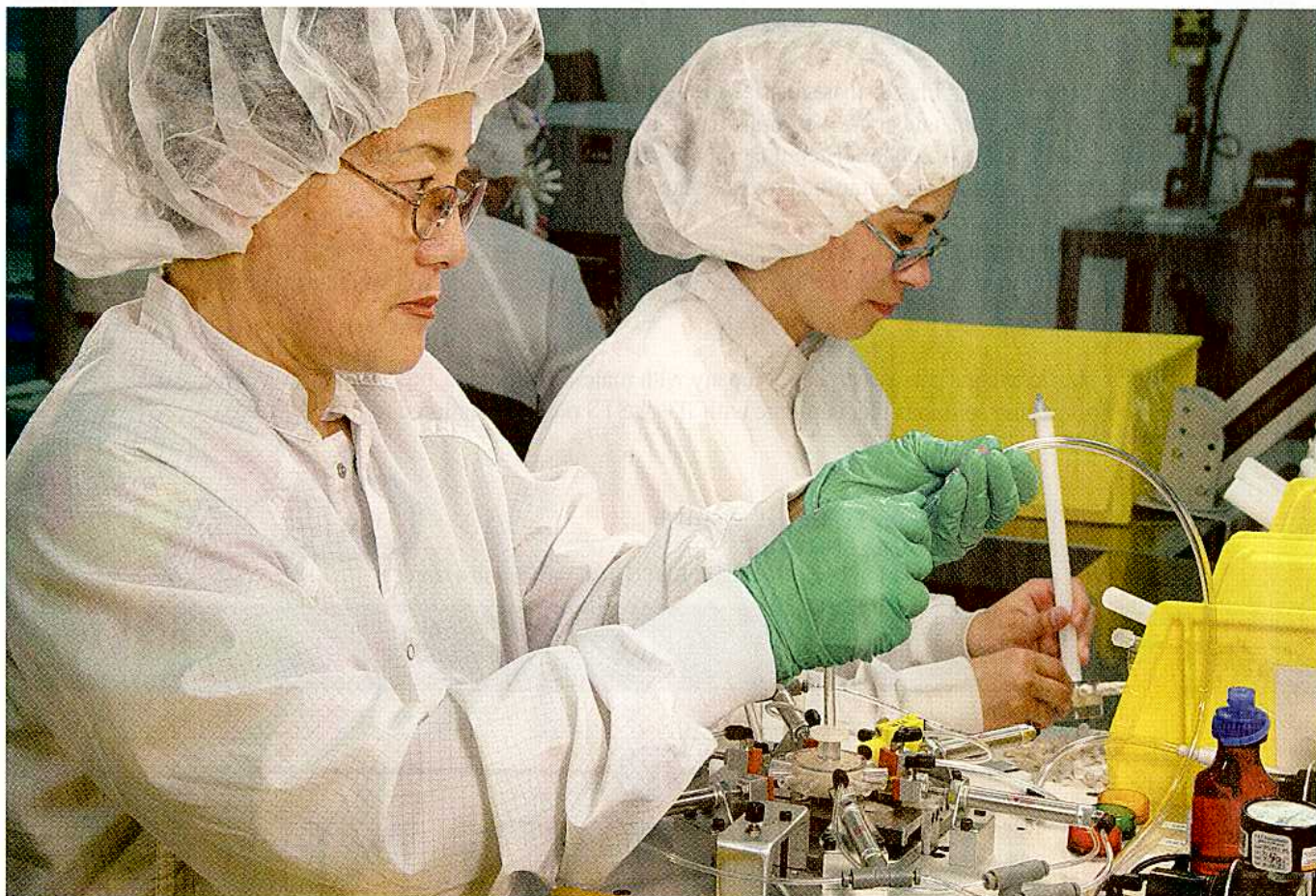
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keeps the firepower coming	

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# Founded on safety

*Baxa Corporation has been making hospitals safer and more effective for almost 30 years.*

*John O'Hanlon gets the story from Steve van Engen, vice president of operations*

**Above**  
Segregated manufacturing lines in the cleanroom feature one-piece flow

**B**axa was founded in 1975 by Brian Baldwin and Ronald Baxa. At the time, oral liquid medications were dosed with teaspoons or graduated cups. Worse still, oral doses were sometimes drawn up into syringes, raising the possibility of their being accidentally injected. The Exacta-Med Oral Dispenser, with a special tip that does not accept a needle, was designed to provide a highly accurate, completely safe method for dosing oral liquid drugs. It quickly became the industry standard, and remains a key part of the

Baxa product line today. Since its foundation, the company has stuck to liquid medication systems for hospitals, a specialized but vital niche in which it has consistently innovated.

About a year ago, Baxa moved its manufacturing facility and world headquarters (it has a subsidiary in the UK, Baxa Ltd., and a sales office in Denmark as well as a distribution partner in Canada) to a new purpose-built facility at Englewood, CO, near the site it has occupied since 1989. With 106,000 square feet, twice as much as it

### Avail Medical Products

Avail is the world's largest and most trusted outsource developer and manufacturer of finished, disposable medical devices—offering full product life cycle management from design to sterile goods. Serving the top 11 global medical products manufacturers, Avail develops and manufactures more products than any other outsourcing company in the medical industry. More than 3,200 people are employed in 13 facilities throughout the United States, Mexico and Europe. Our facilities include class 10,000 and 100,000 cleanrooms, as well as controlled manufacturing environments.

### Fusion Microsystems

Fusion Microsystems is an Information Technology (IT) solutions provider, an Intel Premier Partner and Microsoft Gold OEM System Builder, just one of 149 globally. Our success lies in our ability to custom design IT solutions tailored to our client's requirements. Quick turnaround capabilities, just in time inventory and superior quality are top priorities, and make Fusion Microsystems our clients Premier Vendor.

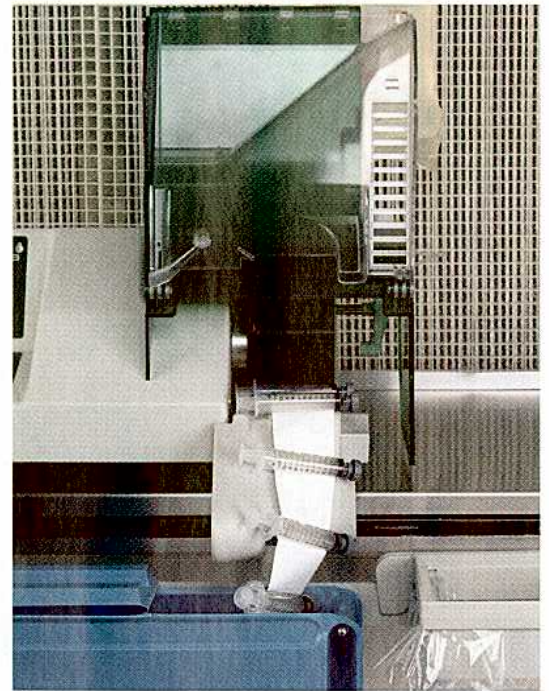
had in the old plant, it now has plenty of elbowroom for the planned expansion of its operations, aiming to bring annual sales up to \$100 million by 2007.

In a move project-managed by VP of Operations Steve van Engen and CFO David Runck, all operations were transferred in just a couple of weeks followed by a period of FDA process validation and an FDA audit. The new factory contains a class 100,000 cleanroom and utilizes specially designed cross-dock flow methodology. At its last annual FDA inspection in August 2003, the second it passed with zero non-conformances, the inspector told CEO Greg Baldwin that in many years she'd never seen a better quality system.

That this move was properly planned and financed, and taken at the right strategic time, is the culmination of a dramatic period of change for Baxa. In 1999, when van Engen joined the company as director of continuous improvement, his job was to facilitate and drive the lean transformation. It looked very different then: "In 1999, Baxa Corporation was around \$28 million in sales. Inventory was a nightmare. There was at least \$5.5 million tied up in inventory to support those sales. The building we were in then was very cramped because of all the finished goods, raw materials, and work in progress. It was almost impossible to maintain any kind of control, and the company was really worried about being able to go on operating there."

As is often the case, he points out, the transformation was born out of the seeds of crisis. It was a three-part crisis. The FDA was unhappy with quality standards, manufacturing lead-time was suffering because of the flow problems and high stock levels. To cap it all, though basically sound financially, the organization was carrying a burden of debt that ruled out moving to a larger premises, even had the reasons for moving been sound. Those three factors thrown together created a real need for change, says van Engen, who gives all credit to the Baldwin family for putting together a leadership team that was fully committed, understood the needs, and fully supported the change that needed to happen.

Radical changes had to be made right out of the gate, van Engen says, "The initial six months to a year were rather tumultuous, you could say. We really drove change and the lean conversion at a breakneck speed." As a result, during that year



nearly two million dollars in cash from inventory reductions were freed up to alleviate debt.

Manufacturing processes were aggressively targeted, he continues. In the course of two or three very focused, major events, the plant was virtually shut down and the entire flow redesigned. The challenge, as van Engen puts it, was to shift from a batch operation, where a particular manufacturing work order may have been open up to six weeks, to daily demand manufacturing. Probably the single biggest obstacle to this was the process of sterilization, which is outsourced. Much of Baxa Corporation's output is in the form of sterile consumable products that are utilized with the hardware, and it was taking upward of 40 days to send these out and get them back from the sterilizers.

"We had to attack those lead times aggressively," says van Engen. "We have been able to develop a strong partnership with these companies—though in some cases we had to develop new partnerships! We use three different types of sterilization—the gamma method, ethylene oxide, and e-beam. The last two are done locally, but we don't have a gamma sterilizing facility closer than Utah. It's an expensive business to get into, there are environmental constraints and it's not our core competency, so it's not really a process we could bring in-house. Today turnaround time is ten

### Above

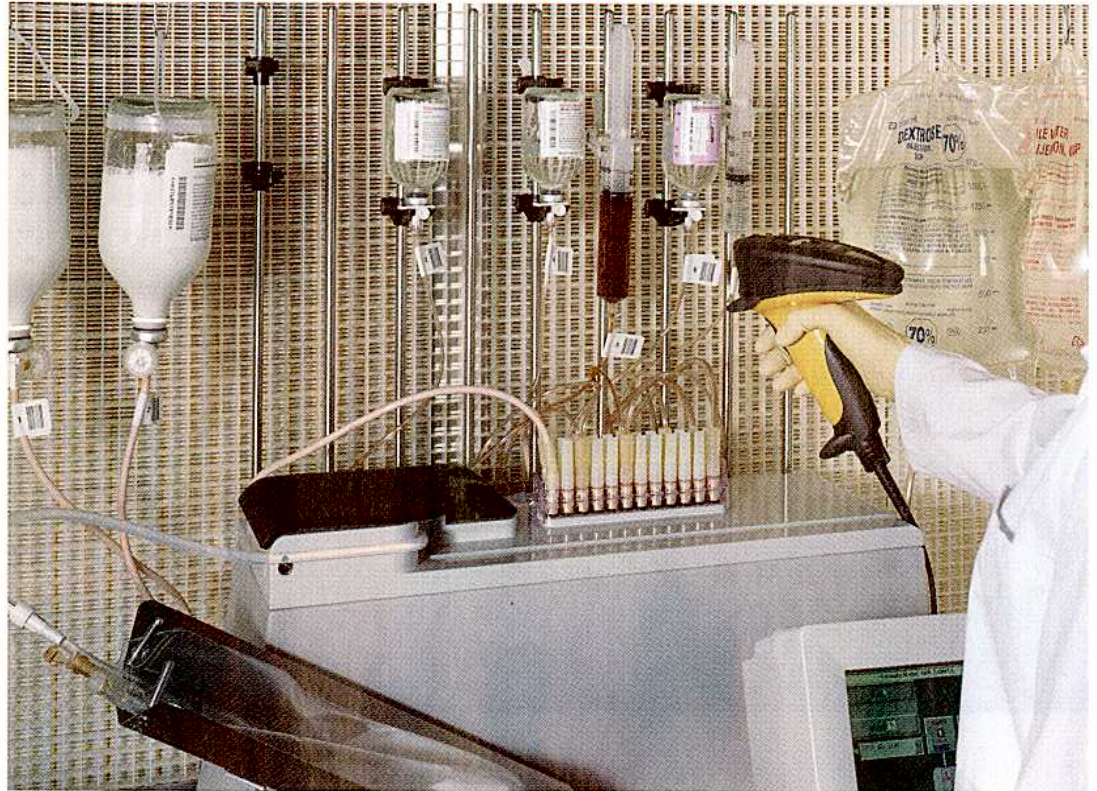
The Rapid-Fill Automated Syringe Filler uses sterile syringe strips to automate the processes of sterile syringe filling, capping, and labeling

**RJD MACHINING**

Manufacturing high quality components is like directing a symphony. Many things must happen with precise timing and skill to reach the desired outcome. Our musicians keep our clients consistently thrilled by hitting all the high notes!

**Sunlite Plastics**

Sunlite Plastics is a manufacturer of custom thermoplastic extrusions. We offer a wide range of tubing. Our capabilities include: single lumen, multi-lumen, paratubing, thermal-bonding, rods, funnel tubing, neckdown tubing, stripes and custom compounding. Sunlite offers medical tubing with Class VI approved materials. Sunlite and Baxa have been partners since 1988. In 1999, when Baxa began their lean transformation, we were one of the first suppliers Baxa began working with. We have monitored their inventory level for years with access to their ERP System and ship tubing to them from inventory held at our facility. Sunlite's partnership with Baxa continues to evolve.



days maximum, even for the product that has to be gamma sterilized at the Steris Corporation plant at Sandy, UT. And those ten days now include our own manufacturing time.”

The other major change in year one was the elimination of the sub-assembly stage of manufacture, which was the rule up till then, he recalls. “Today we don’t do that. When we start a device, we build it all the way from raw materials through completion, so we flatten the bill of material and put everything into a single flow.”

To achieve this, van Engen developed an electronic Kanban system tied to customer orders. “I call it a min/max system,” he says. “We turned off our MRP system but we used the MRP engine to help us calculate an average daily demand. Then we use a formula external to the ERP system on all of our finished goods and all of our raw materials that takes that average daily demand and crunches it down into a maximum inventory level. So our re-order point is the maximum inventory level minus one day’s average daily demand. As long as customers are ordering, that provides the pull to the manufacturing group. It works exceptionally well. Changeovers are not a big problem for us. We don’t have a lot of heavy

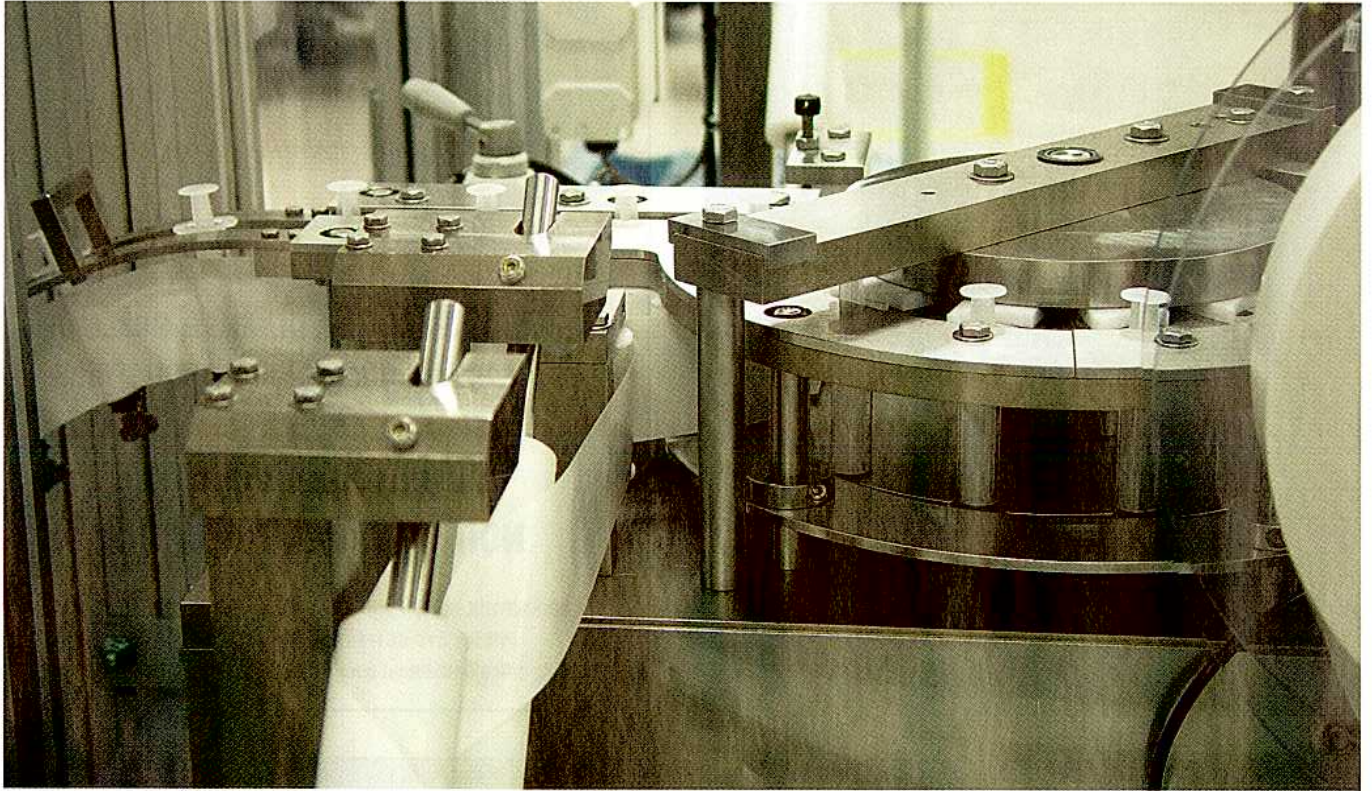
capital equipment, and to tell the truth, the hardest part of a changeover, given the FDA regulated environment, is the paperwork they require. We have to be very efficient and quick with that to keep the product flowing.”

By the end of 2003, worldwide sales had doubled from \$28 million to close to \$60 million—supported by a smaller inventory level than the company carried in 1999. Current inventory is valued at somewhere around \$5 million, but a product distributed exclusively in the US under an agreement signed in the middle of last year accounts for \$1 million of that. This closed system, called PhaSeal and manufactured in Sweden by Carmel Pharma, handles hazardous drugs in such a way that it reduces or eliminates human exposure to toxic hazards in the workplace.

Another highlight has been the improvement in on-time delivery, which was running at about 40 to 45 percent. The goal the team set themselves was to reach 98 percent, and if it’s not yet been reached, there’s not far to go now. By 2001, the figure had leapt to 80 percent. In 2002 it reached 92 percent and in 2003, 95 percent on-time delivery had been achieved. “We focused on cleaning up the trouble in our

**Above**

Baxa sterile inlets, tube sets and valves support the automation of multi-ingredient solution compounding



kitchen," says van Engen. "The results we have achieved speak for themselves."

By 2003, the focus had switched to the supply chain in a more general way, with the development of a strategic supplier management initiative. The idea is to work with the suppliers to remove waste right through the value chain. This is quite a different operation from the specific program aimed at sorting out the problem of sterilization lead times, which was really a production issue. Baxa has 250 suppliers, categorized in four tiers. In tier 1 are "Baxa preferred suppliers," an ideal met initially by only three to five companies. These were identified by their spirit of partnership, their commitment to continuous improvement, their open-book accounting environment, and a willingness to work for mutually beneficial goals. "We don't want to beat them up on pricing—if they are working to improve their own results, we will end up benefiting as their customer," says van Engen. "We want them to be more profitable!"

In tier 2, "Baxa provisional suppliers," are companies where Baxa sees the greatest opportunity for advancement. The goal is to move them up into tier 1, and perhaps six suppliers each year can be expected to make the grade.

Though Baxa is keen to support as much additional work as possible from these suppliers, if they don't deliver on the program, the business may be moved to suppliers in the tier 1 group. Tier 3 contains commodity suppliers and tier 4 non-critical or service suppliers.

Baxa is currently setting up a supplier management council that will meet yearly to evaluate the current situation, set goals, assign resources, and generally work with the suppliers to help them move up the ratings. Both parties will agree on a transition plan, and Baxa may put some of its engineering or management staff at the supplier's disposal on what amounts to a joint project basis.

The five-year plan for Baxa calls for growth in each of its three business lines: oral liquid drug delivery systems, intravenous admixture and administration, and multi-ingredient solution compounding. "Size-wise, we think that will mean we will probably be twice as big of a company in that time frame. We don't expect to have twice as many people, because we are focused internally on doing more with less and becoming a very efficient provider of products that make life in the critical care pharmacy safer and more efficient." ■

**Above**

The cleanroom includes automated manufacturing equipment for high-volume products, such as the Rapid-Fill Syringe strip assembly