

Optimal Outsourcing for Medical OEMs

The question for device makers is not whether to outsource—it's what to contract out, where to do it, and how to begin. *Stacey L. Bell*

Ten years ago, medical device companies wondered if they should consider outsourcing particular projects and processes at all. Today, outsourcing is more a question of which projects will be produced out of house, and when.

"Almost everybody outsources something today—whether it's product development, manufacturing, payroll, or human resources," says Mary Poniktera, business manager of consulting firm Fallbrook Engineering (Valley Center, CA). "A decade ago, people talked about outsourcing. Now it's a given."

Data from Frost & Sullivan support that assertion. From 1999 to 2000, medical technology companies increased their number of outsourced projects by more than 18%. Further, Frost & Sullivan predicts that outsourcing of value-added products by medical device companies in the United States will grow at "17% per year through 2005... [and by 2005,] 42% of the cost of goods sold for value-added products will be outsourced."

Growth in this sector also is evidenced in the expansion and increased number of contract manufacturers. Jack Kincke, principal consultant of NewOps International Consulting (Weston, FL), says contract manufacturers' businesses are growing by 10–20% annually.

While outsourcing has proven a valuable option for many medical device makers, some have endured missed deadlines, poor-quality products, and other travails. Industry experts say companies can avoid common mistakes by mapping out a detailed approach to outsourcing in advance.

First Things First

"Ideally, companies should make outsourcing part of their overall business strategy," says Larry Strauss, a principal in the life sciences practice of global management consulting firm PRTM (Waltham, MA). "Every two to three years, a dedicated, knowledgeable task force, representative of all parts of the company, should look at the company's entire product line to see what can be outsourced."

Older, established products with well-defined manufacturing processes and low margins are strong candidates for outsourcing. On the other hand, newer products that are still strongly tied to R&D and marketing might not be good prospects. They often represent newer proprietary information and undergo continual refinements—although some companies do outsource product development with excellent results.

"Companies that don't go through this process of analysis are probably leaving money on the table and missing opportunities," Strauss says.

Certainly, product life cycle is a significant driver of outsourcing, but a number of other compelling reasons to outsource a project exist as well.

Gaining a Competitive Advantage. If competitors are consistently beating a medical technology company to market with new products or updates, the extra help and resources an outside firm offers can help level the playing field. From providing extra brainpower and expertise in specific technologies to simply offering additional manufacturing capacity, an outsourcing partner can improve an OEM's competitive position and help it meet critical project milestones.



Figure 1. OEMs are using contract manufacturers for strategic and cost reasons. While cost reduction is a driver for many companies, it tends to be as part of a manufacturing strategy, not the sole component of that strategy. (click to enlarge)

"Firms need to look seriously at their competitive strengths and weaknesses," advises Don Caudy, vice president of operations for the contract research organization Battelle (Columbus, OH). "Those weaker areas are candidates for outsourcing."

In addition, an OEM may wish to hire a consulting company to perform developmental work so that the OEM's name won't be associated with the project—and competitors won't notice, says Richard Meyst, vice president of Fallbrook Engineering.

Improving Economics. OEMs often turn to outsourcing to streamline overextended budgets. Contract manufacturing saves the cost and hassle of hiring a large number of new employees who may not be needed after a particular project is complete. It also offers the advantage of shared overhead at the contract manufacturer's plant. "Right now, cash hoarding is hot," Meyst reports. "Projects often progress in fits and starts, and there may be times when there's little for people to do, particularly during clinical trials. For economic reasons, it makes sense to hire technical experts on an as-needed basis instead of hiring additional staff or overwhelming current staff."

A contract manufacturer's high-volume, automated processes can prove profitable for medical device companies. One diabetes glucose-monitor maker recently saved 40% in production costs when it turned over the manufacturing of its product to a contractor who slightly redesigned the product for better performance and streamlined production.

Neoprobe Corp. (Dublin, OH), which develops surgical and diagnostic products, has been outsourcing product development for years, primarily when the company needs help meeting a looming deadline. "We have a staff of about 30, and when we need 10 to 15 additional people working for 18 months—rather than staffing up, then staffing down—we outsource," says Carl Bosch, vice president of R&D. It costs about twice as much per employee-hour to outsource, he says, but if a company can't keep a staff loaded three-fourths of the time, it pays to outsource.

Focusing on the Company's Raison d'Être. Kincke points out that the medical device and diagnostics industry has been "squeezed for profits" for 15 years. "Companies are constantly searching for ways to cut costs and grow business. Outsourcing is one method firms can use to accomplish these goals," he says. Outsourcing low-margin and older products allows companies to concentrate their efforts on core competencies and higher-margin products and innovations. Rather than juggling all the components of 10 different product lines, managers can devote their time and energy to one or two potential blockbusters.

"One company I worked with outsourced different product components," Strauss recalls. "Only 10% of the product was a core component, so the company outsourced the rest of the product. It maintained its intellectual property while getting the benefits of contract manufacturing." He recommends that core competencies critical to a company's continued success and profit margins be kept in-house.

Expanding Capacity without Making a Capital Investment. A diagnostics company that is manufacturing its own PC boards not only has to be cost competitive, it also must keep investing in new capital equipment, like surface-mount technology, to stay competitive, says Don Fuller, a principal consultant for NewOps International Consulting. By outsourcing that project, the company could avoid huge capital expenditures and the pressure of continually upgrading equipment. Further, outsourcing allows access to key technologies and equipment that may not be available in-house.

In early 2000, Endonetics, a San Diego-based start-up company acquired by Medtronic in late 2001, hired a consulting firm to help it meet milestones that its venture capital backers had set. "We were very small at the time—about 10 to 12 people—and we needed to focus on our core strategy. But we needed help and expertise to develop a lot of the design and to start manufacturing several parts for our Bravo pH monitoring system," recalls Michael MacCollum, who served as senior project engineer at Endonetics and is now a consultant with Pro-PE Mechanical Design Services (Poway, CA). "In addition to allowing us to meet our very aggressive timelines, the consultants gave us access to a wide variety of experts whom we couldn't have

afforded as individual hires. We could call on experts in conceptual design, prototyping, injection molding, packaging, and sterilization as we needed them."

Reducing Risk. Some products present safety or regulatory hazards—perhaps they use a volatile material or trigger special attention by OSHA or FDA. Products important for a company's portfolio but difficult to produce may best be handled by a company with expertise in such matters, Fuller says.

Drawing on Diversity. Some companies suffer from tunnel thinking. Bringing in consultants with fresh, different outlooks and new approaches can rejuvenate a project and the staff's enthusiasm, Meyst adds.

Once a company has decided which projects make the most sense to outsource, it should next clearly define its goals. What does it hope to achieve by outsourcing a project, and how will that success be measured?

"A clear definition is critical," Meyst says. "The company must know exactly what it wants to do, have a vision of the outcome, then find the right partner, communicate well with that partner, and achieve buy-in to have a successful outsourcing relationship."

Finding the Right Partner

Since most outsourcing relationships last at least two years and have a profound effect on a company's bottom line and product quality, great care must be taken to find an appropriate partner.



Strauss recommends using the so-called funnel approach. "I'd start with 10 to 15 companies and then winnow that down to four or six companies to [consider seriously]," Strauss says.

Figure 2. Strong commitment to a partnership is more important than explicit oversight and control.
(click to enlarge)

How does an outsourcing company make the cut to the final round? Ideally, by displaying the following qualities: expertise and experience in the medical device or diagnostics industry (especially in the segment of interest to the OEM), appropriate manufacturing capabilities and capacity (including growing room in case the OEM decides to add extra volumes or processes in the future), and flexibility. Other desirable characteristics include strong supply-chain capabilities and experience, excellent quality systems and certifications (i.e., no major warning letters from FDA or other agencies should be on record), acceptable information management capabilities, and solid financial statistics. (Dun & Bradstreet is a good source.) Finally, an outsourcing candidate must have integrity and a positive reputation, and it should maintain a culture compatible with that of the OEM.

Location can be a consideration as well. While some companies choose a contractor outside of the United States to take advantage of steeper cost savings or greater proximity to suppliers or a consumer end-market, others may want a more accessible site.

"It's nice if you can get to their site easily, especially at the beginning of the relationship," Strauss notes. "Can you get there in a few hours in case there's a problem? A location in Mexico might be better than one in the Far East, for that reason."

Once a company has narrowed its list to three or four finalists, a team from the OEM should visit each of the finalists' facilities to see exactly how products are manufactured and managed, and to meet with each facility's management team.

The OEM should also call at least three references. "References provided by the company offer a biased sample, so it's a good practice to ask those customers if they know of other companies that also use the contractor," Strauss says. The key is to talk with the references openly and honestly, he adds. "Ask if things are all rosy, or if there is room for improvement in some areas.

Also, listen to as many voices at that company as possible. Talk to senior personnel in manufacturing and quality, and within the supply chain."

Fallbrook Engineering's Poniktera recommends asking references the following questions:

- Did you stay within budget?
- Did you meet your milestones?
- When did you learn about problems? How were they resolved?
- Were resources added or removed quickly? How?
- Did the firm appear to be more proactive or reactive?
- How did the firm communicate project status?

Building a Firm Foundation

After choosing an outsourcing partner, the real work begins. The same team that was assembled at the beginning of the outsourcing project must build and maintain a successful relationship between the companies.

According to Strauss, having a dedicated, knowledgeable, and experienced team conducting the planning and managing the actual transition is critical to accomplishing the transition on time and on budget, with no [negative] effects on customers.

"The difference between successful and unsuccessful outsourcing often relates to the design of a manufacturing organization," Fuller adds. There's a tendency to outsource a product and thereby eliminate all the manufacturing tasks, but the OEM must still provide project oversight and ensure contract compliance, he says. "A few individuals should be specifically assigned to conduct this oversight, to make sure the outsourcing partnership works."

Although the contract, joint-services agreement, and quality agreement help set the parameters of the relationship, it's essential that OEM team members visit the contractor's premises in person. They should also communicate by phone, fax, or e-mail often—which will likely be daily at the start of the project.

A key challenge in any outsourcing relationship can be maintaining product quality. "Managing quality can be difficult because the contractor may have an excellent quality system, but because that system manages quality for 10 companies, it won't match your quality system exactly," Strauss says. "If the contract manufacturer makes a mistake, FDA will come after the OEM. Outsourcing doesn't abdicate responsibility [on the OEM's part]." An OEM must communicate what constitutes quality from Day 1, and develop systems to work closely with its contract manufacturers on quality issues.

Communication and trust are perhaps the most important factors affecting the success of the partnership. "To get the partnership off to a good start, make sure there is a clear, mutual understanding of the scope and requirements of the project," says Neoprobe's Bosch. The more time you spend defining the requirements, the far better off you'll be in the relationship over time, he adds. "Also make sure you can trust your partner to be disciplined. If you give them a specification, you want them to read it, understand it, and work through it—not set it aside and do it their way."

"We find one common thread among the outsourcing relationships that work," says NewOps' Don Fuller. "It is adjusting the organization to reflect a shift from 'manufacturer' to 'supplier partner overseer.' This means that you do not eliminate the entire manufacturing organization. You certainly eliminate direct manufacturing jobs and many supervisory jobs. But success comes from carefully designing a new organization skilled in quality oversight and assistance, product development assistance, and more." Clearly, with outsourcing there is a degree of loss of control. But with proper organization and contracting, and a realistic approach with the right partner, you can maintain sufficient control and gain greater success, Fuller adds. Trust in the relationship can free up valuable time for the OEM. Endonetics' MacCollum spoke with his outsourcing partner's project manager by phone daily at peak times during one particular project. "If I had a specific

problem, but I needed to focus on something else, I could present [the project manager] with the problem and let him solve it."

Conclusion

Outsourcing is a job that is truly never complete. But because the advantages are numerous, it is likely manufacturers will continue to make the effort. Certain trends also are solidifying the continued growth of outsourcing. Contract manufacturers are offering more development and process engineering capabilities, which should fuel growth. Also contributing to the expansion are rapid deployments of new technologies, increases in margin pressures and competition, and shorter product life cycles.

By investing some extra time and effort in clearly focusing their outsourcing projects, manufacturers should reap great rewards.

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How Contract Manufacturing is Reshaping the Device Industry

By some estimates, the global market for outsourced medical devices is now \$8 billion. Industry executives say that the trends favoring outsourcing are likely not only to continue, but to grow stronger in coming years.

Outsourcing of manufacturing operations has clearly become a widely accepted practice among medical device companies. Potential benefits are many—speed to market, significant savings in capital outlays, quality improvement, and reduced costs to name a few. And outsourcing strategies are being applied to a broader range of operations. Comprehensive programs now involve outsourcing product design and development, packaging, distribution, and service and repair, among others.

MD&DI asked five industry professionals with experience in contract manufacturing to share their views on current trends in outsourcing, key factors that are shaping its course, and potential pitfalls to be avoided.

Participants in this industry roundtable included: Robert F. Doman, President, Leach Technology Group and Vice President, Leach Holding Corp.; Ron Earle, Group Senior Vice President, Burron OEM division of B. Braun Medical Inc.; J. Randall Keene, President, Avail; Joseph P. Lester, General manager and COO of Criticare Systems Inc.; and Joyce Vytlačil, Operations Manager, Command Medical Products Inc.

Readers should note that the five participants in this forum are not meant to be representative of the outsourcing industry as a whole. For practical reasons of space, many leading outsourcing companies could not be included. Just as participation in this article does not constitute an endorsement, so absence from this article is not a gauge of a company's standing in the industry.

***MD&DI:* What is the current state of contract manufacturing in the device industry? And where is it headed?**

Keene: Contract manufacturing has become medical outsourcing, and a market consolidation is under way. There are a handful of major players emerging from what was once a regional, fragmented industry that was focused on individual specialties. The leaders in medical outsourcing today have multiple capabilities, offer engineering support and manufacturing scale, and in essence can act as an extension of the OEM's own operations group.

Development services are also becoming standard components of medical outsourcing. It has become essential to integrate engineering support into every project we manage—from a simple

product transfer to a new product design or process improvement program. The outsource provider of the future must have a strong contract engineering organization to effectively support its customer base.

Earle: There is a strong trend to go to outsourcing. People use the established environment of larger, established firms to market their products. They say, "you've got the distribution." And the distribution folks don't want to get into more manufacturing because products and technology are changing so fast that, by the time they get a product up and approved, the trend has changed—and they're stuck with a factory.

We're finding out that there are many pharmaceutical companies that need devices to help deliver their drugs, which increases the market potential of their product. Now the outsourcing need is even more important because we're crossing into a different market—even though it's within the healthcare industry. Devices and pharmaceuticals have always been kept separate. But we're seeing a tremendous increase in inquiries from companies that want us to help them outsource components that can make their products more useful. How can a product be more useful? It not only can offer improved safety, but nontechnical people can be able to self-administer it.

Vytlacil: Customers now frequently rely on contract manufacturers for value-added services, which include product design, package design, materials selection, and sterilization validation management.

Doman: OEMs view outsourcing as a vital competitive competency necessary to improve product quality, time to market, lower production costs, and reduce capital expenditures.

Industry surveys for the electronic manufacturing services market show growth rates in the 20-25% range. The medical device industry is experiencing the same type of robust growth as more medical device companies show an increased propensity to outsource engineering and manufacturing services. This is driven by the pace of technological advancements in the medical device market and the need to reduce costs or redirect costs in order to invest in their core competencies.

If you look across industries, you can see trends, particularly in outsourcing, that started first in other industries and eventually impacted the medical device market.

Lester: Everyone I'm talking with is outsourcing within the United States, but more and more are going to foreign entities—mainly to Asia. I think the trend used to be to go to Mexico, but that's changing a bit so that now it's more profitable for the companies to go to Asia. So everyone I talk with is either gone or working on going, or they are contemplating outsourcing. When they talk about that, it's not a sales initiative, but a manufacturing initiative. I believe—particularly in the commodity-type products—that if you don't move to that type of manufacturing strategy, you're going to be left behind.

MDDI: How would you characterize the companies that are benefiting from contract manufacturing?

Earle: It's across the board. Focusing on the pharmaceutical business for a moment, they do very little of their own packaging anymore. This is because one drugstore may want to carry the product on cards, but another drugstore chain may want it packaged in plastic bottles. You never know. So they say, "we're not going to invest in any more packaging. We'll make the pill, and then we'll send it to an outside packager to put it on cards, foils, or whatever." Even the over-the-counter and consumer markets are into outsourced packaging now.

Keene: For leading medical device manufacturers, outsourcing offers the ability to minimize the disruption in their manufacturing facilities often associated with the scale down of mature products and the scale up of new products. This benefit is achieved while avoiding internal bureaucratic delays. Working with a firm focused on the processes of manufacturing start up also allows the manufacturer to gain the cost benefits associated with manufacturing specialization.

Outsourcing allows development-stage companies to avoid capital investment in bricks, mortar and fixed overhead before there is certainty of market acceptance. They can focus on the critical aspects of their success in R&D and marketing.

Vytlacil: Everyone benefits as the trend to outsource continues to grow. Those contract manufacturers who are offering a full range of services are benefiting.

We've seen success not in a specific product market but more in a customer segment that is oriented toward innovation and rapid "time to market."

Doman: We see both large and small companies benefiting from outsourcing engineering services and manufacturing. However, the reasons that drive them to outsource may be different.

Small companies and/or start-ups are generally trying to avoid cost in order to preserve cash. In many cases, they do not want to create a large infrastructure—both in terms of human resources or manufacturing. The viable alternative is to outsource the development work and manufacturing so these costs become variable versus fixed.

Large companies are being forced to choose what they consider their core competencies, invest in them, and then outsource other areas they do not consider core to their business. Key questions they ask themselves are: What value-add do we bring to assembling electronic medical devices? Why invest in a manufacturing facility when there are other options? By outsourcing, they can reduce cost and overhead, or redirect expenses to R&D and marketing to drive future growth.

In addition, as devices become more complex and utilize a broad spectrum of technologies, OEMs are forced to become more discerning on what and where they need to invest in internally. The opportunity here is to outsource engineering services in areas not core to them.

Lester: I think it's probably smaller firms at this point. A lot of times with newer products, the companies may not even have manufacturing available to them. And their decision is whether to manufacture or to outsource right off the bat. In other words, as soon as they begin the process of releasing their product, what do they do. Do they put the overhead in place to manufacture, or do they outsource. And I think most of the time, it's better to outsource unless you have a product that is extremely technical, with maybe a little black magic involved in the product and you think that maybe no one on the outside can actually produce it.

As the companies get a little larger, they have manufacturing concerns in other countries, particularly India or China. And then the small companies will go through a representative of a company in China rather than going direct—like some of the larger companies do.

The middle-size companies also have a lot of opportunity. They may be having a hard time making a decision about what to do. Then they may not have the wherewithal or perhaps a supplier base they can trust to go international.

MD&DI: For the company considering the decision to outsource, how can potential pitfalls be avoided?

Vytlacil: Both product design and manufacturing must be married early in the relationship. Failure to do so, along with unplanned "time saving" shortcuts, will add short-term disruption and potentially long-term cost disadvantages over the product life cycle.

Doman: Certainly, you should find an organization that has compatible values, cultures and business processes. When you start a project, make sure you have well-defined objectives and ways to measure those objectives. And, ongoing communication has to be frequent and two-way.

For example, our firm issues weekly project updates to our customer base. Basically, these cover what happened in the preceding week—for instance, what milestones were hit, and what's going to happen next week. Then they have the capability, even if they have not been speaking live with

us, which is rare, to make comments electronically to be sure everybody is on track. This is circulated to all of our senior staff. So, open communication lines are really important.

The idea of having written and published plans that everyone has agreed upon is also important, along with the willingness to share strategies, concepts, and confidential information. You have to look at the contract manufacturer as an extension of your own organization.

The other key thing is that the client customer has the outsourcing resources and infrastructure to support it. You just can't assume that you are going to outsource a product development project; hand it off to somebody; and expect it to get done. It is critical for the success of the project that there are resources on the client side to interface with on an ongoing basis. We find that our most successful projects are those where our customers are closely involved with our teams on an ongoing, if not daily, basis.

Finally, when you are assessing a contract manufacturer, you need to make sure that they have the capabilities needed to meet the project requirements in terms of the quality systems, as well as the program and project management skill sets and engineering expertise.

Keene: Medical outsourcing is a capital-intensive, quality-driven enterprise. It takes years and years to build a reputation and, because we are dealing with sterile finished goods ready for onward distribution, that long-term orientation and market acceptance standard seems appropriate.

Lester: First, you have to pick a company that has a good reputation. Now that can be hard to do when you don't know companies in China, for example. But obviously these people will give you references when you go in to look at them. I think you need to check the references very heavily. Make sure that what these companies say they can do is indeed what they actually do.

I also think that the companies you might be dealing with have to have a very good financial backing. Because they're going to investing up front in materials and such, you have to make sure they can handle it.

I would also say you have to get a strong project team on both sides. And make sure that with whoever the program leader or project leader, that the project is their life. In other words, that all they worry about is the project. They should make sure that the materials are coming in and that there are no engineering problems—everything that's required in a new product startup—and that they're there and supporting you totally. And we've found that communication is extremely important. You need to set up these project teams, and you have to have continuous communication with that group.

The other place we've found potential pitfalls is with documentation. It's really good if you can clean your documentation ahead of time. Have your manufacturing engineers go through whatever product you're designing to go over to Asia with and verify the bill of material, and verify all of the prints. Perhaps they can actually build the product themselves, there on the shop floor to make sure that you can build it the way the prints say to build it. If not, fix it and then release it to Asia.

One of the other things you find is that, because the product has been over here for a long time, particular suppliers have been chosen for materials. When it goes over to China or Taiwan, let's say, they are going to find lower-cost suppliers and vendors. I think it's important to use their suppliers because that obviously helps in the long run. But I believe that part of the agreement needs to be that they can't use a supplier unless the OEM validates the part they're trying to use well in advance.

MD&DI: How would you characterize the regulatory environment in which contract manufacturers function? Is that environment changing?

Earle: Absolutely, it's changing. The customer is depending on the OEM supplier to meet all the regulatory issues and keep them out of harm's way. So their quality assurance people have to

feel comfortable with the OEM supplier, and they have to do more than just audit. They have to believe in the quality assurance program that the OEM supplier has in place.

One point I want to make is that you have companies, with us being a global company, and the globe is regionalized in what products they buy. In one country, they buy economical IV sets and whatever they can get as far as fluid. And in another country where the company has a large marketing force, we may not be able to sell some of those products in the bigger market. So we take those products and look for a partner on an OEM basis to sell them for us. Not a distributor, but some one else—an Abbott or Baxter, let's say— whose line it would complement.

The market is changing because people don't want to spend money on reinventing the wheel. There may be three or four different applications available for doing back surgery. But which one is going to rise to the top. They don't know. And that's the reason they don't want to spend the money and resources on their own facilities. They'll let the OEM vendor break their pick and see who can get them there the quickest.

Vytlacil: With the quality systems established at most contract manufacturers (that is, ISO, QSR compliance), regulatory challenges should not be a key factor today.

Doman: We recognize that someone from our client is going to make a decision internally to choose a partner that is going to develop a product; and, hopefully, get it to the marketplace—on time and at the cost that was estimated—and then manufacture it on an ongoing basis. Internally, somebody is putting their neck on the line. They have to be really confident that the company they choose is going to be able to perform for them. This is particularly true for the regulatory aspects of the project.

Certainly, the regulatory challenges have toughened significantly—both for the contract manufacturer and for the client. Of course, FDA regulates access to the market. So on the client side they are being asked to do more in terms of clinical trials and to do larger trials.

In addition, the FDA has become much more stringent in terms of GMP violations than in the past. So, it is very important that a client become very comfortable with the idea that their contract manufacturer is going to be in compliance with FDA's quality system regulations.

It is challenging on both sides, and it is important that before you enter into a relationship, in which both parties agree on a quality and regulatory plan for moving into the marketplace. This includes how you are going to manage the design history file, change controls, and all the documentation that goes along with that.

You must gain agreement on who is going to be responsible since there are significant legal and financial risks in the environment that we operate in. You are really talking about ongoing management of the product life cycle. The regulatory environment is constantly changing. You need to be sure your partner has the systems and capabilities in place to respond to those changes.

Finally, because most companies operate on a global basis, there is the influence of globalization, which ties into the regulatory side. In many instances, they enter the European market before the U.S. market. The documentation required for product registration and the technical files can be different for different countries, and they can change quite often. So the contract manufacturer has to stay abreast of the requirements and work closely with their client to ensure that they are compliant and avoid potential pitfalls.

Lester: We always make sure that the manufacturing facility is approved by ISO. The other thing we always require is that the facility be FDA registered. And everyone we've dealt with to date was not FDA registered initially, but we helped them register their facilities.

We have to make sure that we audit all of the facilities on a periodic basis to make sure they're following their quality manual and their good manufacturing practices, and making sure that the product coming to the United States is good.

The other thing we always have done at first is that anytime we had a new product, wherever it might be, our manufacturing engineers go over there—maybe every two months—to make sure that the people understand how to build and test the product. Then when that product comes over here to the United States, our quality department and manufacturing engineering department actually tear apart the first run to make sure it was built according to our specifications. Then we retest the product. After we are satisfied that the product is being built correctly, we take so many out of each batch coming in. We don't take them apart at that time, but we do retest them to make sure that all our standards are being met.

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