

Forecast Series Presents:

Critical Outsourcing Questions

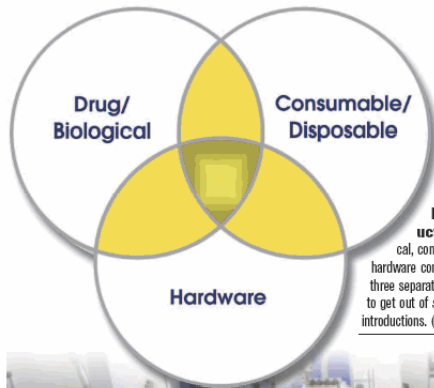
Medical device manufacturers' interest in outsourcing is growing and with it come many misconceptions and questions. This article, based on interviews with experts in the field, will examine the reasons companies choose to outsource, the functions they can outsource, the pitfalls they may encounter along the way, and the steps they can take to make it work. ▶ *By Peter Cleveland, West Coast Editor*

Medical device manufacturers are taking a closer look at outsourcing and the benefits it can provide—not only in direct costs but in organizational flexibility and product quality. But not all functions or products are equally suitable for outsourcing and rushing blindly into an outsourcing agreement can cause problems. What, when, why, and how to outsource are the critical questions a medical device manufacturer needs to answer completely before such an undertaking.

Why Outsource?

The most basic reason that any company considers outsourcing is simply money. "Medical device companies are finally under the same kind of cost pressures that pharmaceuticals and other industries have been under for some time," says David Busch, VP of medical segment at Soletron. At the same time, he continues, "they're under pressure to grow their top line more rapidly." Outsourcing can help in both these areas.

When it comes to cutting costs, says Vicki Tauscher-Phelan, managing director of life science practice, EquaTerra, outsourcing is a way of getting rid of people, especially for companies that have grown through acquisition. "I don't want to sound too harsh," she says, "but . . . the true way you save money is to relieve yourself of real estate and headcount." And she adds, that doesn't mean shifting people from one department to another, it means getting rid of them. However, she continues, this doesn't necessarily mean throwing people out of work; while outsourcing can be a good way to



Many medical products now have pharmaceutical, consumer disposable, and hardware components. This can mean three separate supply chains that tend to get out of sync and delay product introductions. (Photo: Soletron)



Single-use device assembly in one of Avall's Tijuana manufacturing facilities. (Photo: Avall Medical Products)



On the cover: Medical device companies are looking to outsource capabilities beyond manufacturing including design and prototyping, packaging, private labeling, sterilization, and quality control. (Photo: B. Braun OEM Division)

AT A GLANCE

- Advantages of outsourcing
- Anticipated concerns
- Is it the answer for any case?
- Focusing on core competencies

► If there is a single most important thing a company should have before even considering outsourcing . . . it's a clear view of its objectives.

cut deadwood, "if they are good people but you're just eliminating jobs, very often the service provider will take on those people."

When it comes to growing the top line, there are two approaches: "inorganically, buying other companies," says Busch. "Or organically, which is crank out more products faster and enter new markets." Both of these require cash, he says, and CFOs are looking for places to find it. One place is in the vertical supply chain. Many medical products, for example, now have pharmaceutical, consumer disposable, and hardware components, which can mean three separate supply chains that tend to get out of sync and delay product introductions. A contract manufac-

turer, says Busch, can simplify things and at the same time help with product life cycle management: finding sources of supply and arranging for manufacturing locations. "Since a medical device is 65 to 70% material, you don't save a lot of money on labor," he says. "You don't move to China to save a couple of bucks an hour in labor, you move to a lower cost supply base so that you can take costs out year over year in that product."

Another reason to outsource, says Dan Adlon, VP, strategic business development, Integrated Biosciences, is that it can allow you to take a leap technologically that you cannot do yourself, either "because you politically and organizationally and skill-wise can't do it, or it's too dramatic a jump for your organization to handle. For you to do it would take three years and if you outsource it to service provider, they could do it in a year."

Which Functions to Outsource

Outsourcing allows a company to focus on its core competencies. "If your core competency is product design," says Adlon, "you're not necessarily up on what is the latest assembly method or even what's the best assembly method. Whereas somebody who's core competency is that manufacturing obviously stays abreast of developments."

Outsourcing may begin with manufacturing, but IT, finance, accounting, human resources and procurement are also likely candidates, and some companies may not stop there. Tauscher-Phelan cites a pharmaceutical company that outsources all its research, along with manufacturing. While few medical device companies are willing to go that far, J. Randall (Randy) Keene, president & CEO, Avail Medical Products, thinks it may be in the cards. "I think it's coming," he

says, "I just don't know how fast."

A company that grows organically, says Keene, can outsource sustaining engineering and managing older products to focus on breakthrough concepts on new products. Companies "don't want people [and] facilities tied up supporting . . . older products," agrees Busch, and they may ask a service firm to take them over, "do the sustaining engineering, do the refresh design, switch it to lead free if need be, manage the end of life, all that stuff." This may, he adds, mean moving it to a lower cost environment. "We've been asked to take products coming off a lease or coming to end of life in North America or western Europe and sending them to China to be refurbished there for the Chinese market."

But shifting to overseas isn't always a slam dunk. "China does not have a supply base that is ready to make complex medical instruments in low volume high mix," says Busch. "Their supply base is much more geared toward high volume low mix cell phones and things like that." In addition, says Adlon, there can be problems with quality. "We've had programs," he says, "which are actually transfers back in from overseas. The reason they want to bring them back in, they can't get the quality." And, he adds, there are logistics and delivery: "you have to plan on 12 to 16 weeks for any delivery from over there."

Protecting Intellectual Property

Low labor costs can make manufacturing in places like China attractive,



Semi-automatic assembly work cell (Photo: Integrated Biosciences)

but IP theft remains a serious problem. U.S. Secretary of Commerce Donald Evans, in a keynote address to the ambassador's forum on International Property Rights Protection in Beijing January 13, said that widespread piracy and violations of intellectual property rights has cost American companies billion of dollars in sales and has damaged the reputations of their brands.

How can a company protect itself? One method, says Busch, is to be careful about where you do the outsourcing. His company has two Asian facilities, one in Singapore and the other in Suzhou China. Singapore, he says, has good IP protection, so that's where they send work with significant IP. So-called low-IP work—circuit boards, enclosures, and the like—goes to Suzhou. "Worst case," says Dick Rubin, director of marketing, medical, at Solectron, "should something be stolen, it could be ten year old technology where they've moved on to the hot new stuff."

China has done one thing that helps: dropped the requirement that outside companies have a Chinese partner. "Most of the IP theft that we've seen has revolved around one of the Chinese partners taking the wisdom that was given to them by their U.S. partner and reapplying it



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Many OEMs outsource their kit packaging in order to focus on their core competencies and to take advantage of contract manufacturers' existing product lines. (Photo: B. Braun OEM Division)



Package design should be addressed at the initial stage of design. (Photo: B. Braun OEM Division)

under their own label or their own whatever in a separate organization," says Keene. Not having to have a Chinese partner, he continues, "is the single biggest barrier to IP theft." Mexico, he adds, has done the same thing in this regard.

What to Know Before You Start

If there is a single most important thing a company should have before even considering outsourcing, says Tauscher-Phelan, it's a clear view of its objectives. Is it to save money, to gain flexibility, or what? "If your objectives are to save money," she

says, "make sure you understand exactly how you're going to do that and do the course of the whole deal." It's essential, she continues, to have all the steps mapped out in advance. "You want to understand the market; you want to understand your service delivery model, how you want that to look, whether you want it outsourced, insourced, offshored, shared service, or a hybrid of those."

"You would also," she adds, "use an outsourcing attorney who is familiar with not only how you get from point A to point B legally, but also with what the deals that have already been written look like, what's reasonable to expect, and what's not reasonable to expect."

Watching Out for Problems

Outsourcing can go wrong and there are any number of mistakes that can cause disappointment or even failure. Tauscher-Phelan has a list: Not doing your homework up front; not doing all your base case or your financial analysis; not clearly articulating your scope to the service provider, which means expensive change orders for the service provider; not putting in place the right governance structure, for people, processes and tools, "so you either didn't dedicate enough money to your governance structure, you didn't design the right tools to help the processes for that governance structure, or you staffed it with people who were involved in the deal up front who were great on the procurement end, and that was their skill set, but for people who are managing an outsourcing arrangement it's a different skill set."

Keene has his own list of red flags: not a well-defined process; any kind of a quality audit that identified that the quality system was not robust enough; and lack of qualified personnel. "A number of people can parade a specific person that has tremendous talent, but do they have a process that supports that, because are you going to have that one person or those two people that are really talented available to you forever

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Cover Story

in your partnership?" On the other hand, he continues, "If they don't have a well documented process, then you're counting on one or two guys to be really smart for you, and that may be a good bet for the next few weeks but it may not be a very good bet for the next several years."

Many of the problems, says Adlon, can be traced back to a communication error somewhere along the way. "Somebody didn't understand what was being said, or something of that nature," he says. Make

sure the lines of communication are clear, he goes on, so everybody understands what they're supposed to be doing and when.

A Look Ahead

There's every indication that outsourcing in the medical field will continue to grow, and the functions that are outsourced will increase. "As the OEMs focus more and more on what's their core competency, they're outsourcing more and more," says Adlon. "Some of them are even

going to outsourcing the design side of it, becoming just program managers themselves." And some companies will outsource everything, says Keene, "just as it has in many other industries where people used to make circuit boards and now they're making entire phones for companies that don't even touch the phone any more."

Some will reconsider what they've done, says Tauscher-Phelan, first trying to outsource everything, then realizing they've gone too far.

ONLINE

For additional information on the products and technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com and the following websites:

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