

Your Top 10 Outsourcing Problems—Solved

Industry Experts Talk About Their Strategies for Resolving Common Outsourcing Concerns

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This October, while some Americans are getting into the Halloween spirit by watching fright flicks, Phil Stramel need only think about a real-life experience two years ago to feel horrified.

In 2004, after joining startup Novasys Medical, Inc. in Newark, CA as operations manager, Stramel was traveling on business when he received a call that started his head pounding. Immediately before an outsourcing contract was signed, the vendor announced it was increasing its prices by 30%. The company said its board of directors had changed its strategy, and Novasys was no longer an ideal customer.

“There was nothing we could do about it in the short term. We needed product in a month,” Stramel recalled. “We immediately began looking for another supplier and found a company that was better able to meet our needs and do so at the original price point.”

Novasys switched suppliers within a few months, but the violation in trust solidified Stramel’s conviction that outside vendors must undergo a rigorous process before being considered for projects. Kelvyn Cullimore, Jr., president and CEO of Dynatronics Corp. in Salt Lake City, UT, also has experienced the bait-and-switch technique, especially with vendors that provide specialized processes and have little competition.

“If they tell you they can’t do it for the quoted cost at the last moment, you’re left with the difficult choice of pulling the job and finding a different vendor—and possibly missing your market release target—or absorbing that extra financial hit,” Cullimore said.

Either scenario makes it more likely a long-term relationship will not result, which can cost both companies in the long run, he noted. Increasingly, contract manufacturing service providers also have fallen prey to this tactic now that so many are managing entire supply chains for their OEM customers.

Whether the vendors in question simply misunderstood the project requirements, bit off more work than they could execute or changed the rules at the last minute for nefarious reasons, customers that have experienced this problem say they have changed their vendor selection criteria to minimize the likelihood of getting another unwelcome shocker (see tip number five).

The Top Ten

Medical Product Outsourcing recently spoke with OEMs, contract service providers and industry consultants to learn the most common problems occurring in outsourcing relationships today and how they might be solved. Here are the top 10:

Outsourcing before you’re really ready. Too often, experts say, companies decide to outsource a project for the wrong reason. Perhaps the project is behind schedule or way over budget. Someone decides that shipping the project out of house will solve all the problems. Not so, experts warn.

“Before you outsource, you must understand what your needs are,” advised Bill Morton, president of Medical Device Consultants, Inc. in North Attleboro, MA. “Often, what a potential client thinks it needs and what it really needs are two different things.”

For example, Morton noted, a client seeking quotes for outside firms to conduct a clinical trial must know what type of controls to use, how many clinical sites it wishes to employ and whether it would like to conduct a randomized study.

Outside organizations can help their customers determine which processes and procedures will best meet the OEM’s needs, but the OEM first must have a clear understanding of exactly what those needs are. Tom Podesta, vice president of health care for The Tech Group in Scottsdale, AZ, added that customers also must be honest with themselves about proposed projects.

“Some products have inherent problems or deviations from the specification that never were addressed. You need to identify issues and resolve them before sending the project out or realize that they will need to be addressed, which will add time and expense to the schedule,” Podesta explained.

For example, specifications for an older product may not be 100% accurate, and this can add significant delay and cost to a re-qualification once it is outsourced.

Prior to outsourcing a project, scrutinize your company's strengths and weaknesses and then look for a firm that can complement your capabilities. Also make sure that senior management fully supports outsourcing the project.

Waiting too long to outsource. Once OEMs have chosen to outsource a project, timing can make a world of difference in the project's ultimate outcome and cost. As most medical device industry professionals know, a product's design drives its manufacturability, sterilization modality, packaging and delivery—in short, its entire production process until it reaches the end user.

Designs that are set in stone before being handed off to the contract manufacturing partner may use a material or process that inadvertently adds considerable time or expense, warned Jim Brown, executive vice president of The Hi-Tech Group Cos. in Anaheim, CA.

"We prefer to be involved as soon as possible in the design process so that we can provide input," he explained.

Because an OEM may have worked with a certain material or process in the past, it may make assumptions about materials, design or manufacturing techniques without having access to the very latest developments in those areas.

Brown noted that outside experts often can make recommendations that will better meet OEMs' needs. For example, liquid silicone might be better than flashless molding for a particular design.

Too frequently OEMs consider only the device and risk management in their planning, said Carl Martin, CEO and founder of Advanced Scientifics, Inc. in Millersburg, PA. "If we're involved in the process, we can shorten the time frame with our expertise in molding and tooling," he noted.

Poor planning. Do you have an outsourcing strategy? As in other areas of life, it's difficult to succeed without a written plan.

Once you've determined which projects will be outsourced, why and when, you need to solicit bids from at least three vendors whom you believe have the capabilities to meet your requirements (more on this later). Proper planning means making sure you'll have adequate time to solicit quotes; some vendors can turn around bids in days, but others, who may have more detailed responses, may need a few weeks.

The vendor-selection process will take time, as will negotiating a contract. Paul Touhey, president and COO of Fujirebio Diagnostics, Inc. in Malvern, PA, said that the legal wrangling around a contract can take a while, depending on the size of the companies and the size and complexity of the projects involved. "We had one contract that took seven months to negotiate. Others take just days. The most important thing is to communicate constantly and honestly during the process," he said.

Kelly Stichter, vice president of design development for Phillips Plastics in Hudson, WI, offered additional planning recommendations. "To succeed, customers must document as much as they can about what they're trying to do. What are their target ranges for what the final device will cost? What are the performance projections? What are their goals for the PMA? For clinicals? What is the time frame? Which milestones should be met by which times? The more they have charted out from the very beginning, the more accurate the quotes and projected completion dates will be," she explained.

Rich Smith, director of medical programs for De Leon Springs, FL-based Sparton Medical Systems, agreed. "The more detail and good quality detail an OEM can provide an outsourcing partner, the more smoothly the project will progress," Smith said. "Proper bills of material, good-quality detailed drawings, specifications, a qualified manufacturers list, etc. are necessary. This allows for a smoother transition to the outsourcing partner, whether for a design or manufacturing effort. Good input helps the outsourcing partner better understand its costs and, therefore, provide quality pricing levels to the OEM."

Beyond ensuring a more accurate price quote, sharing information with vendors allows OEMs to collect the insights and experiences of additional medical industry experts, letting them craft more complete, well-thought-out plans.

"When we talk with a customer, we get beyond the product," explained Tom Black, vice president of OEM sales and marketing for B. Braun's OEM Division in Bethlehem, PA. "We ask what the product is for, how it's used, who sells it, how it fits in the customer's corporate plan, where it will be sold." Armed with this wide range of data, suppliers then are able to identify areas of potential and risk on the production side that OEMs then can incorporate into their overall project plan.

Holding unrealistic expectations. What's the most common unrealistic expectation, particularly among startup companies? Thinking of outsourcing as a "pick and drop" concept, said Martin. In other words, companies believe that they're picking up a project, dropping it off to an outside vendor and not having to think of it again.

"Too often, OEMs don't want to direct the details, but they want to direct the end result," Martin said. "The problem is, we need their input and to see logical, detailed steps. We need to understand what parts of their design are essential—as a performance value—versus which are only nice-to-haves. In short, the "responsibility for success cannot be outsourced," said Mike Cheek, director of global supply chain for Kinetic Concepts, Inc. in San Antonio, TX.

The most successful companies appoint a project manager and have project champions located throughout the mid- and upper levels of the organization. To ensure the project is progressing smoothly, the project manager likely will be interacting with the vendor daily. Smaller companies also sometimes have skewed, unrealistic expectations about how devices will perform in the field, Martin added.

"They'll expect four of 10,000 to fail in the field, but they've designed a product and perhaps specified a component that has a higher failure rate. Or the product design may be flawed, and all the analytical testing in the world won't deliver different results," he said.

Mismatched expectations have given Kirk Olson, program director at HEI, Inc., Advanced Medical Operations in Boulder, CO, a case of heartburn.

"When we're developing projects for new customers, often they don't have a complete grasp of the development and regulatory processes, the level of design detail required and what the Quality System Regulations mandate as evidence of that. We need to be able to make very serious decisions about the product and project very early on in order for the entire process to go well," Olson said.

Gathering the data and detail required for the design and US regulations, as well as by regulatory bodies in other countries (if the product will be marketed overseas), takes much time and effort that customers may not have included in their initial budget and timeline. Fortunately, outsourcing partners can assist with these tasks.

"Determining and understanding user needs, writing the product specifications, assigning roles and responsibilities and determining who signs off on particular project documentation are just some of the activities with which we can help," Olson noted.

Sparton Medical Systems also has found that customers don't understand how much time some production and FDA submittal processes consume. The company has worked to solve this problem by educating customers about how they perform various tasks.

"Customers then can decide if they want changes to scope to meet the deadline or otherwise modify their requirements," Smith said.

Choosing a vendor for the wrong reason. Choosing the lowest bid when outsourcing work on a medical device—just as selecting the lowest bidder when remodeling your kitchen—could lead to disaster, albeit on a much more serious scale. OEMs should seek quotes from at least three well-qualified vendors when searching for an outsourcing partner, and significant price outliers should raise a red flag.

A 10% to 20% difference in price quotes may be normal; however, a 50% difference should raise eyebrows, Morton noted. "To make sure companies are comparing 'apples to apples,' we ask potential clients to complete a standardized questionnaire that clearly defines the specific tasks presented in our quote," he said. Otherwise, for instance, some firms may include pricing based on a different number of study patients, a different number of monitoring visits and/or a different number of sites.

Ensuring the vendor's capabilities meet your needs is vital, of course. "Audit suppliers right from the beginning, before you outsource," advised Joel Bartholomew, manager of product engineering for B. Braun's OEM Division. "Go on-site and talk with the technical people, both on the engineering and manufacturing sides. Check the companies' weaknesses and look at their core competencies so you can tailor your design to your vendors' strengths to improve the chances of success."

Assessing capabilities appropriately ties into making certain you've defined your product and project parameters effectively. For instance, "there are lots of molders out there, but what are your specific requirements?" asked Dan Adlon, vice president of strategic business development for Integrated BioSciences, Inc. in Lewisberry, PA. "Do you need cleanroom molding? What's their typical lot run size? Some companies are better at high runs, others at small or specialized jobs. We assess vendors with a self-survey we ask them to complete. We ask how big they are, who their typical customers are, what type of quality systems they have. We follow that up with an on-site audit where we can meet and get to know the

personnel and see how they respond to us.”

Black also recommended that OEMs understand exactly what they’re getting for the price they’re paying. “Some companies supply just a widget. Others manage FDA requirements, packaging, sterilization, quality control, etc. You have to compare cost versus service and support issues,” he said. Making a decision based on the lowest price per unit is not the best way to choose a vendor, agreed Nelson Holton, director of new business for HEI, Inc. Advanced Medical Operations. “You need to determine and rank your goals first and then select a vendor based on all of the offerings it provides: quality, industry relationships, flexibility, working in-line changes, depot service, finished goods warehousing, reliability, etc.,” Holton explained.

Looking at a potential partner’s finances is paramount, too, advised Bill Sherman, president and COO of The Hi-Tech Group Cos. “In evaluating a source, you need to know if that company can afford to buy the equipment you need, and if it has the resources—including staff members—available to meet your needs. Larger companies with greater resources can mitigate some risks for the OEM.”

Ignoring the potential for a culture clash. Some companies’ personalities and processes simply aren’t a good fit. How each company’s employees respond to each other during the RFQ (request for quote) process and on-site audit can indicate if a potential culture clash may be in store.

Adlon pointed out that how quickly calls are returned throughout the RFQ process as well as how you’re treated during the on-site audit will speak volumes.

For instance, during the tour, does the sales director lead the visit, or do you get to meet and talk with staff members who would be working on your job? How well do your personalities mesh? How organized are the facilities? Does it look like everyone is already overwhelmed, or could they easily find time to help you, too?

“Each company is structured differently, communicates differently, has different goals and views on taking risks differently. Understanding and valuing each other’s culture will go a long way toward easing the relationship,” Bartholomew said.

He noted that initially you can gain a sense of corporate culture by reviewing the organizational chart, ascertaining who the decision-makers are and how much authority others have to make decisions. By joining forces with companies that complement your firm’s mind-set, you’ll both be positioned for a smoother workflow and marketplace success.

Providing unclear specifications. OEMs recognize what contract service providers say can be a big problem: specifications aren’t as clear as they could, and should, be. “Half the time we have problems, it’s because we failed to give proper specifications or details,” Cullimore noted. “When you describe something you understand well to someone else, you think you’re being clear, but it’s entirely new to them, so they may have a completely different understanding.”

For example, you could describe a cat to someone, but if he or she has never seen a cat, and you don’t give specific details, measurements and images, the person might end up envisioning a dog. After all, both have four legs, could weigh about 10 lbs and have a tail and pointed ears.

“We try to specify particular parts, even naming specific brands, such as noting ‘must use a T1430 processor.’ We also call attention to critical components,” Cullimore said.

Stramel noted that vendors also have misinterpreted Novasys’ manufacturing processes. “They’re written in a manner that we’re finding can sometimes be interpreted in more than one way,” he said. “We’ve discovered the misunderstanding after seeing the result—poor quality parts or parts that work but aren’t made to our specifications. There have been subtle changes, but they make a difference. “We’ve rewritten our manufacturing processes to make them less ambiguous. We’ve implemented a review procedure in which internal, nontechnical people read through the processes to ensure they understand them. We then have our most skilled operator go on-site to train the manufacturer’s operators and observe them implementing the processes,” Stramel said.

Sherman lamented that too many two- and three-dimensional CAD files his company receives are incomplete. “Customers rarely provide full tolerancing or quality limits, and that’s where the problems start,” he noted. “Quoting gets very difficult.”

Taking the time at the beginning of a project to ensure specifications are thorough and accurate will save trouble later.

Introducing too many scope changes. In product development, scope changes are imminent. One way to ensure they don’t knock a project off track is to clearly define the product’s and end users’ requirements.

“Changes to scope or requirements without recognizing their impact on the cost and schedule of the project

can be a big problem,” said Peter Riddell, vice president of business development for Invetech, based in San Francisco, CA. “By clearly communicating the impact changes will have, we’ve found that customers sometimes change their mind about a proposed change.”

Glossing over quality systems. Particularly with vendors located overseas, it’s crucial to ensure any vendor selected has in place quality systems that will meet the OEM’s requirements. “It’s not always common knowledge what it takes to get each step of the medical device manufacturing process approved,” Stichter warned. “It’s essential to put in writing at the beginning of the project what quality systems will be used and who is responsible for checking for problems and making sure they are fixed.”

Not communicating, or not communicating clearly enough. Don’t let its last place on the list fool you—communication is the key problem facing outsourcing relationships today, according to nearly every individual who spoke with *Medical Product Outsourcing*.

Think about this: How many times have you left a meeting in your own company, with people you’ve worked with for years, and had an entirely different understanding of the boss’s instructions than someone in another department? People in operations have a different understanding of certain lingo than do people in R&D than do people in marketing or accounting. Is it any wonder that misinterpretations arise when you’re communicating with people in other organizations in other parts of the country or of the world?

“We try to educate our customers about what we mean when we use certain terms that could possibly be misconstrued,” Stichter said. “A picture is worth 1,000 words, so we use WebX (Web meetings) frequently to show a database or images on-screen to aid in understanding. We’ll hold workshops on design tips, injection molding and other topics, so that customers can see how we perform our processes.”

Adlon advised that instructions be written down to increase understanding, because people hear things differently and note-taking skills vary widely. “When I see a written response to me, I can see if they’ve understood my instructions—before I get a part that doesn’t meet spec,” he explained.

Outsourcing teams most often have an assigned project manager/ point person at each organization who handles daily interactions, but experts advise that a full team be in communication.

“We strongly endorse multilayer communication where people who understand each other’s disciplines and domains at each end are speaking as well,” said Jari Palander, vice president, North America for Invetech. That is, mechanical engineers talk to mechanical engineers, manufacturing personnel with their counterparts, etc. Project managers are copied on all communications, so they know where everything is at any given moment

To further aid communications, Invetech also has co-located its employees at customers’ locations if that makes sense for a project. “Customers will work in our laboratory or we’ll work in theirs for some time,” Palander noted.

And contrary to the “pick and drop” outsourcing mentality, experts agree that most outsourcers have nearly daily contact with their customers via phone, e-mail or Web portals. In fact, many gather monthly or, in some cases, quarterly (when distance is a factor) in face-to-face meetings to discuss issues that have arisen during the past few weeks, the solutions and the project’s progress.

Commitment Is Key

Most companies that have outsourced have experienced at least one of these problems over the course of their projects. Dave Busch, vice president, medical market segment for Solectron Corp. in Milpitas, CA, noted that his company’s strategy for successful outsourcing is to build strategic alliances. Otherwise, when you run into these tactical problems, it becomes a bigger quandary than is usually warranted, he said.

“If you’re living together as customer-vendor/supplier, and you encounter one of these problems, it’s easy to say, ‘You caused this problem’ and walk out,” Busch explained. “If you’re married, so to speak, you realize that there will be rough patches, and when you hit one, you’re committed to the relationship and working it out.

“It becomes a collaboration,” he concluded. “That’s when you get the most success. The OEM sees financial and operational benefits and is able to outsell its competition. The contract manufacturer makes money, too. Everyone wins.”