



Offshore outsourcing: shopping in a global market

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In our price-competitive, technician-deprived industry, offshore outsourcing is becoming an increasingly viable business strategy. For many U.S. laboratory owners, it is also a key factor in their ability to grow their laboratories. Although their use of offshore outsourcing varies—for example, some owners only outsource non-precious units while others are outsourcing the majority of their work—

these owners are unanimous about one point: it's working for them.

Overseas labs that cater to the U.S. market offer cost-effective pricing—fees that are typically one-half to two-thirds lower—and many are high-volume production facilities that are open 24/7 and offer a full range of services. By using their services, U.S. laboratory owners are able to meet the needs of cost-conscious dentists while maintaining their desired profitability. Offshore outsourcing also minimizes the stress of finding and training new technicians and gives the laboratory a competitive advantage by allowing it to offer all of the latest services without the capital investment.

“Laboratories are being pressured from all sides. Dentists want lower and lower prices and more and more product choices. We can't find qualified technicians and, at the same time, dental technology schools are closing and over-the-shoulder training doesn't produce results quickly enough. Because of these chronic problems, I felt chained to the bench. Offshore outsourcing set me free,” says Gary Spadaro, owner, Liberty Dental Lab, Schenectady, New York, who outsources all of his C&B work.

There are two ways these laboratories are outsourcing their work offshore: by shipping to a U.S.-based broker laboratory—also referred to as a virtual lab—that, in turn, sends the work offshore or by shipping directly to the overseas facility. Both approaches have their pros and cons.

Working with a U.S.-based broker laboratory is, by far, the easier scenario since it's similar to domestic outsourcing. You send your work to the broker and it handles all of the shipping and offshore logistics for you. Most brokers have technicians and managers on staff to handle minor adjustments and perform quality control checks before returning the case to you. Some also handle remakes in-house but others ship the remake back to the offshore laboratory (something to keep in mind when considering turnaround time).

The broker can save you a tremendous amount of research and legwork. For instance, you don't have to shop for a laboratory in a foreign country, register with the Food and Drug Administration (FDA) (a requirement for directly importing Class II medical devices from another country), handle communication issues or learn the ins-and-outs of overseas shipping and customs regulations. Also, because of the volume of work brokers are sending offshore, they have established relationships with shipping carriers and offshore laboratories, giving them greater clout than a laboratory sending a small or inconsistent amount of work.

However, because you're paying for the added convenience of working with a liaison, you'll pay higher fees to a broker than if you ship direct. One West Coast laboratory owner—who, like several others interviewed for this article, prefers to remain anonymous—researched both options and compared the expense to his own production costs. On a non-precious crown, he estimates he could save \$15 to \$25 per unit going direct, and \$7 per unit going through a broker lab. Although it's less of a savings, he prefers to pay the broker prices because he appreciates its services, expertise and the research it has done to find quality laboratories overseas. In the end, it's a fair trade for the value he gets. "It's worth the extra money because I don't want the hassles," he says. "I haven't ruled out shipping directly someday in the future, but using a broker is a good way for me to get started."

While going direct offers a better fee structure, the flip side is that you're going to pay higher shipping costs as well as take on additional responsibility. You need to consider these factors in relation to your in-house production costs, profit margin and the offshore fees to determine at what volume direct offshoring is cost-effective.

Consider the example of one Midwest laboratory owner who has determined that five units are the least amount per shipment that he'll outsource directly. Although you can negotiate discounts for high-volume shipments, the typical minimum for shipping a one-pound package is \$50. Since he's only responsible for paying outbound shipping, his shipping cost for five units is \$10 per unit. He's paying \$30 per crown so his total cost per crown is \$40—still well under the \$60 it would cost him to produce it in-house.

While he could still save money by sending fewer units, he's also considering more than just the cost in dollars. "It's not strictly a mathematical issue. It's also a logistical issue because we have to track the package and assume the added risk of shipping overseas so we have to send a meaningful amount of work to make it worth it," the owner says.

Outsourcing directly

If you're interested in outsourcing directly, here are some key steps to consider:

Register with the FDA. According to FDA regulations, you would be considered an "initial importer" of Class II medical devices and therefore be required to have a registration number. The names of all U.S. and foreign FDA-registered dental laboratories are listed on a registration database on the FDA's website ([click here to go to the FDA's website and search by laboratory name](#)).

To register, you need to complete Initial Registration of Device Establishment-Form FDA 2891 ([click to download form](#)). There is no charge to register but be prepared to spend some time reading and sorting through a lot of details to find the information that's relevant to laboratories. You may also encounter some governmental red tape. "You have to fill out the form exactly as specified or it will get delayed. It took our logistics expert about seven weeks to complete the registration process," says Mark Frichtel, owner of Pittsburgh, Pennsylvania-based Jesse & Frichtel, Inc.; Jesse & Frichtel Precision Dental Prosthodontics; and JF International, a new laboratory through which he offshores work.

Shop for the right laboratory. While the quality of overseas work has improved dramatically in recent years, you need to feel comfortable with the laboratory that will be doing your work and establish a rapport with its management. “Lack of trust is one of the most challenging aspects of offshore outsourcing. Take your time with the research and don’t rush into the relationship,” advises Dr. John Wu, associate professor of business at California State University, Monterey Bay, California.

Since a number of offshore laboratories are aggressively marketing to the U.S., you might already have some contacts. You can also find them by checking the Internet, searching the FDA’s list of registered labs or looking at LMT’s classified ads.

In addition to asking about pricing, available services and turnaround time, find out who pays for inbound and outbound shipping. Given the cost of shipping, this could be critical to your profitability. For example, a three-pound package which can hold about 10 cases costs approximately \$52 to ship overseas whereas the incoming package with the final restorations and the models for those cases would cost about \$98.

Also ask questions to assess your confidence in the offshore laboratory. How long has it been in business? Who is managing the laboratory and supervising and training its technicians? What type of quality control systems are in place? Are they FDA-registered and using FDA-approved materials? (While the FDA requires this of foreign laboratories, enforcement is challenging; see Dental Laboratory Industry Piques FDA Interest below for more information).

Language barriers and cultural differences can make the U.S.-to-foreign laboratory relationship challenging. Although some overseas labs are staffed by English-speaking managers, laboratory owners say there’s still potential for miscommunication. When Frichtel was shopping for offshore laboratories, his first criterion was speaking with the owner; if he wasn’t able to assess his language skills and reach a comfort level with the owner, he immediately crossed the lab off his list.

Spadaro took it one step further: he invited the owners of the foreign labs he was considering to visit his lab in the U.S. to meet them face to face. He doesn’t work with anyone who refused to make the trip. He also sent the labs an outline of his expectations, explaining technical details such as height of dies on the model work, how high to make the occlusion and how he wanted the contacts. “I’m the customer. I want to make sure they are on my page,” says Spadaro.

Once you’ve identified some potential labs, send a few trial cases to check the quality of the work and get a sense of how the process works. “Make sure you send test cases over a period of time; the initial cases may look great but you want to make sure the work is still good three months down the road,” recommends Frichtel.

Learn about offshore shipping. While some laboratory owners have found their foreign laboratory representatives to be helpful in walking them through the shipping process, others say that the learning curve is demanding. Most major shipping carriers provide software that makes it easy to track packages but even still, bad weather, a U.S. terrorist alert or even a typo can delay an overseas shipment. “Just because a hyphen was left out of a company name from which we were importing, customs held the package for about five days. You really need to dot your I’s

and cross your T's and make sure your paperwork has exactly the same information every time," explains Barbara Murphy, executive assistant, Shu Dental, Morrisville, Pennsylvania.

All imported Class II medical devices must be accompanied by a 510(k) form; list the FDA registration number of the importing laboratory, the package contents and value; and meet the Bureau of Customs and Border Protection requirements (www.cbp.gov). Packages that don't meet these requirements can get held up in customs; some laboratory owners report delays of up to three weeks. The FDA randomly opens and inspects packages; it charges the recipient a \$20 Government Inspection Charge for every package it reviews.

Another potential delay is the country's holiday schedule. For example, during the Chinese New Year, all businesses in the country are closed for two weeks. However, this may change next year as the Chinese government has declared that the New Year is no longer a national holiday.

Consider your increased administrative and logistical responsibilities. If you use a broker, the administrative work may be minimal but if you go direct, it can be time consuming. For example, Murphy says it took about one year to locate all of the proper contacts within customs, the FDA, and FedEx and to get the process at Shu Dental running smoothly.

Another logistical issue to consider is the time difference. "You could be talking about a 12-hour time difference. If the manager of the offshore lab needs to have a question answered right away, you might need to be available to him at 1:00am. If you wait 12 hours, you've just added a day to your turnaround time," says Frichtel.

Contemplate your cash flow. Since credit card payments for offshore work are not the norm because of the fluctuating value of the dollar, electronic transfer is the preferred payment method. This means you're basically paying upfront—perhaps well before you get paid by your customers—so you need to have a cash reserve to cover the lag period.

Formulate a business plan

If you're considering offshore outsourcing—either through a broker or direct—as a way to grow your laboratory, you need to ask yourself a variety of questions and formulate an appropriate business plan. Some important areas to address are:

What quantity and type of restorations do you want to outsource vs. what you'll keep in-house? There are numerous reasons why lab owners outsource work. For instance, they might want to tap into a new market by offering cutting-edge products without investing in new equipment or providing value-priced restorations that they can't produce as cost-effectively in-house. You need to make this determination for your lab based on your staff, the demands of your dentist-clients as well as your desired profit margin and production capacity.

Will you let your clients know where the work is being fabricated? At this time, there is no clearcut answer as to whether or not you legally have to disclose to your clients where your work is being fabricated; this is an issue the FDA is researching. While some lab owners say that complete disclosure is the ethical way to handle outsourcing, the reality is that others feel there is

a stigma attached to it (thus the reason that some of the owners interviewed for this article asked to remain anonymous). They are worried that if dentist-clients know where their work is being fabricated, they might equate the offshore work with substandard quality, feel they are being unpatriotic or want to renegotiate prices.

How will you market the offshore work? In part, this answer depends on whether or not you are disclosing where the work is made. For example, Frichtel thinks it's important to be totally upfront and give dentists the option to make an informed choice. He operates JF International as an entirely separate company from his other laboratories, using distinct prescription forms, invoices and phone lines. "We do not want our clients who are paying top-dollar to think that we're actually shipping everything out and making a killing on it. J.F. International's invoices are a different color and all of our invoices specify the country in which the case was made," he explains.

How will you handle your employees' concerns? While a few laboratories have let employees go as a result of offshore outsourcing, most haven't—and see this scenario as highly unlikely in light of the industry's labor crunch. Still there's a natural tendency for employees to be concerned about their job security. "I'm very conscious about the feelings of my employees. I've been upfront, telling them how we're going to use this as a complement to our lab. I explained that we're only going to outsource overflow production so it will help lighten their daily workloads and also make it easier to schedule vacations," says a Southwest laboratory owner.

A changing marketplace

Offshoring advocates and opponents alike agree that global competition is here to stay and with it comes a new business environment to which we must adapt. The chronic issues of price competition and a lack of qualified technicians persist, but now we also must deal with new developments, such as the pressure of increased competition and the FDA's closer scrutiny of our industry.

As a business owner, be prepared to stay abreast of these trends and evaluate the opportunities and the challenges they pose for your laboratory. If offshore outsourcing seems like a practical business model for your laboratory, embrace it. If it doesn't, find ways to make the most of your strengths to compete effectively. If ever there was a time to be conscious of the changes in the marketplace, this is it.

Dental laboratory industry piques FDA interest

Responsible for protecting public health, the Food and Drug Administration (FDA) has long been actively involved in overseeing the manufacturers of dental laboratory materials. Historically, however, it has paid minimal attention to dental laboratories—until now.

In light of the dramatic rise in imports from overseas laboratories in the past several years, the FDA has become concerned that these low-cost offshore restorations might not contain FDA-approved materials that are legally required to ensure patient safety. As a result, it is taking a closer look at foreign laboratories and consequently, domestic operations.

In addition to dental materials, the FDA regulates manufacturing processes but not the final product. One key area of FDA concern is compliance with its Good Manufacturing Practice (GMP) requirements and Quality System regulations outlined in Title 21 Part 820 of the Code of Federal Regulations, often referred to as “21 CFR Part 820.” The GMP requirements are wide ranging and relate to all manufacturers; the 21 CFR Part 820 regulations are specific to medical device manufacturers, which include dental laboratories.

Simply put, 21 CFR Part 820 specifies that you must have an established, documented “quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of finished medical devices intended for commercial distribution in the U.S.” While these regulations have been in effect since 1997, it’s only recently that the FDA has begun inspecting U.S. laboratories to ensure compliance.

Laboratory owner John Collins, CDT, MDT, who recently had an FDA inspection, believes it was due to the fact that he’s registered as a U.S. broker for a foreign laboratory (which the FDA requires*). Well aware of the GMP regulations, Collins had implemented a number of procedures outlined in Dental Appliance Manufacturers Audit Scheme (DAMAS), a comprehensive quality management system developed in Britain and to which the NADL owns the North American rights.

“We’re not DAMAS-registered but we’re DAMAS-compliant so we had a lot of documentation and standard operational procedures in place. Fortunately, the inspection process went relatively smoothly for us and we didn’t have any violations,” says Collins, Cornerstone Dental Laboratories, Huntingdon Valley, Pennsylvania, who is working with a quality management consultant to further research compliance issues.

Dale Dental in Richardson, Texas was also inspected by the FDA. The May 2004 inspection occurred without warning; an FDA inspector simply showed up at the laboratory and spent the day talking with the facilities coordinator about the laboratory operations and its quality management procedures. “She returned the next day for further investigation and even came armed with a portable printer, and printed out a warning letter on the spot,” explains President Dave Lesh.

Dale Dental works exclusively with other laboratories and one of its services is to package small amounts of porcelain to be returned with its copings. Because the FDA has regulations as to how to repackage and relabel medical products, it cited the laboratory for several repackaging violations and gave Lesh 15 days to respond and explain how he was going to correct the situation.

Lesh hired a quality management consultant, Carter Thompkins, vice president, client operations, Integrated Management Systems, and with his assistance, is in the midst of becoming ISO 9000 certified. Although the process is extensive, time consuming and costly, Lesh feels it’s the best way to meet and perhaps even exceed the FDA’s 21 CFR Part 820 requirements and to avoid future FDA warnings and fines.

Both Collins and Lesh hired consultants because they felt it wasn’t clear cut as to how to comply with these regulations. First, as with many legal and government documents, it’s daunting just to

read the regulations (click here to read). Secondly, the regulations only outline objectives for a quality system that ensures good manufacturing practices but they don't specify methods that must be used to ensure compliance. In addition, not all of the 21 CFR Part 820 regulations are relevant to the dental laboratory setting. Therefore, it's largely up to the laboratory owner to figure out how to be in compliance. "The more you research, the more confusing it becomes because there is no definitive source that can tell you how to comply," says Lesh.

FDA guidance document

As part of its scrutiny of the industry, the FDA invited NADL representatives to a November 2004 meeting to discuss its concerns about ensuring public safety and its ability to monitor the materials used in foreign imports. "NADL representatives offered an overview of the industry, explained how laboratories operate and their relationships with the dentists, and reviewed the available self-guidance/certification programs such as CDT and CDL programs and DAMAS," writes Bennett Napier, co-executive director of the NADL, on its website, www.nadl.org. "The FDA also asked a number of questions about the industry, many of which were aimed at determining the volume of dental work that is being fabricated offshore and how it's being done."

The FDA is currently in the process of developing a guidance document clarifying its regulations regarding foreign dental laboratory registration requirements, QS/GMP requirements, material traceability issues, labeling and disclosure requirements, specific triggers which require domestic dental laboratory registration and a product code classification.

While some issues are being reviewed, the following regulations were confirmed during the FDA/NADL meeting:

All dental laboratories are subject to compliance with the FDA's Good Manufacturing Practice requirements and Quality System regulations outlined in Title 21 Part 820 of the Code of Federal Regulations.

All foreign dental laboratories shipping into the U.S. and U.S. brokers or agents for foreign dental labs need to register with the FDA.

All domestic and foreign laboratories that fabricate sleep apnea or snoring devices—or any other medical device that is not part of the core dental lab function—must register with the FDA as well as submit 510(k) pre-market forms for the product manufactured.

Laboratories outsourcing domestically do not need to register with the FDA.