Offshoring: One Company's Experience

By Gary Haberland

Throughout the past several years, along with growing, waning and sometimes renewed interest in offshoring, there has been a certain amount of confusion in the use of the terms "offshoring" and "outsourcing."

The difference is quite simple. Unless the business is totally self-sufficient and completely vertically integrated, *every business outsources.* It can be something as traditional as accounting services or something more technologically advanced, but it means contracting with a third party for certain tasks or functions.

Where the outsourcing is done leads us to the discussion of offshoring. At its simplest, offshoring can be defined as the relocation of business processes outside the originating country's borders. In other words, businesses in the United States can "offshore" processes to Canada as well to as any other part of the world, although it is more frequently understood to refer to countries such as China and India.

Many types of businesses offshore their processes, including software development, customer service and, in GENICON's case for a four-year period, medical device manufacturing.

GENICON's experience with offshoring

I sometimes say that I was "seduced" by the more attractive features of using an array of vendors located in various locations in China and Thailand. Foremost among these features was cost, as labor and materials were significantly less expensive at that time.

What we didn't realize – and this was a critical difference – is that while these offshore vendors were excellent at *duplicating*, they were much less effective at *replicating.* And, in an

industry such as ours, where human lives are in the balance and precision is king, "close" isn't good enough.

Let's look at how I distinguish between duplication and replication. When you make a photocopy, you are duplicating the original and there will be a certain amount of degeneration or loss of clarity and precision. Then if you copied that copy and continued the process, you would find the final copy to have lost a great deal of clarity. However, when I speak of replicating something, I mean creating another iteration that is so close to the original that it cannot be differentiated from it.

When GENICON manufactures its products, each must meet the same exacting specifications in terms of fit, form and function. Through our quality assurance processes, we expect 100 percent assurance that exact replication will meet our standards and FDA regulations. That is the standard we expected – but did not achieve – with our offshoring vendors.

When our field audits indicated a lack of exactitude, we took immediate action that included:

- Establishment of a vendor vigilance squad to review processes and products
- Initiation of more detailed inspection systems: recognizing that we could not take quality production on faith, we began to inspect 100 percent of items produced offshore. (Ordinarily, inspection would be done on a sampling basis, which dictates for specific industries what the acceptable quality level [AQL] is and the percentage of goods that must be inspected to meet AQL.)
- When we found that results were not meeting our standards, we spent a great deal of time and money to fix the problems and continued to work with these vendors. Our staff members were available day and night to manage the relationships and respond

to queries. I believe we were able to make a difference in the quality level of products our vendors manufactured, but it was not enough to satisfy our requirements.

- We then began the difficult and costly process of "reshoring" or "homeshoring," and expect to be producing 100 percent of our products in the United States by the end of 2012. Although we wish we could make the conversion quicker, this is an understandably slow process.
- GENICON now plans to have every stage of the manufacturing process – from raw materials and molding to component sub assembly, production, sterilization, packaging and shipping – done domestically. We are ISO 13485 certified, the standard for the design and manufacturing of medical devices that has been set by the International Organization for Standardization. We choose to work with other firms that meet this same level of certification.

Some final thoughts

Looking back, the offshore manufacturing environment was quite different when we made our initial decision. Inflation, shipping and labor costs were significantly lower. In addition, the Chinese government provided a 25 percent subsidy to their manufacturers, which allowed them to produce at even lower costs. That subsidy no longer exists.

We believe we made the right decision at that time with the data we had at hand. However, in the ensuing years, we realized the overall benefits were greatly diminished, while the margin for error grew. Had we been in another industry, we might still be offshoring, but when lives hang in the balance, we believed there was only one choice to be made, and that is what we did.

We've decided to share our experience in the hope that other manufacturers will think twice before leaving what we consider the "best in class" site for production – the United States.

Gary Haberland is CEO of Winter Park, Fla.-based GENICON (http://www.geninconendo.com), an emerging leader in the design, production and distribution of patented surgical instrumentation focused exclusively on laparoscopic surgery that he founded in 1998. GENICON products are now distributed to 44 countries around the world.

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