

## **Biopharmaceutical Manufacturing and Offshoring in Puerto Rico: Linguistic and Cultural Challenges**

Due to the pressures of bringing new therapeutics to market faster at a lower cost, pharmaceutical and biotech companies in the United States and Western Europe are outsourcing product development and offshoring their manufacturing needs to new markets around the world. Many developing countries offer a significant reductions in cost compared to the more economically developed nations.

Among the countries that offer lower manufacturing costs, a good track record and consistent quality determine the best candidates. Currently, the most prominent new offshoring locations include several countries in Asia (Japan, South Korea, Singapore, Taiwan, India, and China) as well as many countries in Europe (Poland, the Czech Republic, Slovenia, and Hungary), and Latin America, Mexico, and the Caribbean.

As offshoring in the pharmaceutical and biotech industries is becoming increasingly common, the factors that affect the success of manufacturing abroad must be well understood prior to establishing facilities around the globe. Several factors determine the offshoring capabilities in each country. Among the most important are a good existing infrastructure, reliable utilities, access to technical expertise, and compliance with regulatory procedures. Many countries have implemented current Good Manufacturing Procedures (cGMPs), providing greater quality assurance of biopharmaceutical products manufactured outside the United States and Western Europe.

### **Trends in Offshoring**

Trends in the biotech and pharmaceutical industries have also influenced growth in offshoring. In particular, the manufacturing of intermediates, Active Pharmaceutical Ingredients (APIs), and finished biopharmaceutical products is becoming a growing multinational phenomenon. Biotech medicines now account for 20% of marketed products, and 50% of products in clinical trials. Jan van Koeveringe, head of pharma global technical operations at Roche Basel, explained his company's latest activities as the following "Experience in biotech manufacturing will be a competitive advantage in the pharmaceuticals market of the future" (Van Arnum 2004).

India and China, countries strongly established in generics manufacturing, are both currently in the process of increasing their large-scale biologics manufacturing capacity (especially for biogenerics), and in several countries of Central and Eastern Europe, manufacturing of biogenerics is a growing enterprise.

The Caribbean island of Puerto Rico is another example. Previously well established in conventional small molecule, pharmaceutical manufacturing, Puerto Rico is currently expanding its biotech manufacturing potential.

### **Why Puerto Rico?**

According to research conducted by a banking investment company which specializes in cross-border business transactions between North America, Europe, and Asia, (Morgen, Evan & Company Inc. 2007), the major concerns of biotech and pharmaceutical companies related to offshoring in Asia include language barriers, cost effectiveness, and a long- distance work relationship. Reduced manufacturing costs in Asia may be offset by added costs from shipping, regulatory differences, and lack of infrastructure. Furthermore, because of the distance between Asian countries and the West, many companies have begun to look to Latin America and the Caribbean for offshoring alternatives. Language barriers have also played a major role in the selection of global manufacturing locations, despite the fact that many Asian countries are considered relatively bilingual.

Many Caribbean islands, such as Puerto Rico, Barbados, and the Netherland Antilles, offer low-cost, low-tax opportunities for manufacturing. Along with significantly lower labor costs, their geographic proximity to the United States, and coinciding time zones further distinguish these countries from other developing nations currently emerging as new locations for biopharmaceutical manufacturing. One Caribbean nation in particular, Puerto Rico, is already well established as an important offshoring location, particularly for U.S. pharmaceutical and biotech companies. Puerto Rico's close political and economic affiliation with the United States, in addition to its largely bilingual population, has made it a primary location for global manufacturing. However, some language barriers exist, even in Puerto Rico.

### **Advantages of Offshoring in Puerto Rico**

Puerto Rico provides many of the same advantages as other Latin American and Caribbean countries, along with several additional ones that can be attributed to its territorial status. As a result, Puerto Rico has become a major offshoring location for the production of biotech and pharmaceutical products.

The island is considered to be the world's fifth largest pharmaceutical manufacturing region after the United States, United Kingdom, Japan, and France. Furthermore, in addition to its role in manufacturing, Puerto Rico has also established its position as the world's largest international pharmaceutical distributor.

Various factors have contributed to Puerto Rico's prominent role in the global manufacturing of biopharmaceuticals. First, as a U.S. commonwealth, Puerto Rico operates under the security of U.S. laws for customs, federal currency, and intellectual property. It has the added advantage of being able to allow companies to waive federal taxes until their profits are repatriated. Furthermore, local taxes are relatively low (7%). Several other factors include an educated, bilingual workforce, a well-developed infrastructure, a good transportation system, a digital telecommunications system, and manufacturing facilities that operate under cGMP guidelines. Lastly, although Puerto Rico has the same labor laws as the United States wages are approximately 20% to 30% less than on the mainland (Brower 2004).

### Recent Changes in Puerto Rico

Recently, however, the pharmaceutical and biotech industries in Puerto Rico have undergone a transformation due largely to an increase in energy costs and changing tax rules. This has led to a trend to reduce the number of working manufacturing facilities in order to increase efficiency. As a result, biopharmaceutical manufacturing on the island has scaled back. Currently, more than 60 pharmaceutical and 65 medical devices manufacturing facilities are located on the island, representing some of the most prominent companies in the industry. However, over the past few months, five major drug manufacturing plants have either closed or announced plans to do so (Melia 2007). Further plans to cut back manufacturing facilities have been reported (Barnes 2008). Local tax breaks will continue to provide some advantage to foreign companies (including U.S. companies) in the area for now. With an established network for biomanufacturing already on the island, Puerto Rico still produces many of the top-selling U.S. pharmaceuticals including Lipitor and Viagra, and it is seeking future solutions to the changing environment.

A recent shift to increase the size of the biotech industry by offering tax break incentives has helped to offset the trend to decrease manufacturing in the area. The government promotion of the biotech industry has greatly facilitated growth in biotech manufacturing.

In fact, the growth of the biotech industry in Puerto Rico is reportedly second only to San Diego, California. (San Diego specializes in biotech research & development, while Puerto Rico specializes primarily in the manufacturing of pharmaceutical products, biologics, and medical devices).

### **Issues of Language in Puerto Rico**

Although it is a U.S. territory, Puerto Rico shares both language and, to some extent, cultural traits with parts of Latin America and the Caribbean. Thus, despite the fact that both English and Spanish are the official languages of Puerto Rico, many manufacturing employees are not adequately fluent in English. To ensure compliance with manufacturing regulations, employees must have a clear understanding of the procedures that they are expected to perform. It is therefore required that all manufacturing Standard Operating Procedures (SOPs) be translated into Puerto Rican Spanish. In addition, all regulatory documents must be translated into English for FDA approval of manufacturing procedures (cGMPs).

The translation is not always as straightforward as one might expect, however; well-qualified translators familiar with biopharmaceutical manufacturing terminology are needed in order to avoid potential pitfalls. In addition, plant managers should conduct standard periodic visits in the presence of a well-trained native interpreter so that employees' concerns or issues can be effectively addressed. Most experienced managers already know that offshoring in most of the developing world involves using local interpreters for plant site visits. If the language barrier is not addressed, however, numerous problems can arise including production delays, unexpected changes in manufacturing SOPs, and noncompliance with cGMPs. Ultimately, all these factors directly affect the quality of the product being manufactured.

### **Translation Challenges**

The translation of manufacturing SOPs has many linguistic challenges leading to significant problems if not addressed. Simple phrases used in SOPs, such as placing a gasket “face up”, can cause unexpected confusion, as experienced by a biopharmaceutical manufacturing translator in Puerto Rico (Catesby Jones 2004). For a part such as a gasket to be face up, it must have a face (an expression that works best in English). Instead of the word face, a description in Spanish of how a gasket should fit once it is in place is a much more effective way of communicating the task. This example is typical of how a direct translation does not adequately provide clarity of the intended meaning.

Another example of potential miscommunication resulting from the direct translation of terminology is the phrase “checking for leaks” (in the equipment). When this phrase is directly translated into Spanish, it literally means to make sure that there are leaks. Although employees may find this request slightly amusing, it reflects the importance of accuracy in translation.

There are many examples of difficulties with translating SOPs in pharmaceutical and biotech manufacturing that include terms formulated in English which have no equivalent in other languages. Such common production techniques as “to pipette” or “to centrifuge” cannot always be easily conveyed in languages other than English. In Spanish, for example, the verb centrifugar (to centrifuge) already exists, but pipetear (to pipette) does not.

These examples clearly demonstrate the linguistic challenges that must be overcome. Localization experts and native Spanish-speaking translators who are educated in pharmaceutical and biotech manufacturing SOP and GMP terminology are best equipped to overcome any such barriers. However, effective communication with U.S. counterparts who originated the manufacturing protocols also plays a key role in addressing these language issues.

## **Cultural Differences**

Puerto Rico has a rich mixture of cultures. It shares most of its cultural traits with nearby Caribbean nations such as Cuba and the Dominican Republic, although attempts to conform to some U.S. customs are evolving. An understanding of the culture provides insight into the people who live and work in Puerto Rico, and is necessary for ensuring the success of offshoring on the island. Cultural differences in Puerto Rico and the United States determine business management styles and expectations in each country. One study that compares cultural attitudes in several countries, including the United States and Puerto Rico, found that differences in the definition of leadership and teamwork in multinational organizations were ultimately influenced by the local culture (Gibson 1998). For example, in Puerto Rico cultural attitudes dictate the need for a greater distance between managers and employees, whereas in the United States managers and employees tend to work more closely together.

## **Conclusions and Recommendations**

According to several sources, 30% of companies responsible for the development of biological products are currently involved in offshoring. The majority of pharmaceutical, biotech, and medical device companies that are not

offshoring their manufacturing needs are in the planning stages. With the standardization of manufacturing procedures and lower cost incentives in many developing countries, the trend toward globalization will continue to grow. Thus, an awareness of the language and cultural factors that affect the success of offshoring abroad will become increasingly more important. As with all outsourcing in non-native English-speaking countries, effective native language communication in particular will play a major role in overcoming potential communication barriers

In Puerto Rico, where significant pharmaceutical, biotech, and medical device manufacturing has already been established, these issues can be overcome as long as they are addressed with expert translation and localization strategies. Once a good translation system is established, the consistency and quality of the product being manufactured can be ensured.

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## References

1. Van Arnum, Patricia. 2004. "Biopharmaceutical Manufacturing Leads Capital Investment". *ICIS News*; December 6.  
<http://www.icis.com/Articles/2004/12/03/633737/biopharmaceutical-manufacturing-leads-major-capital-investment.html>
2. Morgen, Evan & Company, Inc. 2007. "Biopharmaceutical Contract Manufacturing" Outlook 2007. Industry Report.  
<http://www.audonpartners.dk/documents/pdf/BiopharmaceuticalContractManufacturing-Outlook2007.pdf>
3. Harryman, Roy. 2004. "Caribbean Locations Bring Offshoring Close to Home". *Expansion Management*; December 5  
<http://www.expansionmanagement.com/cmd/articledetail/articleid/16201/default.asp>
4. Potera, Carol. 2007. "Puerto Rico Views Itself as a Bio Island. With the Benefits of Offshoring and U.S. Law, Commonwealth Island Is Manufacturing Hub". *Genetic Engineering and Biotechnology News*; February 1 (Vol. 27, No. 3).  
<http://www.genengnews.com/articles/chitem.aspx?aid=2007&chid=4>
5. Brower, Vicki. 2004. "Going global in R & D". *EMBO Reports*; April (Vol. 5, No. 4): 333-335. <http://www.nature.com/embor/journal/v5/n4/full/7400135.html>
6. Puerto Rico. "The Advantages of Going Offshore". The Security of Being Home. *PRIDCO Overview*; [www.pridco.com](http://www.pridco.com).
7. Melia, Michael. 2007. "Puerto Rico's Pharmaceutical Industry 'Terminally Ill'". *Manufacturing.Net*; November 19.  
<http://www.manufacturing.net/Pharmaceuticals-Leaving-Puerto-Rico.aspx>
8. Barnes, Kirsty. 2008. "BMS mothballs another Puerto Rican Plant". *Outsourcing-Pharma.com*; January 22. <http://www.outsourcing-pharma.com/news/ng.asp?n=82702-bms-puerto-rico>
9. Catesby Jones, Anne. 2004. "Translating SOP's in a Pharmaceutical Manufacturing Environment". *Accurapid*; April (Vol. 8, No. 2).  
<http://www accurapid.com/journal/28biomeda.html>
10. Gibson, Cristina. 1998. Intercultural Analysis of the Meaning of Teamwork: Evidence from Six Multinational Corporations. Paper presented at the Academy of International Business Conference, Monterrey, Mexico, 1997.

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