

# Born in the U.S.A.?

## THOUGHT LEADERS

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### DR. ADEL SAKR

In the United States, a research scientist with a Ph.D. degree has a starting salary of \$65,000 to \$70,000. **A COMPANY COULD HIRE 10 PH.D.S IN INDIA OR 20 PH.D.S IN CHINA FOR THAT AMOUNT OF MONEY.**

Pharmaceutical companies have found success in the offshoring of manufacturing, IT, data management, and clinical-trial operations.

## WILL DISCOVERY BE NEXT TO BE SHIPPED OVERSEAS?

**D**rug discovery symbolizes the birth of a pharmaceutical product and is the first step in its development. Drug discovery also is the latest area to be a considered for cost-cutting offshore measures. Experts believe that this area of the drug-development process will remain primarily in the United States in the near term because of intellectual property concerns in developing countries, the pull of the strong academic community in United States, and cultural issues. But, as pressure on the bottom line grows, pharmaceutical companies have begun exploring the strategy of taking discovery off-

shore to take advantage of talent overseas, as well as the associated lower labor costs.

Recent drug-discovery collaborations with companies based in India by GlaxoSmithKline and Novartis (see box on page 16) are good examples of how companies are starting to look overseas for some discovery support.

Experts also have observed that U.S. pharmaceutical companies are starting to consider establishing their own discovery facilities and laboratories in offshore locations, which could possibly provide them with more intellectual property protection.

### EXPLORING THE POSSIBILITIES

*Industry experts have observed that pharmaceutical companies have begun exploring the strategy of offshoring the drug-discovery process as a cost-saving measure and for increased efficiencies.*

**STAMOS.** During the last five years, companies have been exploring offshoring discovery more and more. Early on, many companies explored this strategy but few tried it because there were too many unknowns. But with the

trend toward more personalized medicine and large-molecule drugs that are oriented toward a smaller population base, pharmaceutical companies have to look very closely at the costs of developing drugs, and this has to be done in the preclinical as well as the postclinical environment.

**SRIVATHSAN.** Companies are doing everything possible to bring down costs, but currently I have not witnessed much offshoring happening in the discovery arena. Most of the

offshore activity is in the development space, such as clinical trials and to some extent toxicology studies. But the core discovery — where the compounds are created through high-throughput screening, chemistry, genomics data — to a large extent is still happening in the United States. There is a lot of talk, however, about companies wanting to move discovery offshore primarily because they believe countries such as India and China have vast pools of well-trained talent, but the movement is not very large yet.

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**DR. CRAIG DEES**

**When offshoring discovery, a company might bring its costs down, BUT BECAUSE OF CULTURAL DIFFERENCES, PRODUCTIVITY MAY ALSO DROP.**

**SINGH.** There are a number of factors that are changing the industry's mindset regarding drug discovery. The No. 1 issue is the profit pressures that continue to escalate for pharma companies. Companies are looking for low-cost ways to do everything. This is simply a continuation of the trend we have seen over the last four to five years. Now companies are digging deeper into their cost base and their comfort zone to evaluate what else they are willing to offshore.

**SAKR.** The whole reason the pharmaceutical industry is looking to offshore functions is cost. For a product to reach the market it takes 10 years to 15 years and it costs between \$800 million and \$1 billion. The most difficult part of the process is finding a drug entity that has a useful therapeutic effect with minimum or no side effects. Scientists will synthesize about 50,000 compounds, so that after five to 10 years a company can have five candidates to bring to clinical trials, and then maybe in an additional five years, it can bring one product to market. It is a long process and very, very expensive.

**ROCCI.** The pharmaceutical industry as a whole is faced with the challenge of reducing the total cost of bringing new drugs to market. Research and development costs are a significant expense for pharmaceutical companies and reducing these costs will help to attenuate further increases in prescription drug prices.



**ASHISH SINGH**

**Now the industry is coming to the point where SOME OF THE HARDER QUESTIONS ARE BEING ASKED as to what to offshore and what not to offshore.**

**VOGEL.** A company in the United States and its partner on the other side of the world can basically be working 24/7. For example, in the case of outsourcing data management to India, when a sponsor and CRO in the United States go home at night, the people in India are starting to work and can transmit data back to the United States that same night. The sponsor and CRO receive the information the following morning. That is a tremendous advantage in time as well as cost.

**ADDRESSING THE BARRIERS**

*Companies need to balance several factors when considering moving their drug-discovery activities offshore, including intellectual property (IP) concerns, as well as language and cultural hurdles.*

**BEEVER.** Initiatives to move drug discovery offshore have lagged some other functions because so much intellectual property is created during the process. Companies have been reluctant to offshore discovery, particularly to countries such as India where intellectual property isn't always as respected as it is elsewhere. Nevertheless, if the floodgates haven't opened yet for this sort of activity, there certainly is more interest than there was four or five years ago.

**SINGH.** Pharmaceutical companies are starting to explore offshoring that relies less on local partners and are looking to set up their own operations in foreign countries. This gives them a level of comfort that they didn't have before and allows companies to access the local talent pool and keep the proprietary knowledge in house.

**SRIVATHSAN.** From an intellectual property point of view, the activities that pharma has

Though drugs comprise a relatively small percentage of each healthcare dollar spent, reducing the expense of researching and developing pharmaceutical products will contribute to containing increases in healthcare spending.

**SAKR.** If the company has access to the same equipment and facilities overseas that exist in the United States, then salary is the main factor when deciding to move operations offshore. If a pharmaceutical company hires a Ph.D. right out of school to work in the discovery area, it will cost about \$70,000 for that scientist, not including a benefits package of about 50% of the salary. In India, that same \$100,000 can be used to hire more than 10 people.

**STAMOS.** An example of cost savings coming from my previous experience is that the fully loaded cost of an engineer in the United States is about \$180,000 a year; the fully loaded cost of an equivalent offshore resource is \$60,000 a year. The cost savings are phenomenal, and that obviously has bearing on any organization that is looking to become profitable.

**SRIVATHSAN.** A major driver behind outsourcing discovery work is that there are too many drug targets to chase. Obviously, it is faster and cheaper to have discovery done outside the United States. But the question is, how much of this activity will move offshore?

## Managing Risk in Pharmaceutical Offshoring

PHARMACEUTICAL COMPANIES HAVE OFFSHORED VARIOUS ASPECTS OF THEIR BUSINESSES, FROM CLINICAL TRIALS TO MANUFACTURING, FOR YEARS.



Bill Gargano

Companies can achieve the benefits of offshoring by managing the complexity that is often involved in outsourcing a project and by understanding the risks and rewards involved and planning accordingly.

Yet, while signs point to outsourcing as a continued growth trend, industry analysts report that many offshored projects do not go according to plan. Clearly outsourcing can have major benefits, including cost savings, greater access to global markets and talent, and improved labor productivity. So how can companies achieve these benefits while managing the complexity of outsourcing a project? The answer starts with understanding the risks and rewards involved.

### MANAGING RISK

An offshore project should begin with a readiness assessment. This means evaluating the risks and opportunities as they relate to the company's needs.

### THE FIVE MOST COMMON RISK AREAS ARE:

- **Project Management:** Risk that the company is not familiar with the processes for managing expectations and deliverables in a distributed development environment.
- **Internal:** Risk that antagonism within the organization would disrupt the project.
- **Financial:** Risk that cost would exceed budget or that the project would not deliver anticipated benefits.
- **Technical:** Risk that the scope of the project would be beyond the technical capabilities of the hardware, software, or available personnel.

- **Security and Compliance:** Risk that company data or business continuity would be compromised.

Any assessment should evaluate such issues as the total cost of ownership, project complexity, the maturity of internal and partner infrastructure, the critical nature of the project or process to be outsourced, and the project's dependence on key personnel. Through this, managers should gain a comprehensive picture of the offshoring possibilities for the company.

The most effective functions to offshore are those that carry relatively low risk and a high rate of return. For example, if a company is evaluating whether to outsource IT projects, it might consider the consolidation of legacy applications or application testing as areas to explore. Functions with a manageable degree of risk, such as a technical help desk, are also worth considering because they can have a higher return. Managers must make sure that their outsourcing partner creates the documents and audit trails needed to ensure that compliance (i.e., Sarbanes-Oxley, 21 CFR Part 11, and HIPAA) is maintained.

### CHOOSING AN OFFSHORING PARTNER

An offshoring partner must be able to help a manager make decisions based on a project's specific technical requirements, security, and compliance needs; completion schedule; and cost goals. Also, an offshoring partner must have a stable workforce, with minimal turnover per year. Additionally, a partner must have the experience to help navigate the cultural issues that can potentially impede work. Ultimately, however, a company must be able to manage its internal projects well if it is going to succeed in an offshore environment, regardless of its partner.

By planning properly and choosing the right partner, managers can preserve resources and free employees for core business functions, while reaping the benefits of the global marketplace for their company.

Source: RCM Technologies, Pennsauken, NJ. For more information, visit [rcmt.com](http://rcmt.com).

moved offshore are those where IP is not a concern. The tactics used to protect IP have not yet been demonstrated in India and China. And until such time as this area is addressed, I would expect the bulk of offshored work to be in IT, some in data management, and a very small percentage in discovery.

**VOGEL.** The United States has very effective intellectual property laws and good patent protection. Companies do not risk losing proprietary information in the United States, and that is attractive.

**STAMOS.** There is significant risk to strategic intellectual property in offshoring discovery work since the crown jewels are molecules likely stored in ChemDraw files. For example, one ChemDraw file can hold a drug discovery jackpot. It is also much more difficult for companies to protect against insider theft, since one can bring in a pen and draw out molecules and take it or just memorize it. For other areas of the process, clinical trials for example, there is concern about theft of a clinical-trial protocol, but it is not viewed as the crown jewel.

**BEEVER.** Distance and language are definitely barriers to offshoring. The discovery process tends to be highly interactive and customized. Communication is more important in discovery work than it is in some of the more routine areas of the development process.

**STAMOS.** Differences in language and culture can be very difficult to coordinate and manage in a remote environment. In India, the language barrier is not the problem, but there are significant cultural barriers that need to be addressed. For example, in the United States, if people working on a project noticed that something was wrong, they would alert their supervisor and initiate a course correction. In India, there is a tendency not to question authority. So if people are charged with delivering on a milestone, even if they understand that something is wrong, they still will deliver on that goal as mandated by their manager. This makes actual realized savings very elusive with offshore outsourcing.

**DEES.** There are a number of instances where

**DR. MARIO ROCCI**

**IT MIGHT BE EASIEST INITIALLY TO TRANSFER DRUG-DISCOVERY ACTIVITIES OFFSHORE** since they are not subject to the same degree of regulations as development activities.

Americans have problems working in European countries. I have worked overseas before where I worked at night and on weekends. The local staff was invisible; they were not as aggressive, and Americans don't understand this attitude.

**SAKR.** Everything is global now, especially with the Internet, and companies can communicate with anyone in the world. Scientists in India and China are not less educated than those in the United States. So a major issue is the facilities in these countries and compliance with the FDA guidelines and cGMP. Currently India and China are beyond our reach because of the issue of cGLP for discovery and for labs. But if a company makes the proper investments, cost savings can be achieved in the long term.

**DEES.** Technical resources are a challenge to discovery offshore. The United States has a very disposable culture. A simple example of this is in the lab. We can go through thousands of \$2 to \$3 disposable pipettes while doing tissue cultures to test drugs. I worked with someone from Russia who adamantly opposed this process. Using disposable pipettes I could run the experiment in a few hours; it took her significantly longer. It is this type of difference in the tools and culture that slows things down.

**THE ACADEMIC CONNECTION**

*The United States remains an appealing location for drug discovery for many reasons, the most prominent being the strong relationship between the pharmaceutical industry and the U.S. academic community.*

**SRIVATHSAN.** Most biotech activities, especially those in the discovery phase, need proximity to large academic institutions. In the United States, Boston and San Diego are biotech hotbeds because of their academic institutions. A country such as India has fabulous academic institutions, and the quality of people who graduate from there are phenomenal, but the activity at these institutions is not on par with what is happening with their academic counterparts in the United States. The type of support that biotech activity would receive in India or China is far less than in the United States. Therefore, biotech companies will want to keep most discovery activities in the United States.

**BEEVER.** To offset discovery activities moving offshore, the U.S. government needs to make sure that the university system continues to be healthy. The United States has to continue to cultivate people who have the skills and capabilities needed by research companies.

**STAMOS.** The biggest advantage the United



**DR. JOHN VOGEL**

**THE OFFSHORING TREND IS BEING DRIVEN BY sponsor needs: the need to get trials started faster; the need to find patients; and the need to reduce costs.**

**Number of U.S. jobs moving offshore by job category, 2003-2015**

	2003	2004	2005	2006	2007	2008	2010	2015
<b>MANAGEMENT</b>	3,500	15,000	34,000	42,000	48,000	64,000	106,000	259,000
<b>BUSINESS</b>	30,000	55,000	91,000	105,000	120,000	136,000	176,000	356,000
<b>COMPUTER</b>	102,000	143,000	181,000	203,000	228,000	247,000	322,000	542,000
<b>ARCHITECTURE</b>	14,000	27,000	46,000	54,000	61,000	70,000	93,000	191,000
<b>LIFE SCIENCES</b>	300	2,000	4,000	5,500	6,500	9,000	16,000	39,000
<b>LEGAL</b>	6,000	12,000	20,000	23,000	26,000	29,000	39,000	79,000
<b>ART, DESIGN</b>	2,500	4,500	8,000	9,000	10,000	11,000	15,000	30,000
<b>SALES</b>	11,000	22,000	38,000	47,000	55,000	67,000	97,000	218,000
<b>OFFICE</b>	146,000	256,000	410,000	475,000	541,000	616,000	815,000	1,600,000
<b>TOTAL</b>	315,000	540,000	830,000	960,000	1,100,000	1,200,000	1,700,000	3,400,000

Note: Numbers have been rounded.

Source: Bureau of Labor Statistics, Washington, D.C. For more information, visit [bls.gov](http://bls.gov). Forrester Research Inc., Cambridge, Mass. For more information, visit [forrester.com](http://forrester.com).



A. SRIVATHSAN

**THERE IS A LOT OF TALK ABOUT MOVING DISCOVERY WORK OFFSHORE** because of the talent pools in countries such as India and China, but there is not a lot of movement yet.

States has is a research environment that is connected to top universities. Many R&D facilities are being opened near universities to take advantage of Ph.D.s these schools are producing.

**SINGH.** Many of industry's collaborations with academia are on the biology side, and less on the chemistry side, so the impact of offshoring in the near term is going to be somewhat mitigated because of these types of collaborations. But, over time, if companies do start to offshore on the biology side there will be some impact.

**SAKR.** A very large percentage of the pharmacy graduate student population in the United States is from India and China. In my 20 years I know only of one case where a student went back home to work. A very large percentage of the students who come to the United States from these countries want to work here because there is a better quality of life.

**SRIVATHSAN.** Oftentimes R&D spending is fueled by government policy and tax issues. The government gives a lot of tax credits for R&D, which act as an incentive. But at the end of the day what the United States offers is a society that is excited by change and has an entrepreneurial drive, and these are factors that are the key to retaining dominance in these fields.

**BEEVER.** There are three factors that drive the

## Brave New World

**TWO MAJOR PHARMACEUTICAL COMPANIES HAVE ENTERED INTO DRUG-DISCOVERY COLLABORATIONS WITH COMPANIES IN INDIA, MARKING WHAT EXPERTS SAY IS THE BEGINNING OF THE INDUSTRY'S EXPLORATION OF CONDUCTING DISCOVERY OFFSHORE.**

**IN OCTOBER 2003**, Ranbaxy Laboratories Ltd., India's largest pharmaceutical company, and GlaxoSmithKline Plc. (GSK) entered into a drug-discovery and clinical-development collaboration covering a wide range of therapeutic areas. Ranbaxy is responsible for activities ranging from the optimization of a lead compound to the generation of a development candidate, with leads provided by either GSK or Ranbaxy.

**FOR A PROPORTION OF THE CANDIDATES** selected within the collaboration, it is expected that Ranbaxy will conduct early clinical work. Once a compound has been selected as a development candidate, in most instances GSK will complete development. GSK has the exclusive commercialization responsibilities worldwide, while Ranbaxy and GSK will comarket in India. Ranbaxy, with the consent of GSK, may copromote in the United States and European Union.

According to Rick Koenig, R&D communications for GSK, the drug-discovery collaboration with Ranbaxy is one of several such arrangements that GSK has established to supplement its drug-discovery activities.

"Like all the other collaborations, this partnership enables GSK to spread the risk of drug discovery by offering to share the reward of successful projects," he says. "GSK has large front-end discovery capabilities in target identification and compound screening. The Ranbaxy collaboration helps us to move discovery forward through subsequent steps, specifically, to advance hits from screening to lead compounds ready to enter the clinic, or sometimes even to take the compounds into early clinical studies."

**GSK HAS ENTERED INTO SIMILAR COLLABORATIONS** with companies in Japan, Denmark, and the United States, as well as with universities. Mr. Koenig says these collaborations do not take the place of what the company is doing in-house but rather complement GSK-based activities.

"Even a large pharmaceutical company doesn't have all the best ideas and talent," he says. "We must avail ourselves of the good work that is going on elsewhere as well as in our own laboratories."

In September 2004, Syngene International, a subsidiary of Biocan, one of India's leading biotechnology enterprises, entered into a contract research agreement with the Novartis Institutes for Biomedical Research to carry out research projects to support new drug discovery and development.

"We have an aggressive program to seek the best collaborations worldwide," says Dr. Jeremy Levin, global head of strategic alliances at the Novartis Institutes. "Our desire is to develop strong alliances with world-class scientific programs in India, and the relationship with Syngene, and its parent Biocan, offers such an opportunity."

According to A. Srivathsan, director of the healthcare practice at Marlabs, these types of collaborations are difficult for many companies to enter.

"Deals in India, such as GlaxoSmithKline/Ranbaxy and Syngene/Novartis, are random droplets," he says. "Other companies in developing countries will find it difficult to replicate these types of arrangements. Many companies in developing countries will not be able to accommodate the scale necessary for a U.S. company."

Source: GlaxoSmithKline, Philadelphia. For more information, visit [gsk.com](http://gsk.com). Biocan, Bangalore, India. For more information, visit [biocon.com](http://biocon.com).


**CHARLEY BEEVER**

**IP HAS BEEN A BIG BARRIER and it is because of this concern that discovery has not been offshored to the extent of some of the other areas.**

United States' success in terms of biological sciences and pharmaceutical discovery research. One is the United States has first-class universities that produce the people who can do the work. The second is the availability of venture capital, which funds a lot of the start-up biotech companies that create jobs. The third is the NIH; the government funding of research under the NIH umbrella is something the Europeans are trying to duplicate.

**ROCCI.** There are substantial domestic efforts in emerging fields of discovery from within and outside of the pharmaceutical industry. These combined efforts, in many instances, have synergized to advance technologies. Offshoring of drug-discovery efforts may make these synergies more difficult to realize, though it is hard to predict at this point whether dominance in these fields would be compromised.

**DEES.** Discovery work in the United States benefits from the resources of other companies, assets, and people that exist in cluster environments. Without that cluster of resources, work would slow down.

### WHAT THE FUTURE HOLDS

*Industry experts predict that the majority of discovery jobs will remain in the United States in the near term, while companies continue to evaluate opportunities for other areas.*

**DEES.** I don't believe the United States is in any danger of having discovery activities move abroad. The more routine tasks will continue to move overseas, but discovery will remain here for the foreseeable future. The United States has the equipment and technology for research and development that other countries don't.

**BEEVER.** There is a tendency to think that a company can offshore everything. But a lesson learned from other sectors is that a company has to offshore selectively, and the criteria that makes offshoring succeed differs by function. It is not an all-or-nothing proposition; it is a matter of being thoughtful and selective about what is outsourced. There has been discovery research

going on in Europe and Japan for a long time, but when we say offshoring, it really means outside the major developed countries. Until very recently, the capability needed to do discovery work hasn't been present in a lot of countries outside those developed economies. I believe that in the long term, some drug discovery and a significant proportion of drug development could migrate offshore. I do not believe that this will have a major near-term impact on the pharmaceutical industry in the developed world, but it might put some constraints on opportunities for research scientists.

**SINGH.** We are in contact with some companies that have expressed a desire to explore this avenue of offshoring. And some companies are investing in their own facilities in countries such as India and Singapore.

**BEEVER.** Companies are offshoring to foreign companies, and they are setting up their own facilities and laboratories overseas. But there are sometimes issues associated with U.S. companies setting up their own facilities. For example, in some countries, nonlocal companies may find it difficult to attract top talent.

**STAMOS.** The trend is going to continue for companies to offshore IT first. At the end of the day, although there is risk with anything that a company decides to offshore, there is less risk in the IT arena, where protecting information and the data sets is better understood.


**NICHOLAS STAMOS**

**Discovery is not as easy to offshore as IT. THERE IS NO COOKBOOK ON HOW TO DISCOVER A DRUG; SO MUCH OF IT DEPENDS ON THE DISCOVERY AND RESEARCH METHODOLOGY WITH NO COMPARATIVE SUCCESS CRITERIA. In the IT world, when it comes to developing a project, there is a known, defined process, and there is a clear project plan.**

**VOGEL.** There is more interest in drug-discovery issues, such as offshoring various types of analytical work. For example, companies are looking for laboratories that have the necessary analytical techniques and how they can derive value from those techniques. Analytic services are becoming a more important part of drug discovery because sponsors are trying to reduce the risk associated with developing new drugs.

**ROCCI.** Companies might find it easier initially to transfer drug-discovery activities offshore, since they are not subject to the same degree of regulation as development activities. Once a new chemical entity reaches development stages, compliance with GXP regulations becomes necessary, and it may take some time for the appropriate systems to be developed to ensure compliance and integrity of the work performed in a development setting. ♦

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