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The promise of the East: India and China as R&D options

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The East provides increasing opportunities for biotech companies seeking to optimize product development and accelerate time to market. But any undertaking in China or India requires close scrutiny of the risks.

Small to medium-sized enterprises (SMEs) in the biotech sector face a long, arduous journey toward successful commercialization of early-stage products. To get their products to market more efficiently and to realize their true commercial potential, biotechs are looking for new resources to tap for a productivity boost, and for new markets for their products.

If pursued wisely, one of the most promising and practicable solutions is the sourcing of selected tasks to Asia, particularly to India and China. Both countries have already attracted considerable investment and involvement from pharma multinational corporations and could provide smaller biotechs with comparable opportunities. Consider some of the potential advantages: a huge and inexpensive talent pool (each country produces annually more than three times as many chemistry graduates as the US does), including an increasing number of Western-trained returnees; a vast patient population available for clinical trials; strong government support for biotech, both through investment (as in science parks) and through policies (such as tax concessions); and increasing private-sector funding and involvement. By making shrewd use of these attributes, and actively working to manage the risks, your biotech could conduct operations in a leaner, more cost effective and perhaps faster way.

There are dangers, however, and a considered approach remains the watchword. First, any involvement in the region should be undertaken as part of a global R&D strategy, not as *ad hoc* and opportunistic forays. Then, you need to think of a regional strategy, not a country-specific strategy: the opportunity is a matter of China *and* India, not China *or* India. You need to consider that the offshoring process, though designed to ease the challenges and expenses of R&D, labors under its own set of complexities and inefficiencies. Although some opportunities will likely suit your company, others, equally appealing, might not, so you need to make precise evaluations each time. And even the surest opportunity involves possible risk—most notably the risk to intellectual property (IP) and the chance of delays through red tape. Biotech SMEs may have more to lose with offshoring than a large pharmaceutical concern does, as they may lack the scale to tolerate IP theft or the failure of an outsourcing venture. They can also ill afford the diversion of internal resources to find the right set of sourcing partners or opportunities. The potential benefits do look increasingly viable, but at this point they remain more potential than proven.

If you are seriously considering outsourcing to India or China, you need to start moving toward an integrated and effective strategy. There are three key issues to consider when doing so: your motivation in investing, the location of investment and the risks inherent in the activity.

Motivations for investment

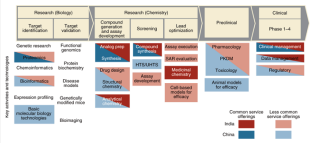
The four likeliest motives for offshoring work to China and India are saving on R&D costs, reducing capacity bottlenecks, accessing talent and increasing market access. When broaching a strategy, you first need to clarify what weight to give to each of these motives. And then you need to assess how the available Indian and Chinese opportunities measure up in each case.

The advantages of cost cutting go without saying, but offsetting them are the dangers inherent in any form of outsourcing: the possible need for greater supervision, and the potential for slower and lower-quality output. Reducing capacity bottlenecks is particularly advantageous for resource-strapped firms; by offshoring lower-priority projects, they can concentrate on higher priorities. Similarly, accessing talent to fill gaps as needed should give biotechs the freedom to concentrate on their core strengths. As for increased market access, the advantages again go without saying. Although the market is currently modest, its potential is very sizeable.

Locating the investment

Although India and China both offer outsourcing opportunities across all phases of the innovation value chain, the capabilities are uneven, and some of the more complex activities remain out of reach (see Fig. 1). But don't make any assumptions: new skills and resources keep coming online. A year ago, you would scour both countries in vain for preclinical services of US Food and Drug Administration/good laboratory practice (GLP)-quality; today, Bridge Pharmaceuticals in Beijing, or CDRI in Lucknow, India, will be happy to oblige. And if you need target discovery or validation, you could try various providers in Zhangjiang Life Science Park near Shanghai, or Triesta Sciences in Bangalore.

Figure 1: Indian and Chinese partnering opportunities along the R&D value chain.



HTS/UHTS, high throughput screening / ultra-high throughput screening; SAR, structure-activity relationship; PKDM, pharmacokinetics and drug metabolism

Though less advanced overall than vendors in the developed world, Asian vendors have a clear advantage when it comes to price, offering cost savings of at least 60% in many areas, such as basic chemistry or clinical trials. Just make sure each time that those cost savings aren't going to be canceled out by extra administrative expenses on your side, or lower productivity on the provider's. With the right provider, you should be able to ease some of your pipeline bottlenecks and capacity constraints at a stroke.

Which country to choose for any particular activity or project? And which to give greater emphasis to when devising a strategy? As things stand today, India's greatest value is in giving you quick access to specific drug-development resources, so it might prove the better bet if your priorities are shorter time frames, easy setup, rapid results and very high cost savings. China's main attraction is in potentially strengthening your foothold in its huge and fast-growing biopharma market, so if you have a particularly commercial agenda—developing government contacts, for example, with an eye to increasing market access—you would probably opt for China. And if you have a longer time frame, you might also favor China, and pursue lengthier projects there through an alliance partner, perhaps one of the prestigious government-funded research institutes.

But a fully rounded strategy will leverage the assets of both countries, rather than just one of them, taking full advantage of their differences. In capabilities, China is considerably ahead in biology, though still at a modest level compared to developed nations standards. Chinese scientists participated in the Human Genome Project, and have made some notable advances in gene therapy and stem cell work. In 2003, Shenzhen-based SiBiono GeneTech was granted the world's first license for a gene therapy medication. In chemistry, on the other hand, India arguably has a solid lead, with some vertically integrated suppliers now able to offer end-to-end services.

As for clinical trials, India once again is quicker off the mark, with contract research organizations typically able to secure approvals and get launched within 3 to 4 months, against a norm of 9 to 12 months in China. India also possesses superior strengths in information technology–dependent areas, most notably biostatistics and clinical trials data management.

There are also some broader considerations. India has the unquantifiable benefit of very high proficiency in the English language. And arguably, its managerial and scientific/educational culture is more Westernized than China's—more open to breaking with tradition and more innovation minded. That said, Chinese scientists with advanced training from Western institutions are returning at ever-increasing rates, often to take management positions at Chinese biopharma companies.

What's more, China has the distinctive strategic benefit of increased commercial potential for biotech products themselves (see Box 1). Companies that invest in China stand to enhance their commercial prospects by impressing doctors, key opinion leaders and officialdom. By

raising technology standards in the country, R&D investors will earn government goodwill that could raise their chances of expedited approvals and easier market access.

The risks, singly and jointly

On the downside, there are risk factors specific to each of the two countries. If operations are ever disrupted by workforce disputes or animal-rights activists, that would be in India; if by government interference, that would more likely be in China. The infrastructure is also far more reliable in China; India still suffers from interrupted power supplies, antiquated ports and inadequate highways in many regions. China's GLP standards are still evolving, and lag behind those of India—with few labs in either country being internationally GLP-approved. And the bureaucratic hurdles differ: the Indian authorities grant approvals for clinical trials far faster than their Chinese counterparts. But at the preclinical stage, Indian regulations are particularly stringent, making it difficult for laboratories to source genetically modified animals and to import and export human tissue or blood samples.

Viewed more broadly, the main risks apply to both countries: red tape and insecure IP. In each case, the two governments have taken corrective steps, easing the bureaucratic constraints and tightening the IP statutes. How these measures translate into reality isn't yet clear. There are cultural and human factors at work, not just regulatory ones. Western ideas of urgency and privacy may take some time to permeate. Although laws that approach Western standards now exist, their enforcement in the realm of biopharma, especially in biologicals has not yet been established (see Box 2 for further details).

Biotechs can reduce their IP risk in both India and China through proactive management. First, you should carefully weigh the critical value of the IP against the perceived benefits of entering India or China, and refrain from any project with an unfavorable balance. When selecting a partner or vendor, you should make all necessary due diligence evaluations of the candidates on your shortlist. In particular, check on their IP-protection measures— physical, electronic, and other. One biotech, for instance, disables its printer drivers and tracks all data downloads. Some local vendors literally erect 'Chinese walls'—separate rooms and facilities for client activities—and even withhold the client's name from the workforce.

And when negotiating contractual arrangements, you should ensure that legal recourse, both local and abroad, is properly registered. Vendors, such as Beijing-based Bridge Pharmaceuticals and Aurigene in Bangalore, maintain US-based operations in part to give assurance that they comply with all US IP regulations—and to give customers the option of pursuing US-based litigation if they don't.

Even if not offshoring work to India or China, biotechs might still consider it prudent to protect their most valuable and vulnerable IP in these countries. By licensing IP to Chinese or Indian companies, they stand a better chance of preempting patent infringement, or of being represented by a party with a 'home court' advantage in case of litigation.

Choosing a sourcing model

Let's assume that after weighing the risks and potential benefits scrupulously, you've decided to take the plunge, or at least to test the water. You now need to choose an optimal business model. There are three basic models—outsourcing, partnership and captive investment model—offering different degrees of flexibility and control. For biotech SMEs, the starting point would generally be the outsourcing model: hands-off and low-commitment, and therefore involving minimal supervision and easy entry and exit. Of course, it also involves minimal control over output and IP, and for those dual reasons the projects outsourced would tend to be low-complexity work of less strategic import.

Once your company has gained confidence and has decided upon a longer-term commitment to the region or to a particular vendor, you may choose to advance to a partnership model, assigning projects of higher complexity or greater breadth to a Chinese or Indian provider, with more of your own participation in supervising, training and monitoring. This would afford you greater control over quality and should improve communication and trust. However, by moving your partner up the learning curve, you risk finding that they use the enhanced know-how of their workforce to serve potential competitors of yours.

The most committed model, captive investment—where a company acquires and operates its own R&D base in China or India—is unlikely to be adopted by smaller or cash-constrained biotechs. It certainly affords increased control and IP security, but at the cost of a heavy investment of time and resources. It also means a host of new responsibilities. There is no longer a streetwise local intermediary to deal with red tape or make good any unexpected infrastructure gaps. One biotech that set up a captive base in China admits ruefully that it has had to manufacture its own rodent cages.

Finding the right partner

To match corporate investors with the right vendor or collaborator, both India and China have quasi-official dating agencies. In China, you would approach the administration in any of the biotech parks, and they would recommend a suitable match from the list of firms based there. In India, you would approach the Ministry of Science and Technology's Department of Biotechnology or the Council for Scientific and Industrial Research, and they would fix you up with a potentially ideal partner.

But it's worth ranging far wider than these sources. After all, finding the right partner will make a big difference to your offshoring experience, so don't stint on the time and effort invested. In both countries develop '*guan xi*'—good relations with influential people—to get the best advice and also some help in sealing the deal. Investors and providers are heavily networked, and you should link in to these networks right up to the last minute, as the landscape changes quickly.

At this early stage, biotechs can afford to be cautious and methodical in their approach, as limited vendor capacity is not currently an issue. Over time, vendor capacity should grow to keep pace with demand, with perhaps more of a focus toward smaller biotechs as the sourcing market develops. That said, the earlier you take the plunge, the sooner you can reap the cost savings and the better your chances of accessing proven and established vendors.

Looking ahead

The virtue of the sourcing option goes beyond cost and time efficiencies. Biotech talent and drive are increasingly abundant in China and India, and innovative ideas, which can't be far off, will be equally amenable to tapping. After all, the governments of the two countries aren't investing in biotech to create sourcing opportunities but to establish vigorous high-tech industries of their own. Specific areas of China and India represent rapidly growing clusters of biopharma expertise and may ultimately be as important to biotech as San Diego or the Bay Area are. You only need to look at all the innovation emerging from the Taiwanese computer industry to see the parallels with Indian and Chinese biotech, and the pattern of success that the countries are sure to emulate. Small Western biotechs with large ambitions and a taste for adventure can get in at the ground floor and harness Asian innovation, rather than simply offshoring their own.

One other possibility that India and China are opening up is a new model of biotech product development (and perhaps of manufacturing, too). Call it the 'modular model,' a kind of decentralized R&D system where different aspects of R&D are distributed globally and conducted almost autonomously in different locations.

But you don't have to look that far ahead. The opportunities in China and India are rapidly developing, with key pieces falling into place. Weigh the options carefully, delve into the realities and risks of operating within the two countries and decide carefully if you want to enter. If you do, devise a precise and methodical strategy, find the right partners and implement the strategy with full commitment. With the right strategy, you stand to give your biotech SME a productivity boost and a handsome competitive advantage.

Acknowledgments

While most of the material in this article derives from client work, it is backed by a detailed survey conducted by the Boston Consulting Group in 2005 and 2006, collating the views and experiences of executives at over 90 vendors in China and India and of officers at several government research institutes in the two countries, and of senior executives at over ten biopharma MNCs operating there. A report summarizing the findings from this study (*Looking Eastward: Tapping China and India To Reinvigorate the Global Biopharmaceutical Industry*, August 2006) along with other publications on the opportunities for biopharma R&D in India and China can be found at http://www.bcg.com

Box 1: The region's market for biotech products

The markets for biotech products in China and India are quite different from those in the developed world—with a far lower proportion of consumers who can pay even a tiny fraction of Western prices. But given the high rate of growth of the region, especially within the middle class, the opportunity may eventually be a lucrative one, especially in China.

China's overall pharmaceutical market is already 2–3 times more valuable than India's, and will remain so. It should rise from $12 billion in 2005 to a predicted $37 billion in 2015 (graduating to become the world's fifth most valuable market *en route*), against India's $5.3 billion and $16 billion, in 2005 and 2015, respectively. What's more, the proportion of generics (currently over 70% by value in both markets) versus branded drugs is declining more steadily in China than it is in India. And the price realization, though lower than that of developed nations, is considerably higher in China than in India. In each country, the target market for high-priced biotech drugs is probably no more than 5% of the population—those with private health insurance. Still, that's 5% of a billion-strong population in each country. It all adds up: sales of biotech products in China reached $2.5 billion in 2005. Drugs that qualify as blockbusters in the United States can reach annual sales of $50 to $100 million in China with rapid success. GlaxoSmithKline's (Brentford, UK) Heptodin (lamivudine) reached $80 million in annual sales in China within five years of launch.

That said, the commercial factor is less a current consideration than a future one. It all adds up: sales of biotech products in China reached $2.5 billion in 2005. Drugs that qualify as blockbusters in the United States can reach annual sales of $50 to $100 million in China with rapid success. Biotechs about to launch new products, at least for the next few years, may best be advised to outlicense them to established pharma companies with proper scale in China or India.

M.Y.

Box 2: IP developments in India and China

Among executives contemplating offshoring, IP protection remains a key concern, especially for discovery work. The main IP laws in both India and China are new and relatively untested, so caution is appropriate.

After major changes in India's IP laws in April 2005 that shifted from process to product protection, India now appears to have a reassuringly tough set of IP standards. Strong trade secret laws and the new Contract Act, based closely on IP statutes in the UK, protect a company against risks related to information leakage or employee switching. In addition, they allow companies to pursue litigation in Western courts against Indian companies for IP breaches. Another source of comfort is the presence of R.A. Mashelkar, director general of the Council for Scientific and Industrial Research. Mashelkar is a leading proponent of biotech partnerships and a global authority on IP protection in developing nations, serving as vice chair of the Commission on Intellectual Property Rights, Innovation and Public Health for the World Health Organization (Geneva). Although India's new IP laws have appeared to work well in other industries, such as business process outsourcing, which handle sensitive company data, it remains to be seen if they will work as well for biotech and for biological products. After all, the Indian pharma industry as a whole does have a tradition of patent challenges and deep reverse-engineering skills.

China too has a strong set of IP protection laws in place, though perhaps not quite as strong as India's overall, and perhaps not quite as strong for biologicals as for chemical molecules. Enforcement has been an ongoing issue, and the judicial protection of IP still has to prove itself. But since its accession to the World Trade Organization in 2001, the country has been subject to the Agreement of Trade-Related Aspects of Intellectual Property Rights, so the government is under pressure to enforce international standards. Its previous efforts to change underlying attitudes toward IP protection were not unqualified successes: the patent process remains awkward, Chinese courts continue to struggle with IP cases and protection is not always applied equally across domestic and foreign parties.

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