

## Seeding a skilled workforce

Gayatri Saberwal

**How might the Indian government spur the development of a biotech workforce with a broader set of skills?**

A country with over 1 billion people and an established generic drug and vaccine sector should be able to develop the drugs needed to ensure the health of its citizens. It is therefore disappointing that so few novel drugs have been developed in India's academic or corporate laboratories. One of the reasons for this is that many of the skill sets needed for drug discovery and development are missing in India today. To identify the specific types of expertise that are lacking, I conducted an informal survey of local biotech executives to ask for feedback on their human resource needs. On the basis of their responses, I outline here two approaches that the Indian government could exploit to facilitate the development of a workforce more suited to the requirements of innovative drug discovery and development programs.

### The workforce

In previous decades, most work carried out by Indian drug companies was limited to the chemical generic and vaccine sectors. The question is whether the Indian workforce that has supported these sectors also has the skills needed to work in biotech companies developing innovative drugs. In principle, India should have enough college graduates, postgraduates and doctorates in diverse fields of study to do most of the tasks needed to bring a new drug to market. But in reality—and for historical reasons—the Indian workforce remains ill equipped to do several of the tasks needed to carry out an innovative drug discovery and development effort.

With the recent establishment in India of more innovative biotech companies<sup>1</sup>, a small number of personnel have started to work on

novel programs, which has led to the nurturing of new sets of skills. In many instances, when an Indian biotech company wishes to build a program for which there is little expertise within the country, an experienced professional from the biopharmaceutical industry in the United States or another Western country is hired; indeed, several such individuals now dot the local corporate landscape in India. Over time, the skills of these individuals diffuse both

within their companies and (if they change jobs) in other companies across the sector. Ultimately, so long as the industry grows, this will lead to a critical mass for each set of skills needed by innovative biotechs that will be less dependent on the success or failure of particular programs or companies. One problem with this type of organic growth is that it is likely to take several years for all the skill sets to become established in the workforce.

### Box 1 R&D skills that are, or are not, available in India today

On the basis of the responses gained from interviewees, several skill sets currently appear difficult to find in the Indian biotech sector (Table 1). One of the reasons for the deficit in skills is cultural—as yet, the transfer of skills from academia to industry remains inefficient. Thus, although there are good cell biology skills in academic institutions, such researchers seem to be unavailable to companies, and the ability to design cell-based assays is a rare skill in the Indian biotech sector. It is also a challenge to attract subject area specialists at the post-doctoral level, especially those with disease-related expertise. Whereas companies have no problem attracting PhD-level expertise to handle sophisticated equipment, they have trouble finding masters' level expertise for such work. Also, aside from technical skill sets, individuals with the ability to communicate and work within interdisciplinary teams needed for novel drug development are also thin on the ground.

In the area of preclinical animal work, veterinary pathology skills are also rare. There are very few facilities dealing with large animals (especially primates) and very little effort is dedicated to creating animal disease models. One anticipates that the situation with regard to the latter problems will change over the next few years with the ambitious National Animal Research Facility being established in Hyderabad.

In the area of the clinic, bioavailability and bioequivalence skills are readily available as a consequence of the strong local generics' industry. Whereas many individuals have experience conducting trials in phases 2 and 3, familiarity with microdosing and phase 0 trials is also nonexistent. Another problem for companies is the difficulty of finding truly independent ethics committees to oversee trials. Current Good Clinical Practice (cGCP)-compliance does not permeate trial sites as it must, and in a significant fraction of trials, those participating in a trial do not give genuinely informed consent. Furthermore, there is an extreme shortage of tertiary care doctors, both in absolute numbers and in terms of their location in hospitals with the right medical infrastructure. Therefore, doctors involved in trials are often grossly overworked. And although there are now plenty of professionals in the area of data management, trial design and biostatistics skills are rare. Thus, local companies gather data, enter it and verify it, but do not do the work of deriving meaningful inferences. The latter work is sent to companies in Europe or the United States.

Lastly, companies also have a limited pool of experts who can handle both Indian and foreign regulatory systems. And as in other areas of industrial activity that are new to India, middle management is hard to find, and this affects many areas.

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**Table 1 Skills that are common or in demand in the Indian biotech sector<sup>a</sup>**

Expertise common	Expertise rarely found
Protein expression	Target identification and validation skills
Protein purification	Medicinal chemistry
Synthetic chemistry	Computational chemistry
Identification and optimization of lead compounds	Combinatorial chemistry
Bioavailability and bioequivalence	High-throughput screening
Clinical data management	Creating and/or maintaining chemical libraries
	Preclinical animal models (especially primates)
	Phase 0 trials
	Trial design and biostatistics
	Regulatory affairs

<sup>a</sup>On the basis of a small informal survey of Indian biotech executives.

If the government wishes to foster the more rapid development of rare skill sets, an important first step will be to identify the skills that are—or are not—readily available in the Indian workforce today.

### Skill sets

As a preliminary investigation into this, I carried out an informal survey of executives in the Indian biotech sector to ascertain what skills are, or are not, widely available. A total of twenty-five interviews—of corporate scientists, some academics and a couple of independent consultants—were carried out between August and November 2008.

The list of missing or underrepresented skills cited by the interviewees are shown in **Box 1** and **Table 1**. As the sample is small, the results are clearly a snapshot of industry views, and a much more comprehensive survey of many more individuals would be needed to create a complete list of human resource needs.

As detailed in **Box 1**, the workforce available to the Indian biotech sector lacks skills in several essential drug discovery functions. Companies also face challenges retaining experienced personnel because of their scarcity in the working population. For example, there have been instances in which the recruitment of several group heads from an existing Indian biotech company to a new company has demonstrably led to a weakening of the former.

Among younger employees, even six months' to a year's experience is considered valuable by prospective employers, leading to much mobility at that level; indeed, the movement of personnel is such that at least one foreign company closed down its Indian R&D operations because of the high turnover. Even in the mature generic pharma industry there is a premium on expertise and experience. From the point of view of the diffusion of skills, it is probably good for the biotech sector as a whole, but for individual companies it might pose

problems if adequate replacement personnel are difficult to find.

### Possible government initiatives

What might the Indian government do to address this skills gap issue? First, it will be important to carry out a detailed and comprehensive audit of biotech companies' human resource needs and the number of individuals with such skills that are required. Once the requisite skill sets have been identified, the government could offer to foot the salary bill—either fully or partially—of specific individuals with rare skills brought in from abroad for about three years. After this time, the selected scientists or technologists could either continue in the same company or look for another position. Such a 'seeding scheme' would take away the risk if a biotech company wished to invest in a new area, such as innovative drug development. The advantage of such time-limited government support is that the scientist would take care to join a company that is serious about the work so that their employment could either continue in the same company if the program succeeds or provide work experience that stands them in good stead for their next move. Depending on the area of work, there may be a need for more than one person to create an effective group.

A second possible initiative is one where a company that carries out a new set of tasks could receive an 'innovation reward' from the government. As above, the reward would apply only in areas where there is a scarcity of the skill in India. Let us assume that the first three companies to build up this skill set would be eligible for the innovation reward. These companies could get either a similar amount or a decreasing fraction of the reward, say 5:3:2. The work of the three eligible companies need not be identical and, in fact, could relate to either products or services: it should merely generate or hone a similar skill set to be considered eligible for the reward scheme.

One question is, how can the government distinguish a new skill set from an existing one? Companies are often hesitant to disclose details of their work. Nevertheless, to claim the reward it would be up to the company to demonstrate this aspect at least broadly, by means of patents, publications or even new or renewed contracts or other deals. The government could then perhaps publicly declare the shortlist of those who seek to be rewarded and open it up for scrutiny by those who may have gone before. The benefit of the reward scheme compared with the seeding initiative is that the work has already been carried out and the risk of failure is zero. Companies could then use this money any way they wished, including strengthening this area or seeding new areas of work.

### Discussion

Several issues have a bearing on the success of the seeding or reward schemes described above. First, should there be a reward for companies that train large numbers of employees on a particular task? As training large numbers of people just for the sake of a government reward may undermine the efficiency of a company, I would argue that the answer is no.

Second, what if the seeding program fails to do what is expected? Is it useful, for example, to come up with a product that nobody buys? If one focuses on the skills angle, then the fate of the product is less important, although some market assessment for the proposed product or service will, of course, need to be made before a seeding grant is provided.

Third, would the reward scheme encourage companies to poach entire teams from other companies? Such things already happen in the Indian biotech sector, and in an environment in which not too many companies do a certain kind of work, this would likely destabilize the companies that are raided. It would be important to build in disincentives to discourage this.

Fourth, if a company that wins a contract for novel work not carried out in the country before then goes on to also obtain a seeding reward from the government, it would be paid twice over. Is this a bad thing? I believe not, for the following reasons. Aside from the immediate benefits to the Indian biotech sector in terms of training personnel, such an effort serves as a demonstration that something can be done in India, and therefore serves to inspire others to do likewise. The latter contributes to building up the critical mass in that area, which happens at no cost to the government. In addition, for any company doing something for the first time in the country, there is a risk, and such risk-taking is perhaps worthy of being doubly rewarded, particularly if it adds to the nation's

welfare at a higher level than mere employment or wealth creation (important as these are). The proposed program would have intrinsic limits: it would not reward large numbers of companies an endless number of times.

Fifth, in principle, a company that is fostering an employee base with a rare skill set could be a small or large homegrown biotech company or even a multinational. Should multinational or large Indian companies be eligible or should the scheme be applicable only to small- to medium-sized Indian enterprises? One might assume that the large multinationals, at least, do not require any funding; however, the Australian government has an initiative to match any dollar R&D expenditure by a company in Australia with 30 cents, and both Eli Lilly (Indianapolis) and Pfizer (New York) have been funded under this scheme<sup>2</sup>.

These are some of the details that will need to be thought through in advance, perhaps in consultation with industry, for the

successful implementation of such government programs. Other details would need to be worked out; for example, there would need to be some quantification of the effort or cost of performing a new task.

This discussion addresses the fact that in the area of drug discovery and development, India lacks many of the required skill sets. What would it take to develop the entire set? I have outlined two possible initiatives—and there may be many more—by which the Indian government could spur this.

The CEOs of some of the early biotech companies in India faced tremendous hurdles in ensuring the success of their ventures. If India is serious about encouraging the growth of an innovative biotech sector it will need to find ways of broadening the skills of its workforce. I believe risk-taking CEOs in the biotech sector may take up the challenges of starting new programs requiring new types of expertise, but are more likely to do so if the government provides a reward or some financial cushion.

The issues outlined in this article also extend beyond India. Indeed, the same challenges in skill-set deficits are faced in several other countries where good health is heavily dependent on drugs discovered elsewhere.

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The author declares competing financial interests: details accompany the full-text HTML version of the paper at <http://www.nature.com/naturebiotechnology/>.

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