

Korean FDA approves Bharat Biotech's manufacturing facility

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Dr Krishna Ella, a PhD from The University of Wisconsin, Madison and a MS, from The University of Hawaii has won a lot of Academic Awards and the Rotary International prize. He is also the winner of the First BioSpectrum Entrepreneur of the Year Award (2003).

Indian Biotechnology is gathering momentum. After decades spent in debating its tangible benefits, the scientific world rediscovered its immense potential only in the last one and half decade. Indian biotech industry is expected to grow to \$1.45 billion in 2005-06, \$4 billion in 2006-07 and more than double that figure - \$9 billion in 2007-08. (Source: Survey finding by BioSpectrum and CII)

The singleminded and dedicated efforts of illustrious scientists such as Prof. R A Mashelkar and Prof. G Padmanabhan and others, have brought this science that can develop life-saving vaccines to combat infectious diseases and path-breaking therapeutics to counter congenital and acquired disease patterns of the world, to the forefront of scientific research and development.

Over the next few years, India is slated to become a major center for custom research, and clinical and biological services. It is already the second largest manufacturer of vaccines used by children and these are exported to over 100 countries.

With the introduction of the product patent regime in 2005, biotech firms in India are preparing themselves for an intense phase that would test the ultimate enterprise and intuitive knowledge of Indian scientific and industrial community.

Human resource issues

The rate at which the biotechnology industry in India is progressing is heart-warming. But the same cannot be said about human resources in biotechnology. There are several issues that need to be tackled to ensure the progress that has been made in this sector.

The issues can be divided into six main aspects:

- . Biotech curricula
- . Training in practical aspects
- . Forging industry-academia partnerships
- . Creating policy framework
- . Creating awareness about biotechnology
- . Nurture and promote bioentrepreneurship

Biotech curricula: The course content of biotechnology as a subject in India needs an immediate relook. Unlike pharma education, which is historically well established with organized syllabus, adequate lab exposure and training, biotechnology curricula is still evolving. Due to lack of exposure, many colleges and universities in the country offering biotech courses are not offering a standardized content material. The course content seems to swing between being either too academic or too general without any specific, well-planned practical training or lab exposure.

The faculty, too seem unaware of the revolutionary changes taking place in industrial biotechnology in the areas of production, R&D;, GMP guidelines among others.

One look at the student output in biotech reveals 1,50,000 M.Sc's, 3,50,000 B.Sc's, fewer post-doctorals compared to the US, and majority have no exposure to industrial research.

This puts biotechnology students at a disadvantage when they set out to carve their career path in the industrial sector.

To fulfil the above requirements, it is important to create a learning program in the area of biotechnology and its ancillary fields. The need of the hour is to envisage a multidisciplinary curriculum that will cover all aspects of biotechnology including understanding process principles, experimentation, animal and plant technologies, bioinformatics, basics of project management, IPR issues, business values and finances in BT.

I propose we create separate modules for students and corporates, which will focus on different themes. The student course will emphasize on practical hands-on training, teaching the ethics of GLP and a fundamental know-how of BT management.

Practical training: Unlike IT courses where lab exposure is minimal, it is imperative that we understand the significance of providing hands-on experience for biotechnology students.

Vocational courses: The BSc course in Biotechnology was started in a few colleges in the country, about a decade ago, as a vocational programme of the UGC, with UGC's syllabus, guidelines and financial support. But subsequently, several colleges in the country were given affiliation for BSc Biotechnology, ignoring UGC's norms regarding sanctioning vocational courses, with the same regulations and syllabus. This needs to be addressed immediately.

Creating vocational courses will ensure a steady stream of HR for Biotech industry. This will spark off another essential aspect – Entrepreneurship.

I would like to add that in this aspect, women can play a vital role in changing the dynamics of industrial biotech. This would encourage women entrepreneurship in creating ancillary industries that support and nurture biotech industry in India.

I propose that the state governments and the DBT, with the certainly feasible support from and collaboration with the industry, establish instrumentation and training centers at a few key locations in different states, where students can get trained and research workers can get instrumentation services on payment of prescribed charges so that expensive facilities required for most of education and training in biotechnology need not be duplicated.

Continuing education for professionals: Taking one step further, it is imperative to create educational opportunities for professionals from related fields such as pharma to hone the necessary skills for creating their career path with biotechnology industry.

The Council (* As per my proposal) could actively create educational resources, self-training modules, information about advanced courses, research and fellowship opportunities, and links to various conferences and meetings around the world.

Each of these tools for continuing education has its own advantages and disadvantages. For example while online tools provide the benefits of a self-paced environment for learning, conferences allow discussion and generation of new ideas.

Example: The World Health Organization's Human Genetics Programme that aims to support an educated and informed health workforce to provide the best health services to populations worldwide and to achieve the best possible health for all.

Forging industry-academia partnerships: In the last two decades a new entity has emerged on the campuses of America's research universities. This entity is known as the University-Industry Research Center or UIRC. Such centers are composed of research groups whose focus is on problems that have relevance to a particular sector of industry; often the centers receive support from that industry. In 1990, more than 1,000 existed and involved more than 35,000 faculty and researchers and 17,000 Ph.D. students. Many more exist today. Why are universities creating such centers?

Strictly speaking, universities are not creating them. In an extensive survey of UIRCs, it was determined that individual faculty members, not university administrations, typically provide the impetus for the center. Motivations vary, but the need to create funding alternatives to declining or uncertain federal support is important, as is the desire to turn research efforts to a practical end. Additionally, nearly one quarter of all U.S. Ph.D. recipients in the sciences are finding positions in industry; so students are looking for training that is relevant to their career prospects.

In India, Bharat Biotech has set such an example: The Bharat Biotech Foundation is recognized by JNTU, Hyderabad. to execute academic research through a Doctoral Programme in Biotechnology.

From an institutional viewpoint, centers like the above cited ones represent one way that the value of academic research can be realized to benefit the institution.

Creating Policy Framework: Biotechnology plays an important role in the economic development of the country in sectors like medical, human health, animal health, pharmaceutical/new drugs, agriculture and environment and it is indeed laudable that the Department of Biotechnology has identified human resource development as an area of high priority during the 10th five year plan in order to generate trained/skilled human resource in this critical and high tech. area of biotechnology.

But creating a specific framework is the need of the hour. Let me quote this example. Currently there are four categories of M.Sc., course in biotechnology in the country supported by the UGC, the Department of Biotechnology, the AICTE (in engineering colleges), the University system. As a result there is a lack of uniformity in requirements, the quantum of financial support and the consequent lowering standards of education.

In view of this distressing situation, which threatens to soon seriously defeat the national effort to derive benefits from biotechnology, I stress the need to put in place a Biotechnology Council of India (BCI), an independent statutory national body, on the lines of the Medical Council of India, Dental Council of India, Pharmacy Council of India, All India Council for Technical Education and the Bar Council of India.

The chief role of such a statutory body would be to ensure standardization in biotechnology education and training in the country. The BCI should be empowered to grant recognition for those institutions that meet such standards, set with reference to qualified and trained teaching staff, infrastructure, adequately equipped laboratories, etc., that are essential for a focused education in biotechnology.

Creating Awareness: The most vital of all the current issues is increasing awareness about biotechnology. Towards this biotechnology popularization, the proposed Council could organize seminars, symposia, conferences, workshops, popular lecture series, biotechnology publications in various languages, organize biotechnology exhibitions, national science day celebrations in universities and institutions.

Promote Bioentrepreneurship: Despite the efforts of thinkers, biotechnology in India, for a long time, remained in the safe waters of premier, academic and scientific institutions. Thoughts of one scientist illustrates this - "Scientists are not supposed to think about the economic perspective on research and development projects. A scientist's work is supposed to provide scientific knowledge. Economics is quite another discipline..."

This mindset has to change. This decade, which is all set to see a biotechnology boom, will belong to those who have the power to convert their dreams into reality. In other words, it will see the rise of the bioentrepreneur. The ones who will move away from the safe waters of the laboratory and convert a patentable/testable research dream into a viable business proposition.

India has the potential to become very strong in biotechnology. There has been a phenomenal increase in the number of start-up companies in this area in the last five years. While the current size of the industry is \$700 million, it is expected to grow at 25-30 percent. India ranks third in Asia in patent filings.

Every bioentrepreneur must thoroughly understand the grassroots features of the biotechnology sector such as research, collaboration, infrastructure, technology and commercialisation capital and come up with an alternative business model to achieve success.