# Managing Biotechnology in Time Transition

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Biotechnology has become the growing sector in international economy as we make transition form one millennium to another. It involves application of biological organisms, systems or processes to the manufacturing and service industries. Biotechnology is often referred to as an 'enabling' technology, that is, a technology that triggers wider applications in a number of industries, including:

- Health - pharmaceuticals diagnostics, gene therapy, biomedical products, medical devices and equipment.
- Agriculture - plant and animal breeding, veterinary products and diagnostics.
- Environment and resources - pollution control, land bio-remediation, water treatment, minerals extraction and processing, wastewater treatment, salinity control, and pest management.
- Food and beverage processing - starters, enzymes, fermentation, food ingredients fractionation.
- Industrial applications - agriculture product processing (oils, fibers, etc.), bioprocessing, and industrial enzymes.
- Energy production - biomass.

From the point of view of economics, biotechnology represents the technological change with potentially monumental impacts. As with any major technological change, it will create winners and losers. Governments all over the world, have had difficulties in designing policies to regulate all phases of biotechnology from research protocols, to testing, to protection of intellectual properties, to licensing for release into the environment, for food safety and for international trade. It is in a issue that has the makings of a major international trade confrontation between the United States and European union. It pits developing and developed countries against each other. The ethics and trustworthiness of the scientific community, regulators, policy maker, and politician have been questioned. Some of the world's largest corporation's are strategically maneuvering to position themselves to capture future market shares in what they perceive as major potential industry (Gaisford et al, 2001).

## Industry

In 2003 global biotech industry includes more than 4300 companies (613 of these are publicly traded) throughout the USA, Canada, Europe, Australia / New Zealand, and Asia applying revolutionary discoveries in science to tackle the planet's toughest health care, agricultural, industrial and environmental challenges( Ernst and Young , 2003). By 2005 European biotech market could double from current valuations to more than $100 billion. Biotechnology is an emerging sector in Asia/pacific experiencing notable expansion in India, Australia, China and Singapore. Global market for biotechnology applications will reach US$50 billion

annually by 2005- strongest growth is projected for agri-food sector. Global value for genetically modified crops grew from US$75 million in 1995 to US$1.64 billion in 1998 and projected at 46 billion by 2005 and to 20 billion by 2010 (Chre James 2003).

There are no authentic statistics on the investment in the Indian private sectors. This is because the definition of biotechnology and its indicators vary for different estimations. An Indian directory prepared by Biotechnology Consortium India Ltd. (BCIL) in January 2001 includes biotechnology activities of about 176 companies in private sector whose products range from those in agriculture, environment and healthcare. On the other hand, estimates have also been made that about 800 companies are operating in various sectors of biotechnology, based on the definition that biotechnology includes basic industry such as food processing and highly sophisticated recombinant products. Employing the same definition one estimate says that 10 per cent (80) of these companies are operating in modern biotechnology sectors while according to another conservative estimate there are only 20 companies engaged in sophisticated biotechnology business. Similarly, it is also estimated that the industry employs 10 to 20,000 people and generates roughly a revenue of US$ 500 million annually. The Indian share of the biotechnology market was estimated at US$ 800 million in 1999 and has risen approximately to US$ 2.5 billion this year. Consumption of biotechnology products is expected to touch the figure of Rs.14.6 billion. Notwithstanding these figures by various estimations, it can be concluded that India's burgeoning biotechnology sector is an oasis of rich picking for investors as the government leads the drive to develop the industry. Building a biotechnology industry is a part of knowledge economy strategy of the government. A growing number of high quality Indian biotechnology investment opportunities exist for both early and late stage investors. Some of the major investors include, Connect Capital, ING Barings, Dresdner Kleinwort Benson, London and Warburg Pincus are evaluating Indian biotechnology investment opportunities (Rao 2003a).

**IT versus BT**

The biology industry is analogous to information technology industry - populated by a large number of entrepreneurial high technology firms. However, comparison between success of Information Technology and Biotechnology expose complications in management of biotechnology.

**Fig. 1 Information Technology Versus Biotechnology**

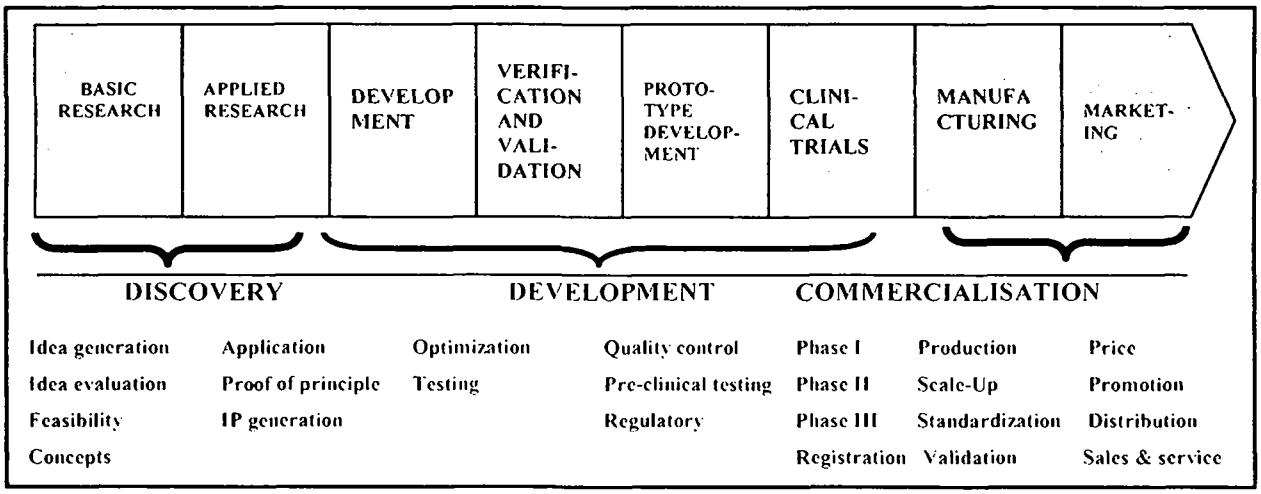
| *Attributes* | *Information Technology* | *Biotechnology* |
|---|---|---|
| Capital Investment | Low | High |
| Product Development Time | Less than 1 year | 3-10 years |
| Product Development cost | Low | High |
| Regulatory Control | Few | Many |
| Failure Risk | Low | High |
| Entry Barriers | Low | High |
| IPR costs & values | Low | High |
| Market size | Medium to Large | Small to Medium |
| VC's understanding | Good | Poor |
| Market Size of Service | > $ 100 billion (software) | < $ 10 billion (CROs) |
| Cross licensing | High | Medium to high |
| Public acceptance | High | Low (sensitivities) |

## Biotechnology value chain

The value chain in biotechnology is considered to be set of activities that are interconnected in an organization and together deliver value to customer, in the form of a product or service. The organizational value chain is the part of a larger stream of activities carried out by other entities, such as suppliers, distributors and customers. Value is the difference between what customers are willing to pay and the cost of producing the value (Porter, 1990).

A detail study by John and Hine (2004) identified 8 definable elements that constitute the biotechnology value change; basic research, applied research, development, verification and validation, prototype development, clinical / field trials, production/ manufacturing and marketing. These major elements of the value chain have sub-activity or sub-task to cater for unique differences between biotechnology products /companies (Fig.2).

**Fig.2 The Value Chain of The Biotechnology**




*Source: Jone and Hine (2004)*

The above value chain is basically applicable to manufacturing of health care products, industrial biotechnology and food and beverage processing. In Agriculture, predominant biotechnology application is production of genetically engineered seeds or genetically modified (GM) seeds. Steps in R&D to seed marketing would take 8-10 years along the value chain after clearances from regulatory prospective and several millions of dollars.

**Stages in Research Development and Commercialization of Transgenic Plants**

| Years | Stages | Regulatory Committees | Acts |
|---|---|---|---|
| 3-5 | Trait<br>Gene<br>Tissue culture<br>Transgenic<br>Molecular analysis<br>Seed set and lab testing<br>Green House testing | Institute Biosafety Committees (IBSC) | Environmental Protection Act of India Under Ministry of Environment Forests |

| Years | Stages | Regulatory Committees | Acts |
|---|---|---|---|
| 2-3 | Limited field trials Toxicity, allergenicity and environmental impact | Review Committee for genetic Manipulation (RCGM) Recombinant DNA advisory committee (RDAC) | |
| 1-2 | Large Scale field trails with All India Coordination (Indian Council of Agricultural Research and State Agricultural Universities) | Genetic Engineering Approval Committee (GEAC) | |
| 1-2 | Breeders seeds - Foundation seeds - Certified seeds - varietal release | Seed notification committee | Seed Act and Plant Variety Protection Act - Ministry of Agriculture |
| < 1 | Cultivation by Farmers | | |
| 1 | Food procurement / processing | Food labelling | Act on prevention of food adulteration and food code |
| < 1 | Consumer | Consumer forum | Consumer act |

*(Rao 2002a)*

**Managing Biotechnology**

The background provided above identifies several stages at which managerial skills and decisions in terms of planning and execution of biotechnology projects are involved. In this paper, the current information on managerial issues concerning success and failure of projects with case examples where available is discussed.

The various stages and activities in the value chains towards commercialization of biotechnology identifies five key stages of management.

- Research and Development
- Regulation
- Intellectual property
- Financial management
- Managing transition

**Management of Research and Development**

Research and Development is playing an increasingly important role in determining the fate of both public and private sector activities in biotechnology. The R&D is a key driver for commercial success requiring critical capability. The financial analysis of modern biotechnology projects look to the R&D pipeline as an indicator of value of company / institution in biotech industry. The key elements to manage at this stage of value chain are described below.

**Priorities of R&D**: Priority setting is the complex process of choosing between alternative sets of research activities. A formal priority-setting exercise aims to make the most effective use of available technical and financial resources by selecting the best portfolio of projects for a research system, institution, or program. The basic steps for priority setting in biotechnology are not different from those for research in general. However, a number of issues require special attention due to particular characteristics of this emerging technology. Among these are (1) uncertainty created by lack of experience and availability of data on the performance of biotechnology, (2) the difficulty of estimating research and development costs in this area, (3) qualitative factors related to human health and environmental effects of biotechnology products, and (4) other factors complicating the measurement of technology performance; for example, the fact that biotechnology research often generates intermediate products for use by related research programs rather than products to be directly used by consumers/ farmers.

Government funded R&D activities differ from private sector in that former is concerned with capacity building in frontier areas and socio-economic development of the nation. Private sector R&D is mostly market oriented. Research managers involved in industrial R&D need to consider two key issues: a) whether priorities are commercially attractive; and b) mechanisms and plans to commercialize the research outcome. An organization may do research to address existing needs with defined specifications or it may do research on the organizations perceived research priorities. The first type of research is aimed at developing technologies for immediate commercial needs, such as expansion of markets shares of existing product lines. The second type for developing new products that can create new markets. Russel et al (1990) categorized R&D as incremental, radical and fundamental. Incremental R&D represents low risk and moderate towards to exploit existing technologies in new ways. It is highly acceptable to industry with few financial resources but eager to gain market shares. Radical R&D may create new knowledge to industry and is often categorized as higher risk and increased reward. It is suitable for companies with strong financial resources and seeking opportunities for diversification. Fundamental R&D crates new knowledge for the world that broadens a company's understanding of scientific areas. Because of its high risk nature and uncertain applications such R&D is usually funded by the Government.

Participation is crucial component of any priority setting process. Decision makers including the promoters, sponsors, research managers; economists/marketing experts; scientists and researchers; production and manufacturing experts are all need to be involved to decide research priority and construct the value chain through a business plan priority setting process is a formal structured decision process that reviews, analyzes and shows which parties are involved, the time frame, information and resources needed, projected outputs, steps to achieve these outputs and their potential marketing or utility.

**Human Resource Management (HRM) and Development**: Biotechnology enterprises either in public or private sector require wide range of skills to take novel scientific data and convert it into useful products. The five key tasks of HRM are strategic planning, assessing needs, analyzing staff capacity, building a plan and building research teams.

Strategic planning defines the direction of the small or big firm intends to move and the framework for reaching the objectives. It emphasizes that ultimate source of innovation is people. The main challenges are Identifying all skills necessary for success on continuing basis and knowing when they will be needed in the life of the project and how they relate to objectives of the organization; auditing skills already present and what is needed to change them to reach the strategic objectives and merging total resource management of people, equipment, chemicals and consumables and financial provision into comprehensive institutional plans. Management tasks include deriving HR targets from R&D programme needs; ensuring a portfolio of skills in biotechnology R&D; and focusing on the most important skills for the research team.

**Building research team** is another management challenge of HRM. It is important to recognize that a traditional research approach may not obtain the desired outcomes in biotechnology research. While the role of individual researcher

following ideas in isolation has a dominant and productive aspects research over the last 50 years, no single individual has the range or skills to bring biotechnology project completion. This can be achieved by teamwork at all stages from initial basic research through the developmental stages and regulatory steps to the release of the final product to consumers.

**Leadership**: The main challenge is to have a good project leader/manager. Project manager requires special skill training in management and there are now inexpensive computer programs that make the task of project manager easier. The main objective of the manager is to take research findings through a product or process that impact on production and public acceptance. An essential task of the project manager is to ensure that value and ownership of the research is retained by its inventors through proper handling of intellectual property. The ability of an individual to act as an interface between researchers, industry personnel, financial advisers and government departments is essential.

**Partnerships and Collaborations**: After priority setting and HRM planning, there is need still to identify suitable partner in many cases who would bring synergy in completion of project. Partner may be required for accomplishing a specialized task, sharing certain tasks, supply certain biological material, and help in scale up, manufacturing, regulatory clearances and marketing. Partnerships/ alliances can reduce costs and time of projects. To build new bioindustries, approaches such as technology transfer, technology assembly and joint ventures with national/multinational companies need to be considered. There are several strategies for such business development in partnership such as (Rao 2002b):

- Teaming up with scientists and technologies to form a new company : As biotechnology industry has long gestation period and financial break even requires long years, a start up company based on R&D may suffer shortage of funds to support the downstream activities as they move on the value chain. It is more effective to invite a company with its own marketing channels , knowledge of products and enough funds to remain partner for driving the business.
- Establish a new business by working with reputable multinational corporations (MNC): Local circumstances in many countries often prevent MNCs from establishing on their own in foreign land. Local companies engaged in R&D and manufacturing of local market goods can form joint ventures.
- Upgrade local companies: Research units can partner with local companies with sound sales network and a portfolio of products aiming at diversification.

One of management challenge at this stage is arriving at term of reference of partnerships. Managers need to be aware of changes and new trends in handling R&D results. Executing confidentiality agreement, joint venture modalities, sharing of Intellectual Property (IP) are certain areas needing special skills and knowledge alongwith abilities for consultations with stakeholders to arrive at consensus.

**Managing Regulations**

Starting from R&D through production and manufacturing activities, the biotechnology products and processes require stringent safety norms to be followed at every stage of operation. The regulations to be followed are territorial and the government through the various acts of parliament issues the guidelines and procedures (Rao 2003b). Familiarity with the guidelines and the procedures for implementation research and production activities is an essential pre-requisite for R&D managers and production supervisors. Organizing regulatory experiments: clinical trials of drugs and pharmaceuticals and field trials for biotech seeds; establishment of General Laboratory Practices (GLP), General Manufacturing Practices (GMP) and accreditation of facilities conforming the norms require interaction with governments laboratory, regulatory agencies and information retrieval from various technical sources. A detailed regulatory dossier for each product need to be submitted with all the requisite data for the national regulatory authorities for approval of the product before commercialization. Management challenges broadly include communication, moderation, liaisoning and documentation. In turn each of these activities could have several steps to accomplish the goal.

## Managing Intellectual Property Rights

Biotechnology is capital intensive as well as proprietary in nature with participation of countries in the World Trade Organization (WTO) and implementation of Trade Related Intellectual Property Services (TRIPS). Intellectual capital is said to be the most valuable asset of many companies today. This consists of technical inventions, know-how, trade secrets, brands, designs, literary and artistic creations and a multitude of other forms of intellectual property, that is, non-material assets, arising from true innovations, expression and creativity (Rao 2002a).

Intellectual property has long been used by businesses as a basis for producing and marketing goods and services. However, there is growing recognition that it is a valuable asset in itself that can bring in revenue through licensing, improve a company's balance sheet, increase stock value or obtain leveraging.

Most of the intellectual capital is protectable by the various forms of intellectual and industrial property rights created over the last 200 years and governed by international treaties and regional and national laws. Patents protect technical innovations. Trademarks protect brands. Design patents or registrations protect industrial designs. Copyright protects artistic works and software. Circuit design registration protects integrated circuit architecture, and so on. Recent years have seen certain examples of crossover protect in like business method and software patenting. Copyright has also received increased attention due to the introduction of digital technologies and the Internet.

The commercial application of new technologies-especially digital and communication technologies and biotechnology-has led not only to the development of new types of products and service, but also to new forms of distribution and methods of infringement. New technologies and business players are emerging so fast in these fields that unless traditional business, governmental and other organizations dealing with intellectual property rights pay attention, they will be overtaken by developments.

The complexity of products, specialization and reorganization of production in order to benefit from economies of scale, are leading to increasingly decentralized productions. Outsourcing, co-operation and collaboration become more important. The partners involved are therefore often separate legal entities in different countries. Adequate protection of intellectual property is crucial to enable the free exchange of R&D results, creativity and inventiveness among such independent partners in different jurisdictions.

Such protection is of special importance to small research companies specialized in the development of new technologies (frequent in the biotech industry) as well as suppliers in developing countries (e.g. software companies in India).

## Managing Finances

As described in the fig.1, compared to IT industry, the BT industry is characterized by intensive research efforts, long gestation period, and stringent regulation. All companies /projects small, medium or big would require adequate investment for their ventures. The financial management aspects are in no way broadly different from many traditional industries. However, start-up companies with scientists technocrats together with small investors as promoters require a venture risk capital. Many government agencies and financial constitutions have instituted venture capital funds. Management of venture capital funds and preparation of detailed project document for seeking such funds requires a close collaboration among experts specializing in specific biotechnologies, finance, marketing and technology forecasting.

## Managing Transition

Biotechnology companies tend to follow a relatively common life as they grow and mature. As they evolve through the biotechnology value change, they encounter a series of points where it become very necessary to alter the ways in which they organize and manage their businesses. A survey done by Kanter in (2003) revealed that the biotech company have to undergo significant organizational transformation, triggered by both positive and negative events-confirming the view that companies should assume

there will be no "steady state" organizational model and be prepared to adjust their operations periodically in response to changing business conditions. Clearly, the ability to anticipate, the need to redefine organization models and the skill to be able to effectively execute a transformation should be seen by biotech top managers as critical success factors.

**To conclude**

Implementation of biotechnology programmes both by public and private sector entities require a multidisciplinary approach. The managerial tasks and challenges are encountered all along the value chain from research to markets. A highly coordinated proactive management system with talented individuals in different disciplines particularly in research, regulation and intellectual property protection are essential. Therefore, there is a need for specialized training in management of biotechnology both in the government and industry. Many educational institutions and universities have started diploma or certificate courses and Masters in Business Administration (MBA) to address human resource development. In this complex field involving many interdependent variable factors for successful ventures. Adequate field experience through apprenticeship arrangements with industry and academia would go a long way for creating a critical mass of biotechnology managers. By the dawn of 21st century, biotech companies around the globe have realized that major restructuring of firms was needed due to rapid advances in technology and regulations. It was realized that there is need to have balanced approach between technical prowess and managerial and leadership skills.

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