

Thinking out of the Box



V.P. Kamboj

Associated with DBT since its very beginning, Dr. V.P. Kamboj has been playing a useful role on various committees and taskforces formed by DBT from time to time for specific initiatives. Dr. Kamboj recounts his experience as a fellow traveller with DBT.

It is heartening to know that the Department of Biotechnology (DBT), Government of India, New Delhi has completed 25 years in the service of the nation. My association with biotechnology goes back to mid 1984 when the Director, Central Drug Research Institute (CDRI), Lucknow asked me to attend a meeting called by Dr. S. Ramachandran, Head of National Biotechnology Board in the Department of Science & Technology, Government of India on animal house facilities. After this initial discussion he asked me to present the CDRI needs for developing a Good Laboratory Practices (GLP) compliant animal facility for training of science & technology manpower in maintenance and breeding of

quality animals. The project of setting up of National Animal Facility for producing quality animals and human resource development (HRD) in animal sciences (maintenance, breeding and experimentation) at the CDRI commenced on 1.4. 1985.

From 1986 onwards, the newly created Department of Biotechnology continued strengthening this facility and added supply of GLP bred animals to other scientists/ animal houses all over the country. CDRI, in fact, had already started a scientists / researchers / technicians training course in 1984 in anticipation of sanctioning of this facility. The Institute has so far trained 197 technicians and 43 scientists from 1984 to 2001. 77 more scientists /

research fellows / technicians from 2002 to 2007 drawn from as many as 72 national institutes / universities / industry from 20 states and union territories across the country, have also joined this force.

I was inducted into DBT Task Forces on Medical Biotechnology and Immunological Approaches to Fertility Regulation in 1993. From 1997 onwards, I was a part of almost all the policy planning committees of DBT including scientific advisory groups, HRD committees, Indo-US Vaccine Action Programme, Indo-US Programme on Contraception and Reproductive Health and Indo-Swiss Committee on Biotechnology. The primary focus was to identify thrust areas and support science driven basic and applied projects in front

line areas and also upgradation of infrastructure. The liberal funding helped generate biomedical, agriculture and environmental scientists with varied expertise to do cutting edge science in international level laboratory facilities. The projects were discussed in an academic atmosphere and good quality science was supported. Clinical studies with B-hCG demonstrated that vaccine approach for contraception is feasible. Pregnancy in women was protected as long as plasma antibody titers were maintained above a minimum threshold level. Further trials were suspended because primary and secondary non-responders could not be converted to responders for want of a good adjuvant. FSH vaccine for male after Phase I clinical trial was not indicative of further trials.

I was closely associated with the Task Force on Biotechnology Product & Process Development from 1997-2005. The task force funded projects in universities, national laboratories and medical institutes in a big way aimed to generate leads, their optimization and process development by synergy amongst academia from universities / national institutes and industry and networking projects for field evaluation. The focus was on the areas of human and animal health care, agriculture, environment and diagnostics using microbial processes, genetic engineering etc. A few projects generated viable leads that were further supported for optimizing and scaling-up. The main thesis was that technology innovations will lead to self-reliance, development and economic security of our country. The aim of academia from

universities and research institutes, however, was to do good quality science and publish in high impact factor journals. The generation and optimization of leads, their scaling-up and conversion into products were given low priority by researchers because of peer pressure and career development since product development is risky, involves long gestation and results are published in not too high impact factor journals. Furthermore, the industry also showed little interest to absorb and upgrade technology. In spite of this, the tangible outputs were liposomal Amphotericin-B (Fungisome) for the management of kala-azar, plasma western blot for HIV-1 & HIV-2 (HIV W-Blot), NEVA HIV-1 & HIV-2 in whole blood (NIV-HIV) for the detection of HIV, site specific gene/drug delivery system and cholesterol biosensor etc. in health care sector. In the area of environment security, high expressing microbes for xylanases for paper and pulp, cellulose for textiles and proteases for leather industries, tannery and dairy waste treatment bioreactors and bio-leaching of metals (gold & silver) were successfully demonstrated to the

industry. The Secretary, DBT and member-secretary task force visited tannery and dairy waste treatment bioreactors to see demonstration of bio-leaching of gold with enhanced recovery of about 50% and silver by 30% in mining industry were also demonstrated. But none of these pollution free and eco-friendly pilot scale technologies were scaled-up and marketed by the industry.

My most challenging experience was when the Secretary, DBT asked me, immediately after I superannuated from CDRI to rehabilitate the sick (and under Bureau of Industrial and Financial Reconstruction) oral polio vaccine production unit of DBT namely Bharat Immunologicals & Biologicals Corporation Ltd. (BIBCOL) at Bulandshahr and bring it out of the red. While BIBCOL had serious finance and HR related issues, the technical facilities were world class and technical manpower was first rate. The strategy outlined was to get orders for the supply of polio vaccine from UN and Ministry of Health and Family Welfare (MOH&FW) and then win confidence of bank and lenders against the supply orders. The banks agreed after some persuasion.



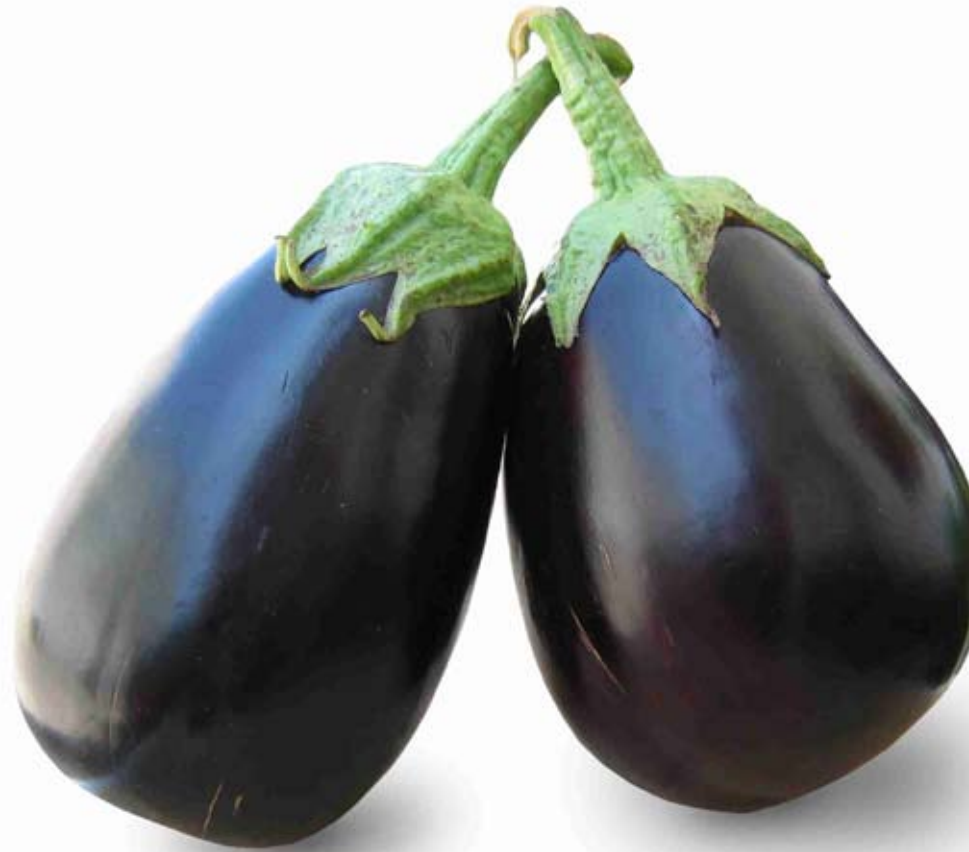
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Suppliers too were convinced to supply on credit with payments deferred for, but assured, after a few months. Senior staff was asked to stay at Bulandshahr and not to operate daily from New Delhi while we worked with district administration of Bulandshahr to improve safety of staff in night shifts and improve power supply.

The Managing Director and marketing staff with the support of Secretary and nodal officer (for BIBCOLD), DBT worked hard to secure orders from both MOH&FW and UN and thus strategic planning worked as planned. The faith and support of the Secretary, DBT, support of nodal officer of DBT for BIBCOLD, and dedication, commitment and hard work of the Managing Director, scientific, technical, administrative, marketing and contractual staff and support of Bulandshahr administration helped not only to pay all debts but also build a sizeable bank balance by scaling-up production from 20 million to 300 million doses within three years. This was achieved without adding a single new staff to the unit. The hard work and dedication of staff of BIBCOLD helped it come out of BIFR. BIBCOLD once again was loan free and a profit making company. Having turned a new leaf in its history, BIBCOLD had plans to diversify and manufacture some more vaccines with Govt. support, or from its resources. Even though the Secretary, DBT gave wholehearted support, the Ministry of Finance, Govt. of India did not agree to the proposal. In the mean time my tenure ended and I decided to leave the company.

In 2006 I was associated with the Review Committee on

Genetic Manipulation (RCGM) with the mandate to accelerate and streamline clearance of projects as also to update regulatory guidelines, protocols and SOPs for Pharmaceutical and Agriculture sectors. RCGM in its first meeting decided to act as a facilitator but with strict pursuit of rules and regulations. It also decided to invite the Industry to present and defend data to get clearance for next phase of activity. The pharma and agriculture industry presented and discussed data in the RCGM meetings in an academic atmosphere. The lacunae in the submissions were discussed with the industry representatives and revised dossiers were cleared in a fast mode. Likewise, monitoring teams monitored agriculture trials at site with the assistance from state agriculture universities. Agriculture trials data at each stage and bio-safety data were presented by the industry to RCGM, discussed in a free and frank mode, resubmissions accepted and approved before recommending to GEAC (Genetic Engineering Approval Committee and now Genetic Engineering Appraisal Committee) for approval. These steps brought transparency in decisions. RCGM meets every month on a predefined date. In fact the schedule for the year is decided in the beginning of the year. All projects received 15 days prior to the date of the meeting are reviewed, discussed, approved or resubmissions requested for want of data as per regulatory requirements. RCGM decisions on pharmaceuticals are immediately put on the DBT website whereas agriculture area decisions are placed on website after GEAC approval. The guidelines, protocols and SOPs



for pharma and agriculture sectors have been updated in conformity with international developments and developed country regulations and after consultation with industry and seeking comments from all stake holders by placing on DBT website. Biosafety guidelines for agriculture crops in India are most robust considering pursuit of Codex Alimentarius Commission, Codex Plant guidelines and their recent annexures and AGBIOS data requirements on health, food/nutrition and environment biosafety norms.

Recently, agri-biotechnology and national regulatory mechanism received a major setback due to a moratorium on Bt brinjal by the MoEF due to unfounded fears and noise by activists despite clearance by RCGM and GEAC and other expert committees. Pertinently, the introduction of GE cotton in 2002 met with similar protests from activists. However the science based regulatory clearance and acceptance by farmers and satisfactory performance in the field negated the protests. Resultantly, cotton production in the country has nearly doubled without much increase in land area and India has moved on to become a cotton export country. In Bt brinjal and GE crop introductions, data discussion starting with agriculture scientists, farmers and then the public will be the right approach. Post marketing surveillance to monitor side effects will win public confidence.

The efficient and smooth functioning of RCGM is due to dedicated inputs by members who review all submissions before attending the meeting and hard work and inputs by the Member-Secretary and Co-Member

Secretary and their secretariat.

Various Secretaries of DBT, particularly Dr. Manju Sharma and Prof. M.K. Bhan with whom I have closely interacted, always generated cordial atmosphere during discussions and supported decisions of task forces and committees without interference. They gave full freedom and authority to RCGM and never modulated its decisions. The Secretary attended the meeting of RCGM only when advice on some policy matter was solicited. The RCGM took all decisions in conformity with rules & regulations and guidelines published by DBT and without bias. I must say that during my long association with DBT, Secretary and other officers of the department have always respected views of experts and implemented recommendations of expert committees in a time bound mode. All committees have taken decisions after free and frank discussions with consensus of opinion.

I have enjoyed interacting with DBT scientists throughout my close association of over 18 years and have seen DBT responding to national challenges speedily. I have noticed its approach of building infrastructure and HRD development to supporting and encouraging scientific excellence to academia-industry joint programs to industry promotional programs and translational research in health care, agriculture and environment sectors.

I wish that DBT's activities supporting academic excellence and industry continue in the times to come and make the nation self-reliant and enhance its health, food and environment security through science and technology. ■