

## **Pharma Technology Upgradation.**

Events like Pharmacongress and Chemtech Pharma-Expo encourage meetings, intellectual stimulations and above all information exchanges and sharing. On 22<sup>nd</sup> January 2003, on the sidelines of Chemtech, while having lunch at the Renaissance, Mumbai, with Dr. A.V. Ramarao and Dr. J.M. Khanna among others, we were discussing about recent trends in Technology and the future need to evolve a suitable educational model which has no frontiers between Chemistry and Biotechnology.

To make the point easy to understand, let me take you to the now popular musical “Jugalbandis” of Indian Classical Instrumental music and the more experimental “Fusion Music” which has been making international waves and reviews. What we need urgently to meet the emerging challenges of Technology Development, is a review of our approach to Chemical and Biotechnological or more appropriately, Life sciences arena, where one could operate in both fields with synergistic, mutually supportive and supplementing design of operations.

In my last article, I did refer to a comment that a Biotech entrepreneur does not need to know or understand Biotechnology to which I could not agree. However, what Dr. Ramarao mentioned, appealed to me, which is as follows.

A Life science specialist, including medical, pharmacological, chemical experts finds it extremely difficult to learn Chemistry, especially Synthetic Organic Chemistry.

However for an Organic Chemist to learn and master, even at an advanced age or to an advanced stage, Life science or Biotechnology, is much more easy, smooth and feasible. It should therefore be possible for more and more chemical and bulk drug manufacturing entrepreneurs to learn to diversify into biotechnological processes for chemical operations or even for Biotechnological product developments.

Any amount of emphasis and publicity for “Bio informatics” and CADD / WLDD would not diminish the importance of the “Real” (vs. virtual) Drug development through Synthetic Organic Chemistry, which routinely involves hazardous chemicals, obnoxious and explosive gases and issues of safety, human health and Environment. The bursting of the bubble of the dot com business proved conclusively that it is the manufacturing and the “brick & mortar” service industry which sustains and will continue to provide fundamental support to the global economy.

Indian Bulk Drug Manufacturers are doing a wonderful job, not just locally but globally. Those who have the will to break their self imposed mind-set chains, will move into the global mainstream in a big way, with increasing support from venture capitalists (who have now considerably slowed down their real “chase of virtual business”) and industrial research and finance companies.

If the scenario is that rosy, what does one need to do to get into the “Big League”? Simply keep moving into the “In-Techs”. Upgrade your technologies; don’t continue to do the way you do or used to do for all times to come. How about productivity? How about more and more automation? Do you want to be called “Bucket Technologists”? Once you are into technology upgradation, you will start harvesting the benefits. Higher yields, Lower wastages & waste generation, better cost controls, more recoveries and recycling, more value addition from wastes and emissions, fewer problems with pollution control departments, so on and so forth. Once you set up the “technology traps” for your unwanted outflows and convert them into saleable by products, you would have become a “green technologist” an eco-friendly neighbour and social peer. What or who becomes a pollutant thereafter? Of course, the Pollution Control Inspector!

However, this is not done easily, you need to develop or outsource technologies. Using State & Central Govt. Agencies, Industry Associations and other (like NGO’s), the tailor-made processes for each individual manufacturers need to be acquired, adopted and adapted from specialize consultants, companies and countries like Israel, Scandinavian countries and even industrialized Asian countries.

Kaizen is not enough, though for all times. It is all right to make small improvements in what one does routinely and continuously. Periodically, it is essential to undertake a “re-engineering” exercise, an overhaul of ones, product range, processes etc. including the methods of analysis and process controls. Extensive self-inspection review and validation of quality control and quality assurance procedures, documentation protocols and S.O.Ps are essential at flexible / fixed intervals. Introducing newer (affordable) techniques of high vacuum and fractional distillations, chromatographic techniques, technologically superior filtration, separation and isolation systems are all useful and unavoidable. The customers and buyers are going to demand finer purity materials. PPMs are changing PPB’s. Impurity profile sharpening, isolation and characterization of impurities, making dossiers for each customer-based solutions become routinely practiced, often outsourced. From traditional and conventional equipments like HRHPLC, HPTLC and MS-LCMS, to HR-NMR and newer x-ray crystallography and use of softwares for a wide range of applications, all become optional tools of technology upgradation.

Chemical Synthesis and Organic Chemistry can no more live in isolation. These are times when the barriers are breaking and falling like “Kingpins”. Technology is no exception. Manufacturers of specialty chemicals, drug intermediates and bulk drugs are increasingly resorting to bio-transformations, bio-processes and bio-conversions, which are economical, eco-friendly and above all leading to value-added quality and low impurity profiles.

In line with current trends, chemical and bulk drug manufacturers will do well to look into the recent developments in new drug research. More and more biotechnology products and processes are emerging to replace conventional high risk, low safety hazardous technologies.

This is where we started. Organic Chemists could easily and smoothly undergo transformation to Biotechnologists. Those who see the opportunity and are adventurous to undertake the orientation could do it by self-motivation and training. New frontiers of genomics and proteomics are opening up for traditional organic chemists.

This means that 21<sup>st</sup> century science is cutting across scientific knowledge boundaries to an unprecedented extent. Peptides, proteins, vaccines and genomics make future drugs more biological and less chemical in nature, use of informatics in innovation and healthcare business has now come to stay. Technology-based pharma / bulk drug companies are being increasingly preferred by venture capitalists (compared to product-based companies). This means that knowledge-based companies with versatility and cutting-edge technologies have tremendous future. New terminologies and services like Bionimetric Chemistry, Combinational Chemistry, Life Chemistry, Structural Biology, Biological Chemistry, Gene Technology and many more are emerging. Natural product chemistry, not only plant and mineral based but also based flora and fauna from sea are receiving renewed attention. Pharmacogenomic research has moved upfront in genomic and proteomic field. All this means, greener pastures in technology for the traditional, conventional organic chemist to poach with pleasure.

Where does all this lead us to? A new tomorrow! New challenges in a new emerging world! What do you need to carry with you into this new world order? Definitely not the squeaking luggage baggage and heavy baggage of “doing things the way we used to do things yesterday”. We need to carry a light-weight highly positively charged mindset full of self-confidence and a will to succeed. Using Information Technology tools advantageously, it is now possible to take informed-decisions with Low-risk and high-success quotients. You seek and all the inputs and logistics will follow, why? Because

everyone else all over the world is more, believe me, more nervous than you about the challenges of tomorrow. If you don't believe me, you ask them "Be honest! Are you afraid of me in the new world order?" Ha, ha! Now you know! You are on the right track. Believe in yourself, seek new ways of doing things. Seek doing new things, based on new knowledge and by being better informed and equipped with newer systems and techniques.

Go out into the market place. Find out what the market / or your business customers need. Give it to them better & faster than anyone else can do. Become computer savvy. Use internet and software to the best of your advantage. Be better informed. Protect your Intellectual Properties. Use combinations of copy rights, Patents, Trademarks, designs (Engineering & plants for example) and trade secrets to deny your competitors the pleasure of night-raiding you. Introduce good tight, but with a human face, confidentiality agreements with your employees and collaborators and service providers. Enter into "smart" agreements on technology transfer and licencing out or licencing in. Start patenting. Remember the days of our elation when we were making chloramphenicol from L-Base, Erythromycin from TIOC, Ethanbutol from DL-2 Amino butanol and of course Sodium Citrate from Citric Acid and claming to be an "Industrialist". Patenting is like that. You start learning the "rope trick" of patenting those minor improvisations and improvements you have made in your plants and processes and you keep moving into a better and loftier plane of "ideas" and one day, before you realize, you will be licencing out your processes and you will join the "big league" of new drug research, genomics, proteomics and stem cell research, hopefully leading to a better world order, but a definitely positively promising one for the Indian bulk drug entrepreneur and for the great Nation of India.