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India should focus on biomanufacturing

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Maturity of a industry will always be based upon the amount of revenue generated besides the kind of products developed to show its presence on the ground. Therefore, only research and development followed by large scale manufacturing can fulfil that.

Reaching the huge target of $100 billion by 2020 is a tedious task for the industry. While government agencies and industry associations are doing their best to promote the growth agenda, companies at the individual level have to be an active part of the exercise. But, that has not been the case due to a host of issues that they get caught in.

According to Dr Anuj Goel, chief scientific manager at Biocon, "Discovery has been second priority for most of the companies. There is adequate infrastructure built up but the challenge that remains is regulation and right talent."

To reach targets such as $100 billion, Dr Amulya Panda, senior scientist, National Institute of Immunology, agrees on the need to have a robust manufacturing industry. "We all talk about system biology but money generation is important. We must analyse why big companies such as HAL have been shut down. We need to set up an industry that can sell to India. We are just running after vaccines. We can have alcohol and chemicals," says Dr Panda in his frank assessment.

Dr Sanjay Singh, chief executive officer, Gennova Biopharmaceuticals, who had to quit the International Center for Genetic Engineering and Biotechnology (ICGEB) when regulations became scary, says his hard malarial molecule lead had faced a big struggle. But as per him, he got partners and survived. "90 percent of research comes from academia because it is being funded by National Institute of Health (NIH). We can only succeed if we are very specific. Government cannot be blamed only for the mess," said Dr Singh.

"All stakeholders have to be on one level. Biosimilar guidelines are an example. We require a catalyst. Government must ask where the money is going. We don't have to face competition. We have a huge population that can serve as a market. We have an indigenous population," added Dr Singh.

Mr Subir Basak, president of Jubilant Drug Discovery Services of Jubilant Life Sciences too finds lot of positivity around. "When I came back, there was no BIRAC. Things have changed a lot on the ground. Biomanufacturing has lot of opportunities to explore. There is existing talent and we need to forward it. We have a lot of experience but what is lacking is the connection between the dots."

Moving away from conventional areas, and looking at the Indian energy requirements, 70 percent of the consumed engery is imported. Industrial biotechnology can play a significant role in providing an answer. Textiles from corn rather than fossil fuels (chemicals) is one such example. The relation of textiles with biotech can be explored.

While Dr Amulya Panda feels that large scale bio-manufacturing is a challenge, Dr Sanjay Nene, senior scientist, National Chemical Laboratory, is of the opinion that collaborator model can be a good option. Dr Nene says, "We require policies to consolidate interests in Indian companies so that there is no trespassing. Improvement of the process for starch is also underway at many companies. The government policy is to have aÂ plantation dedicated to creating biomass. Now looking at the biomass conversion, there is no clear idea about the amount of biomass available for it. But it is said that 150 million tonnes of biomass is still unused in India."

At the moment, close to Rs six lakh crore worth petrol is being imported into the country. "Phosphate based detergents have been happily used in Indian households. The enzyme based detergents are ignored. The textile policy needs to be revisited. The approach has been unprofessional," said an owner of a small scale firm.

Juggaad vs Innovation

In pursuit of newer discoveries and inventions, companies can either follow the proven path or take a short cut route. The latter can give quick results but quality might get compromised in the long run. There are divergent views on the usage of term 'Juggaad' in the context of biomanufacturing.

Dr Anuj Goel believes that there are no short cuts for quality. He says, "Basics need to be followed. Finding critical quality parameters for your processes is important. Biomanufacturing is not just making drugs but involves various aspects related to development. The concept of cluster will work well here."

Dr Harish Iyer, CEO, Shantha Biotechnics, part of Sanofi Aventis Group that deals with vaccines is of the opinion that the primary job is to create indigenous vaccines. "About 80-90 percent revenue comes from outside. Jugaad is a big no for me. We have to be careful not to loose the trust of the clients," said Mr Iyer.

Most agree that the approval process is a pain in India. In last six months itself, there were 20-40 warning letters issued by US-FDA to Indian companies for failing to comply with its guidelines.

Dr Sanjay Singh proposes that DBT not be related with the approvals. He points to 31 independent clearances for approvals to drugs and the need for single window clearances. "Our biosimilar guidelines are closer to US FDA parameters. We have signed an agreement with the US FDA for vaccine development, he added

Dr Subir Basak is of the firm belief that the quality controller has a moral responsibility irrespective of profits. He cites his credentials as a former deputy drug controller with US FDA and points to the fact that the 40 percent of the drugs globally come from India. "Steps taken to rectify the issues ailing the industry: Quality does not mean high degree of documentation. To me, it means the kind of bottle, the quality of ingredients for my parents. Erythropoietin being one example," mentioned Dr Basak.