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“PLI scheme’s umbrella needs to be expanded to cover key aspects of biotech industry & biosuppliers”

10 July 2023 | News

On the verge of completing five decades in the biotechnology industry, Mumbai-based HiMedia Laboratories was one of the prominent players during the global fight against COVID-19. After overcoming all the challenges brought about by the pandemic on the nation and industry’s growth, the company is now set to venture out into new areas towards portfolio expansion and greater opportunities. After winning the BioSpectrum Special Recognition Award 2023 for Best Innovator for COVID-19 solutions, Dr Vishal Warke, Director- R&D Cell Culture and Immunology, Himedia Laboratories talks about the company’s growth plans and the future of Indian biotechnology sector.

Please share more details about the new projects at HiMedia Labs during FY23-24, and beyond.

We have developed an exclusive and comprehensive serum-free media range that supports the development of vaccines by nourishing the cell lines involved in the process like Vero, HEK293, BHK-21, etc. The diseases covered are both human (including COVID-19) and veterinary (Foot and Mouth Disease- FMD). We also provide adjuvants and stabilising chemicals for the vaccines. We provide them to all the vaccine manufacturing facilities in India and the rest of the world.

A very crucial ongoing project from Cell Biology division is our project on the development of media for biosimilars. This

project has been awarded a grant from both National Biopharma Mission (NBM) and Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT) in 2020 for development of serum-free, chemically defined media for monoclonal antibodies-mAbs (produced using CHO cell lines) and non-mAb protein therapeutic molecules.

The NBM's mission is to make these Biosimilar products available to our patients at affordable rates; hence we are scaling up the production volume of our media to millions of litres per annum at cost-effective prices to support the Biosimilar production needs of our Indian Biopharma. All this will not only ensure the reduction of prices for Biosimilars in India but also make us self-reliant in this field. This is necessary because of what we saw happening to India during the pandemic for vaccines.

During COVID, many vaccine companies could not get the required media from overseas. It caused a lot of critical shortages especially during the deadly second wave of the pandemic.

Today, we have the complete set up—from media design and development to process optimisation and scale up through 1.5, 4, 10 and 50 L bioreactors. This is coupled with advanced analytics such as metabolomics, peptidomics, proteomics and other analytical tools. A very proud moment for me and my wife, Dr Priti Warke, was when we won the BIRAC Innovator Award 2020 for this project.

We are now exclusively working upon how to support autologous organ transplantation in India through 3D cell culture and 3D Bioprinting. We are developing bioprinters, bioinks, and bioscaffolds for this to be possible. We have previously developed media for the sake of organ transplantation and storage for heart, skin, and cornea.

As we also provide media for the expansion and maintenance of various pluripotent stem cells, both these initiatives will give a much-needed incentive for the development of lab/organ-on-chip and lab-grown organs in India. Based on 3D cell culture, we also are developing various defined and customised culture media to grow cultured meat in India.

These initiatives are well inclined with the Make-in-India concept being pushed by the government. What are your views on this, particularly with respect to the diagnostics sector?

Self-reliance is very crucial for our nation, as we painfully realised during COVID. Our dependence on foreign nations for the raw materials of many assays is very high. That is one key area where we need to work on. Moreover, today either the full machine or at least the components for the diagnostic equipment are imported into the nation. This must be changed by adequate support and schemes from our government. Current Production Linked Incentive (PLI) schemes are the right step in this direction, but their ambit and scope must be expanded to cover more areas.

According to you, what are the current challenges facing the biotech industry, and what is the way forward?

Due to inflation, cost of funds due to rise in interest rates internationally (current repo rate 6.5% in India), there is a slowdown in foreign economy because of which exports from India to these countries is affected. Also, PLI scheme's umbrella needs to be expanded to cover key aspects of biotech industry and biotech suppliers.

Dependency on China for critical biological raw materials such as amino acids, hydrocolloids, cofactors, enzymes, indicators, biochemicals, and fine chemicals needs to be addressed urgently with the support of government funding and other supportive policies. Economies of scale are very critical for us to be cost-effective. We need to build large volume manufacturing capacities with healthy export volumes to be able to drive the prices down for our own domestic use.

Lastly, in-house, or local manufacturing of critical machine components such as small pumps, chips, ready to use printed circuit boards (PCBs), etc. for the diagnostic and biopharma industries are the major challenges.

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