

## “A network of Biofoundries, will boost ecosystem’s value creation status as Innovator”

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After a policy shift under Narendra Modi’s regime, biotechnology research and biotech startups are prioritised and have taken centre stage. Now the centre has announced a BioE3 Policy aimed at ‘Fostering High Performance Biomanufacturing’. The policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of AI, digitalisation with ‘omics’, and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country. In an interaction with BioSpectrum, Dr Manish Diwan, Mission Director, Make in India for Biotech Sector, Biotechnology Industry Research Assistance Council (BIRAC) and Head, Biofoundry, NCR Biotech Cluster & IVCOL shared some insights about new BioE3 policy and plans for upcoming iBRIC Biosciences Innovation Park and goals of this pioneering facility.

**Could you give us an insight into the iBRIC Biosciences Innovation Park’s upcoming plans for biotech innovations, especially in the precision therapeutics space?**

The iBRIC+ Biosciences Innovation Park, a 200-acre campus in the serene Aravali hills on Faridabad-Gurgaon highway, would be India’s first model Biocluster powered by the Department of Biotechnology (DBT) and BIRAC. It will address a large infrastructural gap that currently exists in the innovation ecosystem by setting up a pilot and pre-product development facilities for startups, and SMEs. The biocluster would nucleate the best talent, industry and investments to create a world-class ecosystem.

The campus already has a presence of 800+ researchers, top-of-the-line research institutions - Translational Health Science and Technology Institute (THSTI) & Regional Centre for Biotechnology (RCB), BioNEST incubation centre, BSL3 facility,

India's largest vivarium, India's only Ferret facility, a primate centre and Indian Biological Data Centre. The cluster will integrate complementary strengths of engineering, medical and business schools, international capacity centres and capability centres of national and international R&D companies. Lifesciences deep-tech startups, SMEs would be able to lease out space to set up their independent R&D, and early-stage manufacturing facilities. The translational research leads from startups, SMEs, and DBT's research institutes particularly National Institute of Immunology (NII), International Centre for Genetic Engineering and Biotechnology (ICGEB), National Brain Research Centre (NBRC) and National Institute of Plant Genome Research (NIPGR) that are located in NCR and others which are spread out across the country, would become accessible for development through this Innovation Park. A new i3C-RCB PhD programme initiated in August this year would create a pipeline of industry ready skilled PhD scholars who could be locally employable. Enabling stakeholders of the innovation ecosystem like IP, legal, regulatory, financial service providers, Funders, Angels, VCs, Knowledge Process Outsourcing (KPOs), industry associations, etc. would have local offices. On the lines of MassBio in the US, and Biopolis in Singapore, the NCR biotech cluster would emerge as a vibrant bio-innovation hub and draw in private investments and Public-Private Partnerships (PPP).

Under the guidance of the recently approved BioE3 policy priorities, the lifesciences deep tech innovations and pre-product development would take the central stage at this cluster. The primary strength would include biologics, precision medicine, cell and gene therapy, live biotherapeutics, in vitro diagnostics, biological data and sample repository for pre-clinical development. The Medical Research Centre at the iBRIC+ Bioscience Innovation Park which is likely to be functional in Q1 2025, is preparing to offer capacities for first-in-human clinical studies, controlled human infection and challenge studies, metabolomics, genomics, biomarkers and clinical pharmacology studies.

**Are iBRIC's goals aligned with the framework of the new BioE3 policy for biomanufacturing? In the coming years, how would iBRIC strategise to capitalise on the momentum the BioE3 policy is set to provide?**

The BioE3 policy would pave the way for India to become a \$100 billion Bio-manufacturing Hub. It has identified Bio-innovation and Bio-manufacturing as the two key drivers for promoting India's BioEconomy for the 'Viksit Bharat'. The iBRIC+ Bioscience Innovation Park at NCR biotech cluster would have capacities to promote the progression of life sciences innovations up to pre-product development which is currently a rate-limiting stage in the innovation ecosystem. DBT/ BIRAC have successfully nurtured a biotech startup ecosystem in the country that has reached 95 bio-incubation centres and 8500+ biotech startups from less than 6 bio-incubators and 50 biotech startups in 2012. For the progression of innovations, from ideation to Proof of Concept level, the infrastructure of bio-incubation centres is adequate. But to progress to the pilot and validation stage, the startups struggle and perish. They have to depend on industry-scale service providers to prepare pilot and validation batches, avail development expertise, regulated facilities and infrastructure which are highly unaffordable and not easy to access. This has become a valley of death for most life sciences startups.

BioE3 policy recognising this gap, has envisaged the setting up of domain-centric Biofoundry and Bio-manufacturing facilities that would provide pilot and validation level infrastructural and expertise access. iBRIC+ Biosciences Innovation Park at NCR biotech cluster would plug this gap. Research leads from NCR and across the country in the biological sciences domain would be able to access all this in the biocluster. Thus, preparing a pipeline of projects for bio-manufacturing.

The Department of Biotechnology would set up additional bioclusters in the country under the scope of the BioE3 policy.

**iBRIC's biofoundry infrastructure presents a unique PPP model. Can you tell us more about the implementation that goes behind establishing a sustainable PPP model, especially in the context of fostering product innovations and scale-up for intricate precision therapeutics space?**

Public Private Partnerships is the central thesis of the iBRIC biofoundry and the cluster model. For an innovation to evolve into a commercial product and used by a target customer, it takes expertise, resources, and support of several stakeholders. Government as a central enabler, through DBT/ BIRAC in this case, is creating the grounds for different actors to come together with their expertise to partner and perform.

Let's understand this with an example, a vaccine candidate is tested by THSTI scientists in laboratory and animal models to establish the Proof of Concept. This 'research lead' would need pre-clinical and clinical development before going to market. Then there is manufacturing, sales of millions of doses and post-market surveillance. This is the forte of the biotech industry and has a limited in-house 'research lead' pipeline, therefore, bringing the two together. Funders and Investors join to support the two parties' commitment increasing the overall probability of success in such partnerships. We all remember the convergence of several such PPP for COVID-19 vaccines at the NCR biotech campus.

Likewise, value chains for CAR-T/NK cell therapies, monoclonal antibodies, diagnostics and therapeutics solutions are to be created with the engagement of relevant stakeholders from India and overseas.

Biofoundry would be run in a PPP model to provide scientists access to professional expertise and high-end infrastructure on a pay-per-use basis. Participation of the supporting industry i.e., equipment and reagent with latest products, is encouraged.

**In general, how are Biofoundry infrastructures and a robust 'Design-Build-Test-Learn' approach positioned to drive biotech innovation, and what strategies can be undertaken to make Biofoundries more accessible to researchers and industries that are at varying levels of expertise/business scale?**

Co-localisation of Biofoundry with research institutions, startups & SMEs would enable the fertilisation of high-level innovative ideas. The translation of existing ideas into Proof of Concept and demonstration of pilot-level success. Biofoundry setups would be affordable, scientists would be able to avail the common access facilities and take operational & intellectual assistance from professional experts running the operations. This enabling module would enhance turnaround time (TAT) and the probability of translational success of research leads from academia and startups.

A network of such Biofoundries, will boost the ecosystem's value creation status as 'Innovator'. With the success of each such proposition, the number of startups growing in the industry would go up. This would transform India's growth journey in 'Amrit Kaal'.

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