

PARLIAMENT QUESTION: PROMOTION OF ENTREPRENEURSHIP AND INDIGENOUS MANUFACTURING IN BIOPHARMA SECTOR

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The Government of India has taken steps for promoting entrepreneurship and indigenous manufacturing in the biopharma sector.

Department of Biotechnology (DBT) has set up Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8 Public Sector Enterprise, in 2012, as an interface agency to nurture and strengthen the startup ecosystem and encourage entrepreneurship with a focus on healthcare sector that covers Pharma and Biopharma. BIRAC through funding grants has supported startups, SMEs, and innovators. Some of the key achievements of BIRAC include:

Funding and supporting early-stage innovation

Launched flagship funding schemes such as BIG (Biotechnology Ignition Grant), SPARSH (Social Innovation Programme for Products: Affordable & Relevant to Societal Health), Equity Schemes like SEED Fund (Sustainable Entrepreneurship and Enterprise Development) and LEAP Fund (Launching Entrepreneurial Driven Affordable Products), to strengthen the startup ecosystem and incentivize private sector R&D by addressing funding gaps post-ideation and pre-commercialization. Nearly 1000 Startups and entrepreneurs have benefitted from BIG scheme and SPARSH has awarded 150+ fellowships, creating 100+ startups and 65+ IPs.

Strengthening India's biotech innovation ecosystem

BIRAC has established a strong network of incubators, including 94 Incubation and pre-incubation centres, supporting 3000+ incubates and fellows, across 25 states and UTs of the country. Opportunities have been provided through BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies) and E-YUVA (Empowering Youth for Undertaking Value-Added Innovation Translational Research) schemes.

The Department of Biotechnology (DBT) is supporting the National Biopharma Mission (NBM), a Cabinet approved Program entitled Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals – “Innovate in India (*i3*) Empowering biotech entrepreneurs & accelerating inclusive innovation”; being implemented through Biotechnology Industry Research Assistance Council (BIRAC). This Program is enhancing India's innovation research and product development capabilities, especially by focusing on development of vaccines, biologics and medical devices for combating public health concerns.

Some key achievements of NBM include:

- Under NBM, support has been provided to over 100 biopharma-oriented projects, involving many MSMEs/startups, and facilitating creation of shared facilities (testing, validation, manufacturing) — driving domestic capacity for biologics, vaccines, diagnostics.
- *Product Development-* The Mission has successfully delivered 02 COVID-19 vaccines, ZyCoV D and Corbevax, biosimilar Liraglutide for diabetes, pegylated interferon alpha-2b for COVID-19, first indigenous MRI scanner, single-use bioreactors, 09 Covid-19 diagnostic kits, ventilators and reagents, Laboratory Information Management System, CHO Cell culture media, which have been developed and commercialized.
- *Ecosystem strengthening-* NBM has supported setting-up research and GMP manufacturing facilities where over 500 services have been rendered via 18 functional facilities. For the first time in India a network of 7 Technology Transfers Offices (TTOs) has been set up to facilitate patent filings and technology transfers. A network of 46 GCP-compliant clinical trial sites has been set up to facilitate trials for vaccines and therapeutics.

DBT with the approval of the Cabinet, has subsumed its 13 Autonomous Institutions (AIs) and created one Autonomous Body, the Biotechnology Research and Innovation Council (BRIC), as a registered Society. BRIC is intended to integrate the multi-disciplinary research, training, and innovation programs operational across various DBT institutions. BRIC By-Laws have enabling provision for supporting scientific entrepreneurship and research commercialization. The operational guidelines and approval mechanisms for availing the provisions of the scheme while in employment at iBRIC have been simplified and notified.

DBT with the approval of the Cabinet, in 2024, is implementing the BioE3 policy towards fostering High-performance Biomanufacturing in the country impacting the economy, environment and employment.

Under this initiative, Biofoundries and Biomanufacturing hubs are being established across the country in all the identified thematic verticals of the Biomanufacturing program including "Precision biotherapeutics" for promoting domestic manufacturing of monoclonal antibodies, mRNA therapies, cell and gene therapies and other such advanced precision medicines. The programs are under support.

Also, the Department under its “National Biotechnology Park Scheme” supported a project to establish a Biopharma Growth Phase park (B-Hub) at Genome Valley, Hyderabad with the aim to provide a platform for biopharma start-ups and companies to conduct proof-of-concept study at its scale-up manufacturing facility. Currently, the Park is under construction.

Department of Pharmaceuticals is implementing Production Linked Incentive (PLI) scheme for Pharmaceuticals, which has a total budgetary outlay of Rs. 15,000 crore, aims to enhance India’s manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector. Under the scheme, biopharmaceuticals are covered as one of the eligible product categories, where incentive at the rate of 10% on incremental sales is available.

Achievements:

- As of September, 2025, 46 biopharmaceutical products including vaccines are being manufactured under the scheme.

- The cumulative sales (from FY 2022-23 till September 2025) of the eligible biopharmaceuticals under the scheme is worth Rs. 26,832 crore which includes exports of Rs. 16,290.

Indian Council of Agricultural Research (ICAR) Animal Science Institutes are advancing entrepreneurship and indigenous biopharmaceutical manufacturing. ICAR–NIHSAD (National Institute of High Security Animal Diseases) develops priority vaccines and diagnostics. The ICAR–IVRI (Indian Veterinary Research Institute) Pashu Vigyan Incubator under RKVY-RAFTAAR supports livestock biopharma startups through ₹5 lakh (Navodaya) and ₹25 lakh (Samridhi) grants, along with providing R&D infrastructure, mentorship, and regulatory/ commercialization assistance.

Some key achievements:

- Indigenous poultry vaccines and diagnostics now commercially produced, reducing import dependence.
- Four companies are manufacturing NIHSAD’s H9N2 vaccine, enhancing avian influenza preparedness.
- One industry partner has commercialized the Indirect ELISA kit, enabling affordable nationwide surveillance.
- Genext Genomics Pvt. Ltd., funded under RKVY-RAFTAAR, developing diagnostics for Classical Swine Fever and Brucella and advancing therapeutic antibodies, cell lines, and biosimilars.

Council of Scientific and Industrial Research (CSIR) promotes entrepreneurship and indigenous biopharma manufacturing through its laboratories. The details and achievements are as below:

- *Venture Centre (CSIR-National Chemical Laboratory (CSIR-NCL), Pune)*: Established a GLP-compliant Centre for Biopharma Analysis to support companies with R&D and regulatory analytics. It has enabled development of the first Liraglutide and supported Serum Institute’s US-FDA submission for the Covavax platform.
- *CSIR–Indian Institute of Chemical Technology (CSIR-IICT), Hyderabad*: Develops indigenous bioprocess technologies for APIs and intermediates; provides pilot-scale facilities, analytical validation, affordable tech transfers, impurity profiling and product validation. Outcomes include commercialised bioprocesses, import substitution of critical materials, and strengthened industry partnerships.
- *CSIR-Central Drug Research Institute (CSIR-CDRI), Lucknow*: Develops indigenous biomedical and diagnostic technologies and enables MSMEs/startups through affordable tech transfer. Developed a nucleic-acid staining dye leading to two commercial products—GreenR DNA Stain and Real-Time GreenR Master Mix—now available on Government eMarketing (GeM) portal.
- *CSIR-Institute of Microbial Technology (CSIR-IMT), Chandigarh*: Established a GMP-compliant Microbial Cell Bank Repository and signed multiple MoUs with pharma companies for R&D in biotherapeutics and vaccines.
- *Atal Incubation Centre (AIC)-CCMB established at CSIR-Centre for Cellular and Molecular Biology (CSIR-CCMB), Hyderabad*: Supports innovation-led biotech startups under Atal Innovation Mission; provides funding support, regulatory facilitation, skill development, and industry–academia collaboration. It has supported 220 startups in the last 7 years, facilitated investments of ₹250 crore, and enabled at least 12 product launches. During COVID-19, it helped build indigenous capacity in diagnostics, therapeutics, and vaccines.

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