



Affordable Biopharmaceutical Development *(Identifying Novel tools/technologies and Process optimization)*

Biotechnology Industry Research Assistance Council (BIRAC), a Not for Profit, Sec 25 (now Sec 8) Public Sector Undertaking of Department of Biotechnology, Ministry of Science & Technology, Government of India, has been set up to nurture the Biotech Innovation Ecosystem, support Start-ups and SME's for innovation research and promote affordable product development through public-private partnership.

BIRAC's vision is to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly startups and SME's, for creation of affordable products addressing the needs of the largest section of society. Considering the immediate requirement in the area of biopharmaceuticals, BIRAC intends to announce a call for identifying tools/technologies and for optimizing existing processes so that biopharmaceuticals become affordable to largest section of society.

Background:

Biopharmaceuticals (therapeutic biologics) have become, of late, an important therapeutic option as they provide an alternative to small molecule drugs and may provide novel treatments to previously untreatable diseases as well. According to a new market report published by Persistence Market Research "**Global Market Study on Biopharmaceuticals: Asia to Witness Highest Growth by 2020**", the global biopharmaceuticals market was valued at US\$ 162 billion in 2014 and is expected to grow at a CAGR of 9.4% from 2014 to 2020, to reach an estimated value of US\$ 278 billion by 2020 (www.persistencemarketresearch.com).

The Indian biopharmaceutical companies are making considerable progress in this area by developing and manufacturing biologic products for global and national needs. They are offering professional pharma outsourcing services to global biopharmaceutical companies with their capabilities in downstream process including development & optimization of cGMP-compliant manufacturing process, continuous & fed-batch production, large scale separation & purification, bio-analytical method development, purity analysis & profiling, stability testing, product characterization etc. The Indian biopharmaceutical sector therefore provides a significant possibility of fast growth, particularly in the global bio-manufacturing outsourcing market. Despite this considerable success in this sector by Indian industry, the affordability of biopharmaceuticals is confined only to limited population in India. Given the Indian context, it becomes pertinent to focus on low-cost affordable product development. Major biopharmaceutical therapeutics currently range in cost from Rupees 1-10 lakhs (per year) and these costs have to come down considerably for making these critical therapeutics affordable in India without compromising on safety and efficacy.

**Key Goal:**

The goal is to identify innovative tools/technologies, specific areas in product development value chain and optimize existing processes that will contribute to cost reduction and result in affordable biopharmaceuticals.

Key Features of the call:

The following are identified as priority areas, but not limited to, for submitting the proposals,

- Development of novel, stable, high-expression cell lines (microbial and mammalian) and expression vectors.
- Glycoengineering.
- Technological solutions encouraging Continuous processing.
- Low-cost, in-vivo bioassays.
- Technologies for pharmacological characterization.
- Reactor engineering for bioprocess.
- Formulations offering, at least, short term stability at room temperature.
- Low-cost alternatives to key consumables including Protein A resin and viral filters.
- Fermentation processes, serum free media development, purification or chromatographic techniques.
- Simulation models or novel process to improve downstream technology.
- Faster and novel process analytical techniques for quality assurance.

Any idea that provides innovative and technological solutions for alleviating the process economy issues associated with biopharmaceutical manufacturing will also be considered based on strong scientific justification.

The following will not be supported under this call

- ✓ Facilities creation/development



- ✓ Projects focussing on technology/process development with no preliminary data and based only on hypothesis
- ✓ Products not having application in the biopharma industry

Proposals to be considered under SBIRI:

- Identification and validation of novel bioprocesses for biopharmaceuticals at lab scale (5.0 L)
- Innovative R&D solutions for upstream and downstream process optimization

Proposals to be considered under BIPP:

- Pilot scale validation of novel processes
- Demonstration of novel engineering processes for existing technologies

Who can apply?

A single or consortia of Indian company (ies) registered under “The Indian Companies Act 2013” with minimum 51% Indian ownership, and DSIR recognized in-house R&D unit, are eligible to apply either alone, or in collaboration with a partner from another Company/Institute/University/ Organization.

(Companies in the process of obtaining DSIR recognition may also apply; however, their funding would be subject to getting DSIR recognition).

How to Apply?

Proposals for the Scheme are required to be submitted online only. To submit a proposal online, please log on to the BIRAC website (www.birac.nic.in).

No Hard Copy to be submitted. Proposals submitted online only would be considered.

Last date for Submission of Proposals: 31st March, 2016

Details of the scheme including eligibility requirements, categories for proposal submission; guidelines for support as grant agreement templates etc. are available at www.birac.nic.in

BIRAC will ensure maintenance of strict confidentiality of the proposals as per DBT norms.