



# Department of Biotechnology Ministry of Science and Technology Government of India

The Implementation Plan for Biomanufacturing and Biofoundry has now been uploaded as Annexure. Applicants are requested to submit their proposals, aligned to the Implementation Plan, on or before 14<sup>th</sup> November 2024 (17.30) hours).

**DBT-BIRAC Joint Call for Proposal** 

# मूलांकुर BioEnablers: Biofoundries and Biomanafacturing Hubs

#### 1. Introduction:

Recognizing the potential of Biomanufacturing to power green growth, the Department of Biotechnology (DBT), Govt. of India has undertaken an initiative on Fostering High Performance Biomanufacturing.

Proposals are invited for setting up of Biofoundries (for early scaling-up of proof-of-concepts) and Biomanufacturing Hubs (shared pilot-scale and pre-commercial-scale facilities) to support research, innovation and scale up in the following thematic sectors/subsectors:

- (i) Bio-based chemicals, Bioplastics, Active Pharmeceutical Ingredients (APIs), and Enzymes
- (ii) Functional Foods and Smart Proteins
- (iii) Precision Biotherapeutics (monoclonal antibodies, mRNA therapeutics, cell & gene therapy)
- (iv) Climate resilient agriculture (agribiologicals)
- (v) Biofuels and Carbon capture
- (vi) Futuristic marine and space research

The applications may be submitted either solely or in partnership by 1. Academia, 2. Company/LLP 3. Societies/Trust/Non-Government Research Organisations/ Foundation and 4. Start-ups. Support is envisaged for co-development of Biofoundries and Biomanufacturing hubs as programmatic research support for scaling-up and biotech product development through biotechnological approaches. These Biofoundries and Biomanufacturing hubs are expected to provide research resources and scale-up support to advance in-house research projects as well as provide services to other organizations, biotech start-ups, SMEs, and industries.

The funding mechanisms for the proposed activities will be as per the 'Implementation Plan' (Annexed).

# 2. Scope of call:

Proposals for seeking support to establish Biofoundries and Biomanufacturing Hubs should clearly indicate any one of the following categories:

- A) using existing facilities
- B) augmenting existing facilities
- C) setting up of new facilities.

#### The detailed proposal should also highlight the following but not limited to:

i)	Available Facilities and resources
ii)	Biological systems and processes
iii)	Product Portfolios
iv)	Demonstrated experience of setting up such facilities and enabling access to start-ups (for projects in PPP mode)
v)	Modalities of engagement and business model to sustain the proposed facility
vi)	Resource commitments
vii)	Any other relevant points

# 3. Eligibility:

Following documents need to be submitted by the entity during submission of detailed proposal (whichever is applicable):

# A. Companies: -

- a. Incorporation certificate.
- b. CA/CS certified share holding pattern as per BIRAC format (Companies having a minimum of 51% Indian shareholding/ individuals holding Indian passports are only eligible) mentioning UDIN number.
- c. Details regarding in-house R&D facility, if any; or Incubation Agreement with recognized Incubator.
- d. Audited financial details of latest last three financial years,
- e. Copy of passports of the shareholders if required (in support of 51% eligibility criteria).

#### B. Limited Liability Partnership: -

- a. Incorporation/Registration Certificate.
- b. Partnership deed; CA/CS certified certificate which states that minimum half of the partners are Indian citizens mentioning UDIN number.
- c. Copy of passports of Indian partners/subscribers
- d. Research mandate/ details regarding in-house R&D facility, if any/

Incubation agreement

e. Audited financial details of last three financial years;

Companies/LLP if recommended have to provide a declaration stating that Company/LLP is not in default of BIRAC OR any other organization. Further there are no Legal Proceedings going against the applicant.

#### C. Indian institution/ universities/ public/private research organization: -

- a. Affiliation/registration certificate or statute reference for establishment.
- b. Details regarding in-house R&D facility, if any.
- If the institution/public research organization are registered under/as Society or Trust, then they have to submit the documents as mentioned for trust/society

# D. Society/ Trust/ NGO/ Foundation

#### i. Society

- a. Society Registration Certificate
- b. Byelaws of Society
- c. Details regarding in-house R&D facility, if any.
- f. CA certificate (supporting the fact that half of the members of the society are Indian citizens) mentioning UDIN number.

#### ii. Trust

- a. Trust deed and Registration Certificate
- b. Details regarding in-house R&D facility, if any
- c. CA certificate (supporting the fact that half of the trustees are Indian Citizens) mentioning UDIN number

#### iii NGO /Foundation

a. For NGO, or Research Foundation, submission of proper registration/ accreditation from a government body is mandatory like UGC affiliation certification AICTE, CSIR /DSIR/SIRO certificate/Bye laws of society/Trust Deed etc whichever is applicable.

#### E. Start-ups

The company must be no more than 10 years old from the date of

incorporation at the time of closing the call

#### Other Documents Required:

- I. Expression of Interest (EOI), MOU or support letters as scanned copies executed on relevant Letter Heads to show the mutual partnering arrangements in case of collaborating Project/Project.
- II. Documents related to the conveyance of legal interests in the background technology/IP.

# 4. Intellectual Property Governing Framework:

Existing Guidelines of DBT and BIRAC will be followed.

## 5. Operational Modalities:

- Applications from academia proposing facilities to be located in institute premises
  are encouraged to have an industry collaborator who should operationalize and
  run the facility. Such applications should show co-investment plan from industry
  and academia. However, academia can submit applications solely. In that case,
  accounts have to be maintained separately.
- Implementation plan may be referred for upper cap on funding and details on applicant's contribution for biofoundries and biomanufacturing hubs.
- Budget heads to be funded by BIRAC/DBT would include Non-recurring (refurbishing, renovation, equipment, accessories etc), Manpower, Consumables (repair and maintenance of equipment, chemicals, consumables etc.), Travel, Contingency, Training & workshops and Outsourcing. Any kind of land/construction cost will not be considered under project cost.
- As per clause 3.1 of Implementation plan
  - ➤ For Biofoundry: A list of technologies proposed to be scaled up must be provided along with their PoC. The biofoundry must also support projects by external users, the budget for which shall be provided by the biofoundry as per the implementation plan.
  - ➤ For Biomanufacturing hubs: a list of technologies proposed to be scaled up is to be provided. In-house technologies are also to be mandatorily included in the list provided. PoC/validation data available for such technologies need to be provided.
- The proposal should be accompanied by a brief description on how the biofoundry/biomanufacturing hub would generate revenue and plan for cash flow

projections. The business plan is mandatory for the biomanufacturing hub and biofoundry.

- Facilities developed/operationalized through this programme should be accredited by a reputed accreditation agency i.e. Good Laboratory Practice (GLP), National Accreditation Board for Testing and Calibration Laboratories (NABL) etc, if required.
- The facilities developed/ operationalized through this programme should adhere to relevant regulatory compliances, environmental authorizations and appropriate approvals. Proposals that have already secured the relevant clearances or are close to obtaining them will be prioritized.
- BIRAC/DBT may reach out to the PI if further information is required to consider the proposal as complete.

# 6. Other requirements and criteria relevant to specific category are as follows:

# Category A & B. Development of biofoundries/biomanufacturing hubs using existing facilities or augmenting existing facilities

- The applicant seeking BIRAC support for augmenting the existing facility should have an operational facility at the time of application.
- The applicant should have proven track record in providing services to the startups/researchers.
- The applicant should have adequate expertise and infrastructure to support biomanufacturing activities.
- The applicant should preferably have an existing ISO 9001/2015 certified facility and ISO 14001certification
- The applicant should give commitment for developing cataloguing and data management capabilities

**Duration:** Project duration will be up to 2 years, extendable upto 5 years based on performance.

# Category C. Setting up of new facilities (only for biomanufacturing hubs)

- Applicant should have land available with them to set up the Biomanufacturing hub. The land could be either owned by the applicant or the applicant should have long term lease (min 10 years).
- The applicant should have adequate expertise and resources to support

biomanufacturing activities.

- The applicant should give commitment for developing cataloguing and data management capabilities
- The facility, once operationalized should preferably comply with ISO 9001/2015 and ISO 14001certification.

**Duration:** Project duration will be up to 2 years, extendable upto 5 years based on performance.

# 7. <u>Usage and access to resources/ facilities/ platforms</u>

- The Facility supported under the Biofoundry/Biomanufacturing programme should provide access to its high-end equipment and infrastructure to entrepreneurs and any public/private entities to scale up their innovations.
   Once established, their websites are expected to reflect Infrastructure facility usage forms with well- defined usage charges terms and conditions.
- The website of the Biofoundry/Biomanufacturing hub shall host a well-defined link for the facility enumerating the details of user charges, terms & conditions, mode of application and timelines for the decision on the applications.
- The user charges shall be separately defined for different categories viz.
   Research Institutes, Universities (central, state, private), colleges and start-up/ Entrepreneurs.

# 8. Acknowledgement:

Acknowledgement of DBT/BIRAC support: Acknowledge the assistance of DBT/BIRAC while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with the "Disclaimer" that reference therein to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by the BIRAC. Use of DBT/BIRAC logo is not permitted without written approval.

#### 9. Discretion

DBT/BIRAC shall reserve the discretion on determination of sanction of funding and processes as per its standard norms and such determination shall be final. The selection process is not open to review.

#### 10. Governance Framework

The programme shall be governed by the relevant Government/DBT approval, DBT orders, corresponding call of proposals, project GLA and the BIRAC norms.

Contact Information: Further information can be obtained at <a href="https://www.dbtindia.gov.in">www.dbtindia.gov.in</a> and <a href="https://www.birac.nic.in">www.birac.nic.in</a>

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