

Guidelines for

मूलांकुर Bio-Enabler: Biomanufacturing Hubs

Enabling Access to Infrastructure and Resources [Bio-foundries] for Bio-manufacturing



जैव प्रौद्योगिकी उद्योग अनुसंधान सहायता परिषद
(भारत सरकार का उपक्रम)
Biotechnology Industry Research Assistance Council
(A Govt. of India Enterprise)

Guidelines

मूलांकुर Bio-Enabler: Biomanufacturing Hubs

Enabling Access to Infrastructure and Resources [Bio foundries] for Bio-manufacturing

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.

Against this backdrop, Biotechnology Industry Research Assistance Council (BIRAC), a PSU under the aegis of DBT, invites proposals from Industries/ Academic Institutes/ Incubators etc. to set up biomanufacturing hubs.

The proposals are envisaged in the Public Private Partnership (PPP) mode with financial co-sharing to co-develop integrated infrastructure (bio-foundries) including automation, workflows, processes, scale up facilities and related resources for access by start-ups and research communities engaged in biomanufacturing.

2. **Objectives:**

Proposed facilities will support process innovation for rapid design and testing of organisms and scale-up engineering to accelerate biomanufacturing processes in the sectoral areas including but not limited to: functional foods and smart proteins, bio-based chemicals and enzymes, precision bio therapeutics, climate change and resilient agriculture, carbon capture and utilization, futuristic marine and space research.

3. **Scope of call:**

Public announcements for funding opportunity shall be through Call of Proposal. A detailed proposal may be submitted by the applicants separately under the following categories to develop bio foundries:

- Using existing facilities (facility to provide services on immediate basis to fund recipient)
- Augmenting existing facilities (to provide services once the facility is upgraded)
- Setting up new facilities (to provide services once the facility is ready and operational)

The detailed proposal should highlight the following (which may be considered by the committee for evaluation) 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
v)	Modalities of engagement and business model to sustain the proposed facility
vi)	Resource commitments
vii)	Any other relevant points

Detailed proposals would undergo administrative eligibility and review process for further evaluation and selection.

4. Eligibility Criteria:

The proposals can be submitted by Companies established under the Companies Act 2013/ The Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008/ Academic Research Institutes, Universities, Research Foundation, Medical Colleges and Institutes – both public and private who are valid legal entities such as Trust, Society or established under central or state statute, Recognised Incubators. Applications from academia proposing facilities to be located in institutes premises should mandatorily have an industry collaborator who should operationalize and run the facility.

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 recognised 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 research organization: -

- a. Affiliation/registration certificate or statute reference for establishment.
- b. Details regarding in-house R&D facility, if any.
- c. 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 Public or Private Institute, University, 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.

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.
 - i. **Disqualification of Applicants:**

Proposals submitted by companies defaulting on repayment of loan, royalty or are irregular with regard to repayment of installments to BIRAC will be considered ineligible.
 - ii. All companies who have withdrawn their proposal after approval from the committees or whose project was foreclosed due to inadequate funds or any other irregularity would be debarred from submitting fresh proposals for 1 years.
 - iii. BIRAC reserves its right to disqualify promoters/ promoting companies with a track record of legal and financial defaults during due diligence.

5. Intellectual Property Governing Framework:

A. SCOPE OF IP GENERATED DURING THE CONDUCT OF THE PROJECT

- a. The New Intellectual Property (IP) rights belong to the recipient of funds, in a joint manner unless mutually agreed otherwise. Provided, this Project is not determined as a “Nationally Important Project” to be governed through specific Order of BIRAC“. Such cases of “Nationally Important Project” shall have specific terms of licensing, pricing or March-in-rights for the purposes of public interest/ demand of Government of India.
- b. It is the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP). They shall bear the expenditure involved in protecting the New IP.

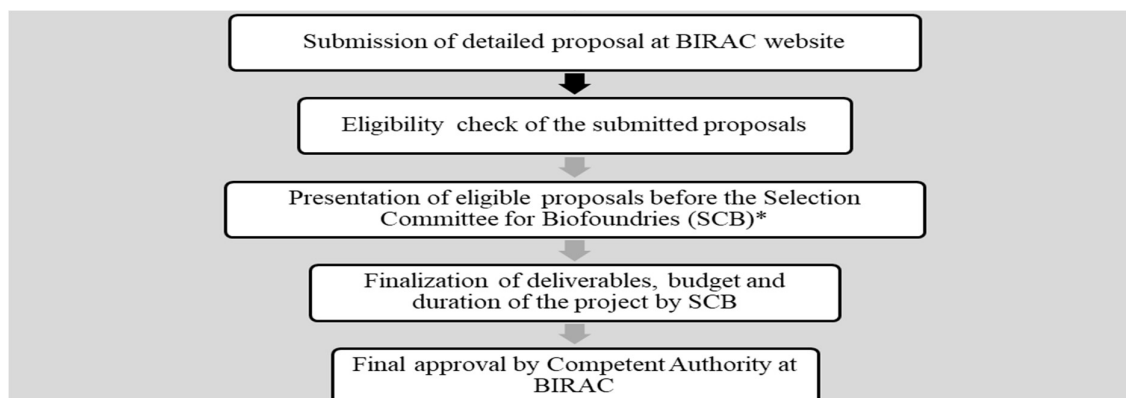
6. Selection Process:

- The Call for proposals shall be published as an open call with a closing date of the

proposals submitted within the specific period

- The proposals received through the open call will be processed through review mechanism.
- After receiving the full proposals, an internal Preliminary Screening Committee (PSC) comprising of members from DBT and BIRAC would be constituted to determine the eligibility of the proposals. Eligible proposals would be called for presentation.
- A Selection Committee for Biofoundries (SCB) would be constituted with the members from DBT, BIRAC and relevant subject area experts to evaluate the proposals during presentation and make final recommendations. Further evaluation steps if required for the proposal, may be included at the discretion of the committee. Total cost, fund distribution between BIRAC and applicant, Fund disbursement, duration and final deliverables of the project would be recommended by the SCB during the meeting.

7. **Process flow:**



*** Further evaluation steps if required for the proposal, may be included at the discretion of the committee.**

8. **Operational Modalities:**

- Applications from academia proposing facilities to be located in institutes premises should mandatorily have an industry collaborator who should operationalize and run the facility. Such applications should show co-investment plan from industry and academia.
- If need arise, collaborations may be forged before submitting the full proposal.
- Resource Commitment from Applicant: Applicant need to specify the form in which their

contribution would be made (such as financial, land, building, equipment etc.). Applicants will have to contribute a minimum 30% towards the project.

- Land and construction cost would not be considered under BIRAC contribution. If land or building cost is shown as resource commitment then the cost should be based on registered cost or lease cost as per current market value. Whenever, promoter contribution is considered by way of land and building already available with applicant, in such cases 100% funding of the project may be allowed.
- Land and construction cost will not be considered as part of total project cost. However, if land/ building is already available with applicant, the same can be considered as promoter contribution based on registered cost/ market value/ lease cost. In such cases 100% funding can be considered.
- The BIRAC funding support will be in the form of grant in aid for refurbishing/ renovation, Capex and operational cost (excluding manpower) and will be based on the need and scope of the project as adjudged by the committee. Budget heads to be funded by BIRAC would include Non-recurring (refurbishing, renovation, lab furniture, equipments, accessories etc), Consumables (repair and maintenance of equipments, chemicals, consumables), Travel, Contingency, Training & workshops and Outsourcing. Construction cost, in case of new facility, may be included under applicant contribution under non-recurring head.
- BIRAC will not support manpower. However, experience and qualification of manpower to be set in consultation with BIRAC. BIRAC may appoint a suitable manpower at selected biofoundries for monitoring purpose.
- Bio foundry supported under this program should provide service model in the proposal.
- The proposal should be accompanied by a brief description on how the biofoundry would be made self-sustainable including revenue generation plan and cash flow projections.
- 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.
- The facilities developed/ operationalized through this programme should adhere to relevant regulatory compliances, environmental authorizations and appropriate approvals.
- Funding would be as per the requirements of the project and there is no capping on funding. It will be based on merit and recommendations of the committee.

- BIRAC may reach out to the PI if further information is required to consider the proposal as complete.

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

Category a. Development of bio foundries using 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.
- Preferably have an existing ISO 9001/2015 certified facility and ISO 14001 certification
- Commitment for developing cataloguing and data management capabilities

Duration:

Duration of support will be upto three years.

Category b. Setting up new facilities

- Applicant should have land available with them to set up the Biofoundry. 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.
- Commitment for developing cataloguing and data management capabilities
- The facility, once operationalized should preferably comply with ISO 9001/2015 and ISO 14001 certification.

Duration:

Duration of support will be upto five years.

10. Usage and access to resources/ facilities/ platforms

- The Facility supported under the Biofoundry programme will be a National Facility and

make available its high-end equipment and infrastructure to start-ups/ entrepreneurs to scale up their innovations. It can also be used by researchers, institutes, universities etc. to develop novel process and technologies for biomanufacturing. 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 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.

11. Guidelines to Reviewers regarding Confidentiality and Conflict of Interest:

- In discharging their duties as Committee members, all Committee members must observe the Code of Conduct, Conflict of Interest and Confidential Information requirements
- These guidelines apply equally to everyone involved in the assessment of applications – including, but not limited to Committee members and Reviewers.

12. Sanction of Fund Support:

- 1) Financial Due Diligence will be done on case-specific requirements as per BIRAC norms.
- 2) The recommendation of SCB will proceed further for financial concurrence, legal concurrence, approval of competent authority and issuance of GLA as per BIRAC norms.
- 3) The start date of the project would be date when legal vetting would be obtained on the executed documents received from the company. Resources contributed by the applicant for the project shall be considered on case to case basis as per the recommendations of the committee.
- 4) After successful execution of the above documents and fulfilment of other formalities, fund disbursement will be initiated by BIRAC as per GLA.

13. Funding:

- 1) The funding support will be in the form of grant in aid will be based on the need and scope of the project as adjudged by the SCB.
- 2) The contribution of BIRAC shall be upto 70 percent of the total cost or as per recommendations of the SCB. Resource sharing of Applicants may be as per submitted proposal and recommendations of SCB. Land and construction cost would not be considered under BIRAC contribution. If land or building cost is shown as resource commitment then the cost should be based on registered cost or lease cost as per current market value. Whenever, promoter contribution is considered by way of land and building already available with applicant, in such cases 100% funding of the project may be allowed.
- 3) The Grant-in-Aid assistance support (hereafter referred to as Funding) will be subject to pre-acceptance of associated conditions and execution of Grant Letter Agreement as prescribed by BIRAC.
- 4) The fund allocation into different budget heads and break-up into milestones will be done as per the recommendations of SCB.

14. Concealment of Information, Foreclosure and Termination:

- i. Any failure by the Grantee(s) to provide the necessary information regarding the services provided or concealment of any relevant information/ inability to provide UC/SOE shall constitute a material breach of the contract. In such a situation, BIRAC is at liberty to terminate the contract and have the right to recover the total grant disbursed by BIRAC alongwith the fine equal to 12 % of the total amount of the financial assistance in the form of Grant-in-aid received by Grantee(s), in addition to any other legal remedies that may be available
- ii. In case, during the Project Duration, it is found that the Project or any Project component is not likely to lead to successful completion, BIRAC may decide to foreclose the Project or the Project component as warranted. The decision of the BIRAC shall be final in all respects. The Fund Recipient(s) shall immediately refund any Grant-in-aid unutilized out of BIRAC's disbursements to BIRAC. BIRAC, at its discretion can allow deduction of the future committed expenses to third party vendors on pro-rata basis according to the quantum of BIRAC's funding. The Fund Recipient(s) shall submit Consolidated accounts of funds received, utilized and unutilized (UC&SOE). If

the fund recipient(s) like to continue the Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions.

- iii. The Fund Recipient(s) may, before the completion of the Project, terminate this GLA by giving three months' notice in writing to BIRAC. BIRAC may also terminate this GLA by written notice in the event of "the fund recipient(s)" committing breach of any term of this GLA and either not rectifying it to the satisfaction of BIRAC or not satisfying BIRAC about its inevitability within a specified period. In the event of termination of the GLA, no further disbursement shall be made by BIRAC. The fund recipient(s) shall be liable to return immediately the amount of Grant-in-aid already availed of from BIRAC with additional simple interest at the rate of 12 (twelve) per cent per annum within 30 (thirty) days of termination of the GLA. Interest on the quantum of funding assistance shall accrue from the date of release of the grant in aid assistance. The Collaborators Institutes shall immediately refund any funds unutilized out of BIRAC's disbursements, to BIRAC, along with consolidated accounts of funds received, utilized and unutilized (UC&SOE). In case of failure to repay, without prejudice to any other rights under this GLA, the amount can be recovered by initiating any procedure available in Law. If later on applicant is unable to put its contribution as per recommendations of the Committee than BIRAC is having right to terminate the Project.

15. Other Formalities:

- 1) Board Resolution should be submitted by Company grantees. Resolution can be by circulation. In case of difficulty in conduct of Board meeting this requirement can be substituted by resolution format signed by MD/CEO/COO along with any other executive Director or Company Secretary. Ratification in any subsequent Board meeting can be undertaken and the resolution can be duly submitted. Letter of Authorization requirements in case of institutions etc shall be considered adequate if the Head of the Institution/ Head of the Department/ Dean of the Institute is the issuing authority.
- 2) Fund releases for the project will be subject to further fulfilment of certain formalities such as opening of no lien account by the fund recipient, submission of savings account KYC details and regulatory approvals as applicable.
- 3) Submit and comply with the Project Risk Management Plan during all stages.

- 4) Appropriate GLA will be issued by BIRAC for the funds disbursed providing for the governing terms and conditions and these shall be accepted by the fund recipient(s) within the time period of four (4) weeks from the date of issue.
- 5) Statement of Expense (SoE) duly certified by a Chartered Accountant (CA) for the expenditure incurred towards the project to be submitted before the release of next tranche of funds in the format provided by BIRAC.
- 6) The Interest earned on the grant in aid disbursed should be reported to BIRAC. The interest thus earned on the grant in aid would be adjusted towards further instalment.
- 7) The fund recipient shall refund such part of Grant in aid disbursed to it that remains unutilized with it, upon completion of all the responsibilities, duties and functions specified in connection with the project within one month of such completion along with consolidated UC & SoE.

16. Post Sanction Process:

- The releases and milestone-based achievement will be monitored through relevant mechanisms. Each selected proposal would be overseen by one BIRAC official and reviewed by 1-2 members from SCB (Project Monitoring Committee) who would periodically review (as per the need of the project) and record its implementation status and advise on further release.
- The fund recipient shall submit technical milestone attainment report and Utilization Certificate/Statement of Expenditure periodically as per the Grant Letter Agreement and subject to fulfilment of BIRAC requirements of fund release.
- The fund recipient is required to comply with all the regulations/ procedures as notified different Departments/ Ministries of Government of India.
- The support may be discontinued at any stage if the PMC is not satisfied with the progress of the project. The decision taken by the PMC will be binding on the fund recipient and no representation of any kind against the decision of the Committee/ will be entertained.

17. Acknowledgement:

Acknowledgement of BIRAC support Acknowledge the assistance of 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 BIRAC logo is not permitted without written approval.

18. Discretion

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.

19. 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 BIRAC website. BIRAC Website: www.birac.nic.in

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