

## **USER ACCESS POLICY FOR DBT/BIRAC BIOFOUNDRIES AND BIOMANUFACTURING HUBS ESTABLISHED AT ACADEMIA/RESEARCH INSTITUTIONS/INDUSTRIES**

### **1.0 Purpose**

**1.1** Department of Biotechnology (DBT) with the approval of Union Cabinet has announced the **BioE3** (**B**iotechnology for **E**conomy, **E**nvironment, and **E**mployment) Policy for fostering High-Performance Biomanufacturing to steer green growth.

**1.2** Biofoundries and Biomanufacturing-Hubs as मूलांकुर Bio-Enablers of Biomanufacturing initiative is envisaged to be established as programmatic research support for scaling up biotech product development.

**1.3** These bio-enablers are expected to democratize research resources and scale-up support to advance in-house research projects as well as provide services to other academia/ research organizations, start-ups, SME's and industries.

Hence this policy has been drafted detailing the access to Biofoundries and Biomanufacturing Hubs for the benefit of various users in the public.

### **2.0 Beneficiaries/Users**

**2.1** Following Stakeholders are to be benefited:

- Start-ups/ Innovators
- Industry
- Research Scientists
- Students: UG/PG/Doctoral/ Postdoctoral

**2.2** The list of established biofoundries/biomanufacturing hubs under different thematic areas with available services to be posted on DBT/BIRAC websites.

### **3.0 Access to resources/facilities/platforms**

- 3.1** The Facility supported under the Biofoundry/Biomanufacturing programme should provide access to its high-end equipment and infrastructure to innovators/public/private entities to scale up their innovations. The facilities after establishment should be published on the organization's website and should reflect infrastructure facility, usage forms with well- defined usage charges and terms & conditions.
- 3.2** The DBT/BIRAC 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. Each Biofoundry/Biomanufacturing Hub should identify a nodal person for liaising with external users.
- 3.3** The user charges shall be modeled as differential service charges for various categories viz. Research Institutes, Universities (central, state, private), colleges and start-up/Entrepreneurs to include cost incurred for consumables, HR cost and overhead. User charges for external users from academic institutes may be fixed at cost deemed appropriate. For Start-ups the user charges may be fixed at a maximum of 5% over the actual cost (consumables, HR & overhead), while for private/section 8 companies this could be upto 15% over and above the actual cost (consumables, HR cost and overhead). User charges may be revisited every year.
- 3.4** The User Charges will be reviewed at least every three years for revision as per Rule 47 of GFR 2017.
- 3.5** DBT/ BIRAC supported Bio-enablers (Biofoundries and Biomanufacturing Hubs) should not claim intellectual property (IP) and authorship in publications for the scale-up services and services should be on charge basis only.
- 3.6** The facilities should make sure that the Products developed/ scaled-up in these facilities should acknowledge DBT/ BIRAC support in publications and products emanating from it.
- 3.7** All DBT/BIRAC Biofoundries and Biomanufacturing Hubs should maintain and report a list of beneficiaries along with the progress report of activities undertaken to DBT/BIRAC.

**3.8** All DBT/BIRAC Biofoundries and Biomanufacturing Hubs should constitute a committee for overseeing the activities with representatives from DBT/BIRAC.

#### **4.0 General Criteria**

Facilities developed/operationalized through this programme should comply to the certifications and accreditations including relevant regulatory compliances, environmental authorizations and other mandatory approvals, as required.