Request for Proposals (RFP) for

(A) Medical Devices and Diagnostics
(B) MedTech Facility

under

Industry- Academia Collaborative Mission For Accelerating

Discovery Research to Early Development of Bio-pharmaceuticals

Innovate in India (i3) Empowering Biotech Entrepreneurs & Accelerating Inclusive Innovation.

Funded by

Department of Biotechnology, Ministry of Science & Technology,

Government of India

Co-funded through World Bank Loan Assistance

(Innovate in India for Inclusiveness Project)

through

Implementing Agency

Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprises)

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Section I - Program Overview - NBM

Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

Funding agency

Department of Biotechnology (DBT) (Program co-funded by World Bank loan).

Implementing agency

Biotechnology Industry Research Assistance Council (BIRAC).

Background [1]

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT) Ministry of Science & Technology has initiated the Mission 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" ("Program").* Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of *i3* Program (Program co-funded by World Bank loan).

The vision of the Program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices and diagnostics to a level that will be globally competitive over the next decade.

This Request for Proposal (RFP) is to seek applications for the following:

1. **Medical Devices and Diagnostics**
   Applications are invited for development of medical devices/ diagnostics technologies/ products and core technologies.

2. **MedTech facility:**
   Applications are invited to set up facilities to address the needs of medical device developers for testing/ verification/ rapid prototyping/ pilot batch production of medical devices.

[1] *For further details of the Program, see the National Biopharma Mission Document*

Section II – Application process, Instructions, Applicant eligibility criteria and other processes for both RFPs at Section III and Section IV

1. Application Timelines

Key Dates

RFP Publication	**15th November 2018**
Application Due Date	**30th December 2018 (5:00 pm)**

2. Application Guidelines and Process

The Proposal can be submitted online as per the required format. The call for the Proposal will be open for 06 weeks. The website will provide detailed user guide to facilitate the online proposal submission.

Process for submitting the proposals online is detailed below:

- Go to BIRAC's website or Go the URL: http://birac.nic.in/nationalbiopharmamission.php
- Click on the RFP on NBM link under Programs and the active call would be highlighted.
- Click on the active call against which you wish to submit the proposal.
- Further details on 'How to Submit a Proposal' would be available in the User Guide available on the website.
- Log on to BIRAC website (http://www.birac.nic.in).
- If you are a registered user, log-in using the credentials, else you need to register your company/organization by clicking on New User Registration.
- In case of new user registration, a computer generated link will be sent to the email-id provided at the time of registration to generate a password.
- Once you login, you will be navigated to the proposal submission page under NBM link.

Instructions:

a. Applicants are advised to fill up and submit their applications early without waiting for the last date in order to avoid any last minute contingencies. The system stops accepting applications automatically at midnight of the last date of receipt of application.
b. Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review. Applicants are advised to provide self contained proposals with essential supporting materials provided as uploads.
c. Requests for changes in the proposal once submitted will not be encouraged.
d. Providing incorrect information intentionally is viewed adversely.
e. Please read through this RFP in its entirety and ensure that your application, budget and organization are in compliance with the eligibility criteria provided. Proposals for projects that do not meet the eligibility criteria and/or do not directly respond to the call area will not be reviewed, regardless of their quality. You are strongly encouraged to contact BIRAC if you are unsure about the eligibility or responsiveness of your project.

f. Proposed budget shall be made inclusive of all applicable taxes and shall be considered accordingly.
g. Information on all relevant pre-existing agreements/ MoUs in connection to the proposed technology, background IP, collaborations, outsourcing, consultancy, joint ventures, consortium partnerships, IP licensing, technology transfer, material transfer etc. should be provided at the time of proposal submission.
h. Applicants for whom grant-in-aid funding from the National Biopharma Mission (as primary applicant and/or collaborator) has been approved are NOT eligible for application (as primary applicant or collaborator) under this call.
i. Risk management proposal for the project should be submitted after scrutiny of the execution aspects of the project.

3. Evaluation Methodology

a. PMU-NBM, BIRAC will screen the proposals for responsiveness to all the specified administrative and procedural provisions required in the RFP. If the application is found to be incomplete or unresponsive to the provisions described in the RFP, the application will be considered ineligible.
b. Proposals that meet the eligibility criteria will be submitted for peer-review by national and international reviewers to assess the proposal merit (and other review criteria as specified above). Reviewers will be checked for conflicts of interest and will sign confidentiality agreements. Information may also be shared with selected third parties for the purposes of independent audit, evaluation and assessment of activities.
c. The Scientific Advisory Group will collate the results of the reviews, make their own assessments and recommend shortlisted applications for further screening to the Technical Advisory Group.
d. Grantees may also be invited for interviews or sought written clarifications when it is felt beneficial to ensure that any outstanding questions are resolved prior to concluding the full review.
e. Technical and financial due diligence process would be carried out by PMU-NBM, BIRAC.
f. A final decision on applications to be funded will be made by the Technical Advisory Group.

All personal data will be stored and used by or on behalf of DBT/BIRAC in accordance with the Acts and confidentiality norms.

DBT/BIRAC reserves the right not to process your proposal should you be ineligible to be a proponent or should the subject of your proposal not fall within the RFPs' remit. Mere consideration of the Proposal in no way implies that section of Grant-in Aid will be forthcoming.

4. Eligibility Criteria

Who may apply

The proposals can be submitted:

i. Solely by Indian Company / LLP / Non-profit organizations / Society/Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ Bioincubator/ Industrial Zones which is a legal entity OR

ii. Jointly by Non-profit organizations / Society/Trusts/ Foundation/ Associations/ Government entities/ Institutes/ R&D Organizations/ Bioincubator OR

iii. Jointly by an Indian Company and Non-profit organizations/ Government entities/ Institutes/ R&D Organizations / Bioincubator

Criteria Particulars for the Proponent entities

- **Indian companies**
  An Indian Company is defined as one which is registered under the Indian Companies Act, 2013 and minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders].

- **Non-profit organizations/ Government entities/ Institutes/ R&D Organizations**
  This will include 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.

- **Incubation centres**
  Incubation centres registered as a legal entity and recognised under different ministries of the Govt. of India and having SIRO certification/ DSIR registration.

Relevant documents for submission in the application:

1. Applicant being an Indian academic scientist and researchers:-

a. Copy of passport (from academic scientists & researchers) or self-declaration of
b. citizenship attested by a gazetted officer.
c. Either incubation agreement; or letter of intent in favour of applicant, issued by Incubation centre (which states that the incubation centre is willing to give facilities to applicant for the project applied for).

2. Companies:-

a. Incorporation certificate.
b. Share holding pattern as per BIRAC format
c. Details regarding in-house R&D facility, if any; or Incubation agreement.
d. Audited financial details of last three financial years (i.e. 2014-15, 2015-16, 2016-17), if applicable.
e. Copy of passports of the shareholders (in support of 51% eligibility criteria) or self-declaration of citizenship attested by a gazetted officer.

3. **Limited Liability Partnership:-**

a. Incorporation/Registration certificate.
b. Partnership deed; or list of subscribers which states that minimum half of the partners are Indian citizens.
c. Copy of passports of Indian partners/subscribers or self-declaration of citizenship attested by a gazetted officer.
d. Research mandate/ details regarding in-house R&D facility, if any/ Incubation agreement.
e. Audited financial details of last three financial years (i.e. 2014-15, 2015-16, 2016-17), if applicable.

4. 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/ Incubation agreement.
c. If the institution/public research organization are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust.

5. Society/ Trust/ NGO/ Foundation/ Association:-

a. **Society**

i. Society registration certificate.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. CA certificate (supporting the fact that half of the members of the society are Indian citizens)

b. **Trust**

i. Trust deed.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. CA certificate (supporting the fact that half of the members of the trustees are Indian citizens)

c. **NGO/ Foundation/ Association**

i. Registration details/certificate.
ii. Details regarding in-house R&D facility, if any / Incubation agreement.
iii. If the NGO/Foundation/Association are registered under/as Society or Trust, then they have to submit the documents as mentioned in the case of Society/Trust

5. Funding Mechanism

Decision to fund will be as per sanction of the competent authority. Successful proponents shall enter into necessary funding agreements. The fund disbursement will be subject to completion of required formalities. The disbursement will be by way of Grant-in-aid assistance. The fund recipient shall be accountable for fund utilization as per the sanction. Re-appropriation of funds can be undertaken only after approval of BIRAC.

Other Requisites for Funds Disbursements to Company

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

- A letter of authorization by the Head of the Academia and/or A Board Resolution from the Company Partner for acceptance of the Grant-in-Aid under NBM.
- **Opening up a No-Lien Account with a scheduled/nationalized Bank.**
- MoU with collaborator(s) (if applicable).

- Commitment to comply with Clinical Research Validation and Management Framework (CRVMF).
- Commit to obtain all applicable environmental authorizations, prior to the commencement of product development activities.
- Include qualified environmental / EHS engineer in the team for implementation of Environment and Health Risk Management Plan (EHRMP). Requirements on Environmental aspects may be found at – **www.birac.nic.in/webcontent/emf.pdf**
- Comply with EMF requirements during all stages.
- Submit and comply with the Project Risk Management Plan during all stages.

6. Program Monitoring Mechanism

a. **Project Monitoring Committee (PMC)**

The projects shall be monitored and mentored regularly by a Project Monitoring Committee (PMC) constituted by PMU-NBM, BIRAC for each project. The PMC is responsible to monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.

Based on the foregoing PMC will assess and recommend:

i. Release of next instalment or part release thereof by the BIRAC
ii. Revision of project duration
iii. Closing or dropping or modifying any of the components of the Project within the overall approved objectives, budget and time-frame
iv. Mentor(s) to overcome any technological problem faced in the Project implementation
v. To advise on issues related to securing of IPR
vi. To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of proposed Scheme.

7. Reporting of Progress

i. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format.
ii. The MCR will be assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget will be released.
iii. The Applicant will have to submit a duly certified Statement of Expenditure for every 30th September and 31st March.
iv. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

8. Contact Information

Further information can be obtained at BIRAC website. **BIRAC Website:** www.birac.nic.in

Contact Person:

Dr. Kavita Singh, Mission Director, PMU- National Biopharma Mission

Email: technical.birac@gov.in

Dr. Hardeep Vora, Programme Manager, PMU- National Biopharma Mission

Email: nbm3.birac@nic.in

Section III - Details of the RFP for Medical devices and Diagnostics – core technologies and products.

The National Biopharma Mission Program aims to support product development of medical device and diagnostic products including core technologies that address Indian health needs.

A. Objective of the call

The objective of the Program is to support:

- Development of medical device and diagnostic products so as to advance their development and bring them closer to the market in next 4 years.
- Development of core technologies which can be used in various products segments leading to development of indigenous medical devices.
- Development of an ecosystem that would spur indigenous manufacturing in the medical devices and diagnostics sector.

B. Scope:

- The primary focus of this call is towards therapeutic and diagnostic equipment for Ischemic Heart Diseases and Chronic Obstructive Pulmonary Disease, the two top leading causes of non-communicable disease morbidity in Indians.
- This call seeks proposals to accelerate indigenous development of medical device and diagnostic products.
- The focus is on generating technologies and products in medical device sector with high market potential and greater cost effectiveness than current products in market.
- This call will support various stages of innovative technology and product development including, preclinical development, product manufacturing and human clinical trials.

C. Technical Scope of the Proposal

I. Core Technology

Each applicant may apply for development ONE core technology component *only*. The developmental scope cannot be based on an inward license of a technology innovated/ held by a third party

Core technologies	Technology Application
▪ CT Tube ▪ CT X-ray generator ▪ CT Detector ▪ CT Collimator	CT
▪ Superconducting magnet ▪ RF coils and Amplifiers ▪ Gradient coils and Amplifiers ▪ RF Pulse sequencing subsystems.	MRI
▪ Cath X-ray tube ▪ Cath X-ray generator ▪ Dynamic flat panel detector (A-si / CMOS)	Cath lab [High powered X-ray (> 60 kW) with motorized C-arm, dynamic flat panel detector and advanced Image processing with DSA]
▪ Transducers (Linear , Convex , Phased Array, TEE probe & 4D Mechanical Probes) ▪ Dynamic Digital Beam former. ▪ Low noise frontend electronics for signal acquisition & conditioning.	Echocardiography with TEE
▪ Gamma Camera (Scintillator + PMT) or CZT Camera ▪ SPECT Collimator ▪ Front end acquisition hardware and signal conditioning.	SPECT
▪ Miniaturized Transducers - Capacitive micro machined ultrasonic transducers (CMUT) for intravascular applications. ▪ Digital Beam Former. ▪ Front end acquisition & signal conditioning	IVUS

II. **Products**

The applicant can submit proposal for development of any of the following products.

1. Heart Lung Machine
2. Ventilator
3. Pacemakers
4. Defibrillators (including CRT device)
5. CPAP
6. BiPAP
7. Oxygen Concentrator
8. Multi Parameter Patient Monitors (with neonatal SpO_2)
9. Ablation Devices
10. Anaesthesia Machine (Gas mixing and delivery module must be indigenously developed)

The product application should address towards developing *at least* 25% technology subsystems development indigenously in order to develop the final product. The number of indigenous components/ technology developed under this funding support should be such that their cost equates to >25% of the total cost of the product.

D. Eligibility Criteria

Preferably demonstrate either of the following

- Collaborations between industry & academic institution along with a clinician will be PREFERRED. The members of the collaboration should demonstrate prior experience in product development.
- Applicants from academic institute should have relevant expertise in the product segment as demonstrated through publication/patent/technology transferred/product under development.
- Proposal solely by company should demonstrate experience in relevant device segment and a competent team

E. Funding mechanism

Allowable costs include

- *Personnel*: All personnel recruited for the development of the product *only* are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants.
- *Technology Consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners. Preference should be given to national service providers.
- Supplies and consumables for the equipment.
- Travel & accommodation: Must be directly related to the execution of the project or travel related to seeking technology transfer.
- Institutional overhead (maximum 5%)

Non-allowable costs:

- Purchase or construction of a building/ space/ land.
- Rental costs for space
- Recruitment costs for staff
- Attendance at conferences
- Legal fees

F. Mechanism of Support

Support provided to candidates selected in this call will comprise of:

- Direct funding of R&D activities- Funding provided would be dependent on the current stage of development and the proposed activities to be conducted.

- Access to a group of experts from industry and academia with expertise in Medical Device discovery, development, clinical validation and trial, delivery experts, Indian health care delivery systems experts, regulatory experts, IPR and legal experts.

G. Evaluation and Decision Making Criteria

a. Proposal merit

- Is the proposal aligned with the objective of the RFP?
- Does the proposal demonstrate preliminary work of the identified product which will be useful for the proposed scope of work?
- Has the applicant provided adequate description of the existing manpower and infrastructure to understand the present capabilities?
- Does the proposal describes prior experience in product development?
- Are objectives and activities well defined?

b. Team/Applicant:

- Is the applicant competent to ensure effective conduct of the proposed work? Does the team have relevant capabilities and appropriate experience for the same?
- Are the team roles and responsibilities clearly defined?
- Has the applicant collaborated/ consulted with a clinician in the respective field for the product development?
- Is need for consultants and/or technology transfer clearly identified?

c. Implementation and Infrastructure:

- Has the implementation methodology and work plan adequately detailed and realistic?
- Have the resources (technical and management people, equipment, collaboration, outsourcing needs etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/challenges that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?

d. Business Strategy:

- Has the applicant provided any market surveillance details for the said product?
- Has the applicant provided any details on cost effectiveness of the product vis-à-vis existing products in the market?
- Has the applicant identified any specific clients or business opportunity for the product after development?

e. Budget Estimates:

- Is the proposed budget reasonable in light of the defined scope of work in terms of milestones and activities? Have reliable references been provided for justification?
- Is the resource allocation across various stages sufficient and appropriate?

Section IV - Details of the RFP for MedTech facility

A. Objective of the call

The National Biopharma Mission Program aims to establish facilities for providing low cost and affordable access to testing services for academia, start-ups and manufacturers who are developing innovative medical devices. These facilities will provide service support for testing and prototyping on a revenue-generation basis.

The facilities are expected to provide innovators and manufacturers easy availability of testing and prototyping facilities at affordable prices so as to support commercialization of novel products.

Applications are invited to set up facilities to address the needs of medical device developers for testing/ verification/ prototyping/ R&D/ batch production of medical devices & diagnostics.

B. Facilities:

The definition of a facility shall include housing of required analytical and testing equipment in a standardized setup within adequate space, providing the services through trained manpower, establishment of ancillary infrastructure such as functional offices, inventory, safety and disposal setups, acquisition of necessary approvals and governance & revenue generation models to evince sustainability beyond the period of funding assistance. Such facility shall be accessible to all other commercial or research institutions on a fee-for-service model with an inbuilt plough-through mechanism.

The following facilities are envisaged within the scope of this RFP, along with the expected infrastructure, standards and accreditations. The equipment which can be requested in the application is listed in Annexure I for each facility. The scope of work will broadly include development, management, operation and maintenance of the facility as mentioned below:

1. <u>Electro-Magnetic Interference (EMI/EMC) & Electrical safety testing facility</u>

a. Overview

This call seeks proposals by applicants who are interested in establishing and operating Electro-Magnetic Interference (EMI/EMC) & Electrical safety testing facility for medical devices and other electronic products.

b. Scope of facility

- To conduct the electrical safety and electromagnetic disturbances tests required for medical devices and IVD`s as per IEC 60601-1, IEC 60601-1-2 , CISPR 11 and IEC 61010-1
- To conduct wireless testing for medical devices as per ETSI EN 300 328.

  The applicant will have to set up one 3 m Semi Anechoic chamber with the following testing units for conducting EMI/EMC compliance testing

  - Radiated Emission Laboratory Unit
  - Radiated Susceptibility Laboratory Unit
  - Conducted Emission Laboratory Unit
  - Conducted Susceptibility Laboratory Unit

c. Standards and accreditation

The test system/facility shall be fully compliant to CISPR 16 standard and shall have automated test setup for performing measurements in compliance with applicable EMI/EMC directives and IEC standards for testing Electromagnetic disturbances.

The applicant will be responsible for acquiring all the necessary registrations and approvals from the applicable authorities, as may be required for operations of such a lab. Compliance to ISO 17025 standards in essential as per international practices.

The applicant will also be responsible to apply for accreditation from national or international accreditation agencies (e.g. NABL).

2. Medical lasers testing facility

a. Overview

Optical radiation safety considerations are critical when designing laser-based products for compliance, particularly for medical lasers. Medical lasers are medical devices that are used for diagnostic , therapeutic and cosmetic purposes , and since . lasers can be focussed very accurately with significant power it can be very lethal to eyes and other exposed organs and needs special attention .. Optical dangers are not considered in general product safety hazard assessments (burn, electrical shock, etc.) and can lead to unacceptable product safety and compliance issues if appropriate design safeguards and testing mechanism are not addressed . Lasers testing facility shall be equipped for addressing the product safety and compliance requirements.,

b. Scope of the facility

- To test lasers for their wavelength, power, modulation, exposure time characteristics and safety evaluations etc., for class 1 to 4 lasers and according to laser related standards.
- To test lasers with focus on medical lasers in compliance with IEC 60825-1, 60825-2 and IEC 60601-2-22

c. Standards and Accreditation

The applicant will be responsible for acquiring all the necessary registrations and approvals from the applicable authorities, as may be required for operations of such a lab. Compliance to ISO 17025 standards in essential as per international practices.

The applicant will also be responsible to apply for accreditation from national or international accreditation agencies (e.g. NABL).

3. Medical Device Rapid Prototyping Facility

a. Overview

Development of medical devices involves many design iterations, which need to be verified by lab tests and validated by user feedback. This requires physical prototypes that need to be fabricated using the materials and processes similar to those intended to be used for mass production later. Most med-tech innovators also need help with industrial

design of their products, for improved functionality, aesthetics, ergonomics and manufacturability.

b. Scope of the facility

To provide industrial design and rapid prototyping services suitable for medical devices having plastic, metal and electronics components, with the required quality, reliability and lead time.

- Industrial design – 3D CAD, CAE (stress analysis), CAM (process planning)
- Plastic components – 3D printing, laser cutting, vacuum (rubber mould) casting and injection moulding
- Metal components – sheet metal forming (bending, punching, blanking, etc.), machining (turning, milling, wire-cut EDM, etc.), welding (MIG/TIG) and finishing (grinding and polishing)
- Electronics fabrication – precision soldering and printed circuit board milling.
- Product inspection – 3D scanning, metrology and surface roughness measurement.

c. Standards and Accreditation

The centre should have qualified and trained staff for providing the necessary services and technical support to med-tech innovators. Privacy and confidentiality of product design data must be maintained. Relevant BIS/ISO/ASTM standards must be followed for materials and processes used in the facility. The facility must follow Good Manufacturing Practice (GMP), and have appropriate Quality Management System, which is ISO 13485 certified by a notified body.

4. Biological and Preclinical Testing facility

a. Overview

The facility will be used to carry out different studies including in-vitro studies, genotoxicity studies, general toxicology and implantation studies in laboratory animals which is GLP compliant. The facility broadly should be able to conduct tests for evaluating the performance and compatibility of new materials and medical devices.

An already established animal facility of small animals (housing, exercise area, experimental room, isolation room, Surgery room and Veterinary care room, etc.,) can apply for augmenting the facility so as to house large animals such as pigs, sheep/goat and dogs and perform in-vitro and in-vivo tests.

b. Scope of the facility

The Biological evaluation performed based on ISO 10993 categorizes medical devices according to Nature of body contact (surface device, external communication device and implant device) and Contact Duration **[**Limited (<24 hrs), Prolonged (24 hrs to 30 days) and permanent (>30 days)].

The facility should be able to establish testing laboratories as per the relevant standards mentioned for conducting various tests.

- *In-vitro* cytotoxicity - As per ISO 10993-5/.

- Genotoxicity (*in-vitro* tests) - To assess gene toxicities caused by medical devices/ materials or their extracts as per ISO 10993-3.
- *In-vitro* hemocompatibility - Changes in the blood caused by a medical device or by chemicals leaching from a device as per ISO 10993-4.

- Microbiological sterility - As per USP 71.
- Histopathological evaluation - Carried out in tissue specimens (hard/soft) for post implantation samples of bone, subcutaneous tissue and muscle as per ISO 10993-6.
- Tests for irritation and skin sensitization- ISO 10993-10

c. Standards and Accreditation

The applicant will be responsible for acquiring all the necessary registrations and approvals from the applicable authorities, as may be required for establishing and operations of such a lab. Compliance to ISO 17025 standards in essential as per international practices, including formation of an appropriate animal ethics committee.

The applicant will also be responsible to apply for accreditation from national or international accreditation agencies (e.g. NABL).

C. Expectations from the facility

a. The governance model of facility will be a fee-for-service model.

b. Maintain the ISO accreditation(s) as outlined in the scope of the individual facilities (including updates to the latest applicable standards).

c. Quality systems should be in place for all staff, equipment, facilities, SOPs, test protocols and reporting including qualified data systems for samples and data RQC systems and independent QA processes.

d. The facility should adhere to testing timelines to get the results within accepted timeframes.

e. The facility should describe the business development plan to identify users and the process of signing service agreements, as well as policies on publication of data.

f. The facility is expected to provide service to multiple medical device innovators and manufacturers. A ready-to-use minimum space of 10,000 sq. ft. has to be ready at the time of the submitting the proposal. The facility should demonstrate capabilities to expand if there is need.

g. The facility should submit a business plan with financial projections for next 5 years once services are initiated.

D. Eligibility Criteria

Prerequisites for applicants:

- Each applicant may apply for ONE facility ONLY. Applications received for multiple facilities by the same applicant (as applicant and/or collaborator) will be summarily rejected.
- Indian Company:
- Applicants presently providing services through an accredited facility for any one of the above may apply for establishing any one new facility mentioned in the RFP.

- Applicant presently providing services through a laboratory/facility may apply for augmenting the present facility.
- Academic Institute/ Universities:
- One department in an academic institution can apply for establishing one facility. However, from one institute different departments can submit independent applications.
- The department applying for establishing the facility should be providing relevant degree course certified by AICTE/ UGC.
- Applicants applying for establishment of biological and pre-clinical testing laboratory must have an existing small animal facility and should be providing services at the existing facility for drug/device testing.
- List of equipment mentioned in Annexure I is suggestive while planning the proposed facility.

➢ In the application, the applicant organizations should preferably demonstrate:

- Prior experience of providing services through an already existing facility for any MedTech testing facility.
- Receipt of prior funding from Government of India and demonstrated capabilities for work related to development of medical devices or testing thereof.
- Existing space for placing high-end instrumentations as mentioned in the expected infrastructure of the facilities (Annexure I).
- Capabilities of data management and maintaining data confidentiality.
- Prior experience of providing a fee-for-service model.
- The selected applicant has to manage the operations of the facility by hiring and deploying adequately qualified technical and administrative staff, depending upon the requirements.

E. Funding mechanism

Projects must be budgeted on a milestone basis. Funding will be awarded for 4 years, subject to the applicant complying with agreed milestones.

Allowable costs include

- *Personnel*: All personnel recruited for the functioning of the facility *only* are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from BIRAC grants.
- *Technical consultants*: These may include both national and/or foreign consultants who provide a service and capability that is not available among the project partners. Preference should be given to national service providers.
- Equipment: As listed in Annexure I for each facility. This is the suggestive list of equipment to be budgeted for each facility
- Supplies and consumables for the equipment.

- Travel & accommodation: Must be directly related to the execution of the project or travel related to seeking technology transfer.
- Institutional overhead
- Infrastructure: Partial Maintenance of Infrastructure of the facilities

Non-allowable costs:

- Purchase or construction of a building/ space/ land.
- Rental costs for space
- Recruitment costs for staff
- Attendance at conferences
- Legal fees

F. Evaluation and Decision Making Criteria

a) Proposal merit

- Is the proposed facility aligned with the RFP's objective?
- Has the applicant provided adequate description of the existing facility to understand the present capabilities?
- Does the proposal demonstrate adequate prior activities of the identified scope which will be useful for the proposed scope of work?
- What is the state of readiness of the applicant's laboratory for the proposed work?
- Does the proposal describes prior experience in providing testing services?

b) Team/Applicant:

- Is the applicant competent to ensure effective conduct of the proposed work? Does the team have relevant capabilities and appropriate experience for the same?
- Are the team roles and responsibilities, governance and organizational structure clearly defined?

c) Implementation and Infrastructure:

- Has the implementation methodology and work plan adequately detailed and realistic?
- Have the resources (technical and management people, equipment, collaboration, outsourcing needs etc.) required over the time frame been comprehensively mapped?
- Has the applicant anticipated difficulties/challenges that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?

d) Sustainability and revenue generation plan for the facility:

- Has the applicant submitted any business plan for the sustenance/ maintenance of the facility?
- Has the applicant provided any differential pricing model for test services to established industry and/or start-ups?
- Are the plans for training and knowledge transfer well-articulated?

e) Budget Estimates:

- Is the proposed budget reasonable in light of the defined scope of work in terms of milestones and activities? Have reliable references been provided for justification?
- Is the resource allocation across various stages sufficient and appropriate?

Section V - Annexure I – Expected Facility and Infrastructure.

The list of equipment that can be budgeted for under respective facility is mentioned below. This list is suggestive, not exclusive or exhaustive.

1. EMI/ EMC and Electrical Safety Testing facility

Equipment List – EMI/EMC testing		
Altitude Chamber	Ball Pressure Apparatus	Humidity Chamber ($2m^3$)
Digital Power Meter	Light Loupe Scale	Test Finger
Earth Bond Tester	Temperature Recorder	Isolation transformer
Digital Multimeter	Torque Gauge	Hipot Tester
Ball Impact Test Apparatus	Water Bath	Vernier Callipers
Slip Gauge	Microwave Radiation Detector,	Thermocouple
Measuring Scale	Signal Generator	Dimmerstat
Weighing Scale I	Inclinometer	Force Gauge
Hardwood Plane	Phantom	Stick Thermometer
Beakers	UV Meter	Aluminium Disc
DC Power Supply	Sound Meter	Billi Blanket Light Meter
Pressure Gauge	Faraday Chamber	Test Bench
Inclined Plane	Dead Weights	Sharp Edge Tester
Servo Stabilizer	Electro Dynamic Shaker	IR Meter
Dry Heat Chamber	Lead Shielding	Digital Loads
AC Power Supply	Leakage Current Tester	Cord Encourage
Stop Watch	Digital Oscilloscope	Density Meter
Equipment List – Electrical Safety Testing		
Dual Channel Power Meter	Wideband Power Sensor (Peak & Average)	EMI Test Receiver (9 KHz - 3 GHz),
Real Time Signal Analyzer	RF & Microwave Signal Generator	Vector Signal Generator
Pre- Amplifier	Amplifier	Synthesized Sweeper
Bi-Log Antenna	Horn Antenna	Dipole Antenna
RF Signal Cables		

2. Medical Laser Testing Facility

Clean area with a laminar flow chamber (class 100).	Optical table with vibration stability
1064 nm, 1310 nm and 1550 nm lasers with a modulation option of up to 20 GHz	ESD free area
Integrating sphere (250 – 2500 nm) and detectors	Spectrum analyser (600 – 1750 nm, resolution 20 pm)
Return Loss & OTDR analyser	Optical attenuators and splitters
Monochromator (180nm – 2200nm & 2000 nm – 12000nm)	Translation and rotation positioners
Climatic chambers (thermal shock -185º to +300ºC, life, etc…)	Mechanical test system (pull, push, torsion)
Power meters for continuous and pulsed lasers	Auto correlator
Lenses and beam splitters	Beam Profiler
Precision Power supplies for low and high powers	

3. Medical Device Rapid Prototyping Facility

Industrial Design	**Plastic Component Prototyping**
3D CAD software (solid modelling)	3D Printers – Different materials (including biocompatible plastics such as medical grade ABS), size range (100-300 mm) and high accuracy.
3D CAE software (stress analysis)	Laser Cutter (plastic sheets)
3D CAM software (process planning)	Vacuum (rubber mould) Casting
	Injection Moulding Machine
Metal Component Manufacturing	**Electronics Fabrication**
Sheet Metal Bending Machine	Precision Soldering Machine
Sheeting Metal Punching & Blanking	PCB Milling Machine
CNC Turning Lathe	
CNC Milling Machine	**Product Inspection**
CNC Grinding & Polishing Machine	3D Scanner
CNC Wire-Cut EDM Machine	Metrology Equipment
CNC Welding Machine (MIG/TIG)	Surface Roughness Measurement

4. Biological and Preclinical Testing facility

The following are the labs required and equipment required for conducting biocompatibility testing and pre-clinical testing as per the relevant standards.

Cell culture laboratory	**Tissue culture laboratory**
Laminar Flow Bench	Laminar Flow Bench
CO_2 Incubator	CO_2 Incubator
Microscope-binocular	Microscope-binocular
Autoclave	Autoclave
Pipette (all sizes)	Pipette (all sizes)
Laboratory water bath	Laboratory water bath
Cryogenic storage vessel	Cryogenic storage vessel
Cooling centrifuge	Thermometer
Weighing balance	Centrifuge
Fluorescence microscope	

Hemocompatibility Laboratory	**Microbiology Lab**
Laminar Flow Bench	**Sterility evaluation**
Incubator	Laminar Flow Bench Type 2A-Biological Safety Cabinet
Thermal Incubator	Incubator
Water bath	Ultra low Freezer
Spectrophotometer (UV Based)	Microscope-binocular
Biochemistry Analyzer	Heating Block
Haematology Analyser	Versatile Mixing
Urine analyser	Refrigerator - Laboratory use
Coagulameter	
Agrigometer	**Decontamination area**
ELISA reader	Autoclave
Flow cytometer	Hot air oven
Anti-coagulated tube	Room fumigator
Microscope-binocular	Refrigerator - Laboratory use
Multiplate photometer	
Centrifuge	**Sterilization area**
Cryogenic storage vessel	Autoclave- Horizontal 1
Thermometer	Weighing balance

Hot air oven	pH meter with flat probe
	Conductive meter

Animal facility	**Histopathology**
Air shower	Necropsy station
Cages, water bottles	Weighing balance
Animal racks	Laminar Flow Bench
Autoclave	Macro Digital Imaging System
Environmental monitoring equipment	Instrument for chemical handling
Stainless steel tank	Tissue processor Embedding area
Fumigator	Tissue Embedding Staining area
RO unit	Auto stainer
	Fully Automated Rotary Microtome-sectioning equipment
	Water Bath
	Trinocular Fluorescence Microscope

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