



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

Empanelment of Agencies in Regulatory and Policy Domains

at

**Biotechnology Industry Research Assistance Council
(BIRAC)**

[No. BIRAC/HR&A/007/2025/ENQ-50]

कार्यालय का पता

5वीं मंजिल, एनएसआईसी बिजनेस पार्क, एनएसआईसी भवन,
ओखला इंडस्ट्रियल एस्टेट, नई दिल्ली – 110020

5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

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सीआईएन सं./ CIN No.: U73100DL2012NPL233152

वेबसाइट का पता/ Website address: www.birac.nic.in

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Biotechnology Industry Research Assistance Council
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REQUEST FOR EMPANELEMENT

1.0 Letter of Invitation

Biotechnology Industry Research Assistance Council (BIRAC), New Delhi invites applications for “Empanelment of Agencies in Regulatory and Policy Domains” at Biotechnology Industry Research Assistance Council (BIRAC).

The BID document containing the details of qualification criteria, submission details, brief objective & Scope of work and evaluation criteria etc. can be downloaded from website <https://birac.nic.in/> and <http://eprocure.gov.in/epublish/app>.

Bid No:	BIRAC/HR&A/007/2025/ENQ-50
Brief Description:	Application Requested for Empanelment of Agencies in Regulatory and Policy Domains at Biotechnology Industry Research Assistance Council (BIRAC)
Category:	Services
Approximate Quantity:	Need Based
Contract Period:	The empanelment shall be effective for an initial period of 03 (Three) Year thereafter can be extendable up to 2 (two) years based on the performance of the agency on mutually agreed Terms & Conditions.
Bid Originating Location:	BIRAC Office, New Delhi
Type of bid:	Request for Empanelment
Cost of bid document:	NIL
Earnest money Deposit:	NIL
Performance Bank Guarantee:	NIL
Issue / Sale of Bid document:	Downloadable from BIRAC Website & Central Public Procurement Portal (CPPP)
Bid Publication Date:	03rd February 2025
Bid duration	21 days
Site/s Visit Dates:	NA
Pre-bid Meeting Date, time & Venue:	12th February 2025 at 02:30PM at Biotechnology Industry Research Assistance Council (BIRAC), 5th Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020
Last Date & Time for Submission of BID:	24th February 2025 by 02:00 PM
Bid Opening Date & Time:	24th February 2025 at 02:30 PM

Place of submission & opening of bid:	Biotechnology Industry Research Assistance Council (BIRAC), 5th Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020
Presentation Date, time & Venue:	(Date & time shall be communicated later to PQC qualified bidders only) Biotechnology Industry Research Assistance Council (BIRAC), 5th Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020
Pre-Qualification Criteria:	As per Clause - 7.0
Bid Validity	90 days from the Bid Closing Date

The eligible bidders may submit their responses in sealed envelope in the prescribed format as indicated in the Bid document.

Prospective bidders should download the Complete Tender Documents from BIRAC's web site **www.birac.nic.in** and **CPPP**. Addendum/ Corrigendum, if any, to the tender documents shall be uploaded on website only. Hence, bidders may visit the same regularly till the bid submission date.

Thanking you,

Yours faithfully,
Head - HR & Admin
For BIRAC

Note: BIRAC reserves the right to cancel this request for empanelment and/ or invite afresh with or without amendments, without liability or any obligation for such request for proposal and without assigning any reason. Information provided at this stage is indicative and BIRAC reserves the right to amend/add further details in the Bid.

This Bid is not an agreement and is neither an offer nor invitation by the Authority to the prospective Applicants or any other person. The purpose of this Bid is to provide interested parties with information that may be useful to them in the formulation of their applications pursuant to this Bid. This Bid includes statements, which reflect various assumptions and assessments arrived at in relation to the Bid that may not be accurate. The Authority may, in its absolute discretion but without being under any obligation to do so, update, amend or supplement the information, assessment or assumptions contained in this Bid.

पांचवी मंजिल, एनएसआईसी बिजनस पार्क, एनएसआईसी भवन, ओखला इंडिस्ट्रियल एस्टेट, नई दिल्ली-110020, भारत
5th Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020, India
Phone : 011 29878000 Fax: 011 29878111 Website: www.birac.nic.in E-mail: birac.dbt@nic.in
सीआईएन सं./CIN No. : U73100DL2012NPL233152

2.0 Background

Biotechnology Industry Research Assistance Council (BIRAC), is a Public sector undertaking registered under the Indian Companies Act 2013 as a Section 8 'Not for profit Company', as an interface agency of DBT, Ministry of Science & Technology, BIRAC was set up with a vision to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry particularly SME's, to make India globally competitive in biotech innovation and entrepreneurship and to create affordable products and services.

3.0 Objective

The purpose of this assignment is to engage a specialized regulatory and policy firm to conduct data driven in-depth analysis of the current regulatory framework and its effects on the biotech industry. The scope is designed to address the critical need for evidence-based policy-making by providing a thorough evaluation of existing regulations and their economic and social impacts. Through systematic research, econometric studies and stakeholder engagement, the aim is to gather valuable insights and feedback that will inform the development of effective, evidence-based regulatory and policy recommendations.

Additionally, the assignment seeks to support the drafting and refinement of new regulatory policies that align with international best practices and promote sustainable economic growth.

The two broad categories of the assignment are:

Category 1: **Regulatory and Policy Research**

Category 2: **Regulatory & Policy Support Engagement**

Please note: Separate bids are to be submitted for the above two categories.

4.0 Scope of Work and Assignment of Tasks

4.1. Scope of Work (SoW)

The scope of the engagement includes:

Category 1: Regulatory and Policy Research

1. To conduct data driven and evidence based in-depth analysis of the current regulatory framework and its effects on the industry. Landscaping of existing regulations and policies in the area of BioPharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc. to identify gaps and challenges.
2. To support drafting and refinement of new regulatory policies that align with international best practices and promote sustainable economic growth.
3. To address the critical need for evidence-based policy-making by providing a thorough evaluation of existing regulations and their economic and social impacts.
4. Performing impact analysis to assess the effects of policies, regulations and related interventions.
5. To utilize evidence-based primary and secondary research methodologies like surveys, case studies, interviews, delphi, focus groups, and existing databases to collect relevant information. Data analysis employing statistical tools and econometric models for formulating actionable policy recommendations.
6. To monitor real-time regulatory updates, collaborating with external stakeholders to identify potential opportunities and regulatory challenges impacting start-ups, entrepreneurs and innovators.

7. To engage with various departments, ministries, Start-ups, MNCs and industry associations and facilitate regulatory dialogue to enhance innovation and growth in the targeted sectors
8. To advice BIRAC in promoting Biotech sectoral growth in the area of regulatory, and policy advocacy through stakeholder engagement.
9. To conduct stakeholder consultations to gather regulatory insights, and align proposed policies with industry requirements.
10. Formulating, and circulating regulatory concept notes, publications, briefs, research papers related with regulatory insights for BIRAC.
11. Crafting clear and concise action points to disseminate research findings and policy recommendations related with new regulatory policies and guidelines for BIRAC.
12. Developing, structuring, and preparing draft related to regulatory guidelines, policy papers and newsletters for BIRAC.

Category 2: Regulatory & Policy Support Engagement

1. To provide scientific and administrative support for developing content and organizing Regulatory/Policy events such as training programs, meetings, workshops, any other such activity in line with BIRAC mandate.
2. Offering expert advice and insights to shape the content and structure of the events
3. To conduct pre-event consultation with Stakeholders to develop the event material/course outline
4. Crafting comprehensive outlines for training modules that cover key regulatory and policy topics.
5. To develop educational material to ensure that professionals within the industry stay abreast with the latest developments.
6. Pre, during and post event branding and administrative support including:
 - Promoting the event including developing a webpage for the event, creating promotional content
 - Handling online registrations (unpaid/paid as required) through payment gateway management
 - On-site support for smooth conduct of the event
 - Facilitating sessions to maintain a productive and engaging atmosphere
 - Providing post-event branding to reinforce the event's impact and reach
 - Assisting with follow-up communications and dissemination of event materials
7. Preparation and submission of technical report and recommendations based on the proceedings.
8. Documenting key discussions, insights, and recommendations to inform future policy and regulatory decisions.

4.2. Assignment of the tasks

BIRAC reserves the right to assign tasks to Empanelled Firms on the basis of quotations obtained from them through limited enquiry as per norms/ on a roster basis.

5.0 Instructions to Bidders

5.1 The bidders are expected to examine all the instructions in the Bid Document. Failure to furnish all information required by the Bid Document or submission of a Bid not substantially responsive to the Bid Document up to the satisfaction of the BIRAC in every respect will be at Bidders' risk and responsibility and may result in the rejection of its Bids.

5.2 Any agency who has pre-exited or terminated any contract with or by BIRAC in last five (05) years as on the date of submission shall not be eligible to apply.

5.3 Language of Bid

The bid prepared by the bidders and all correspondence and documents exchanged between the bidders and BIRAC relating to the Bid submitted shall be in English or bilingual (Hindi and English) language. However, printed literature furnished by the bidders may be in any other language as long as it is accompanied by an English translation of all its contents. In such a case for the purposes of the interpretation of bid, English translation shall prevail.

5.4 Signing the Bid

The bid shall be signed by the bidders or a person duly authorized to bind the bidders to the contract. The authorization shall be indicated by written letter of authorization/ Board Resolution/ agency agreement etc. accompanying the bid. The person or persons signing the bid documents shall initial all pages of the bid, except for un-amended printed literature.

5.5 Cost of Bidding

The bidders shall be solely liable to bear all costs and expenses associated with the preparation and submission of its bid, BIRAC will in no case be held responsible or liable for payment of any costs associated with the preparation or submission of the said bids irrespective of the outcome of the bidding process as also in case the entire bidding process or part thereof is nullified/ cancelled due to any reason whatsoever.

5.6 Validity of Bids

- i) Bids shall remain valid for 90 days after the bid closing date. A bid valid for a shorter period will be considered as non-responsive and be liable to be rejected by the BIRAC.
- ii) In exceptional circumstances, BIRAC may solicit the bidders' consent to an extension of the period of validity.

5.7 Submission Details

Bidders are requested to go through all pre-qualification requirements, scope of work for execution & requirements w.r.t technical / financial capabilities for acceptance and submission of documents for verification by BIRAC. Bids are to be submitted in sealed covers.

Bids are to be submitted in sealed covers as per the details given below.:

- i) Covering Letter (*Annexure - I*)
- ii) Authorization letter (*Annexure -II*)

- iii) The bid shall be submitted in sealed envelope super scribed with **Enquiry number, Subject and Date of closing** prominently underlined, along with the address of this office.

This envelope shall contain the following:

- a) **1st Inner Sealed Cover** - The first inner sealed cover should contain all the documents pertaining to **Pre-Qualification Criteria (PQC)** as prescribed and will clearly be super scribed with **"PQC"** along with enquiry number. This cover should include **Covering letter and PQC (format enclosed as Annexure - III)** with all stamped and signed supporting documents.
 - b) **2nd Inner Sealed Cover** - The second inner sealed cover should contain all the documents pertaining to **Technical Evaluation Criteria (TEC)** as prescribed and will clearly be super scribed with **"TEC"** along with enquiry number. This cover should include **Covering letter and TEC (format enclosed as Annexure - IV)** with all stamped and signed supporting documents.
 - c) **3rd Outer Sealed Cover** - The third outer sealed cover will contain the above mentioned two envelopes i.e. 1st and 2nd super scribed with **Enquiry number, Subject and Date of closing** prominently underlined, along with the address of this office.
- iv) Only one bid should be included in one cover.
- v) The bid which fails to comply with the above instructions shall be summarily rejected.
- vi) Transfer of Bid Document - Non Transferable.
- vii) Late bids - Bidders are advised in their own interest to ensure that bid reaches the specified office well before the closing date and time of the bid. BIRAC will not be responsible for the loss of the bid or delay in postal transit. Any bid received after dead line for submission of bid, will be rejected and returned unopened.
- viii) The cost for preparing the BID including visits by the bidders to BIRAC Office is not reimbursable.
- ix) BIRAC reserves the right to call for any clarifications covered in the broad scope, wherever such a clarification become necessary for proper judgment in evaluation.
- x) No portion of the work of consultancy will be sub-contracted to third party/agency.

5.8 Address of Submission/communication/inspection

The sealed envelope should be addressed to:

Head - HR & Administration
Biotechnology Industry Research Assistance Council (BIRAC) 5th
Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New
Delhi – 110020

5.9 Amendments and Addendum to Bid

- i) At any time prior to the deadline for submission of bids, BIRAC may at its own discretion and for any reason whatsoever whether at its own initiative or in response to a clarification requested by a bidders modify the Bid Documents by notifying any such amendment as may be drafted/incorporated to the original bid

documents.

- ii) The amendment and addendum, if any will be notified by BIRAC or published on the BIRAC website (www.birac.nic.in) before the last date of submission.
- iii) In order to allow the bidders reasonable time to take the amendment in to account in preparing their bids, the BIRAC may at its discretion, extend the deadline for the submission of Bids and any such extension will be notified by BIRAC.

5.10 **Conflict of Interest**

The Bidders shall not receive any remuneration in connection with the assignment except as provided in the “Service and Confidentiality Agreement”.

5.11 **Warranty of the agency**

The agency shall warrant that it is under no contractual restrictions of legal disqualification or other obligations which will prohibit from entering into agreement and that the statement and particulars herein contained in this Bid and in the relevant and supporting documents to this Bid are correct.

5.12 **Bid Rejection Criteria (BRC)**

BIRAC reserves the right to reject any bid if:

1. Received after the expiry of due date and time.
2. Any agency who has pre-exited or terminated any contract with or by BIRAC in last five (05) years as on the date of submission shall not be eligible to apply.
3. It is not given in the prescribed format as per clause 5.7
4. The bid has not been indexed or properly paginated and details provided in PQC & TEC Checklist (clause 7.0 & 8.0) are not submitted.
5. Supporting documents to substantiate the PQC & TEC have not been submitted.
6. Certificates certified by Chartered Accountants must bear UDIN number, in absence of which, it will be considered as invalid and the bid shall be rejected.
7. All Declarations/undertakings/information have not been provided on the Letter Head of the Bidders, duly signed and stamped.
8. At any time, a material misrepresentation is made or uncovered
9. The agency/ firm/entity does not respond promptly and thoroughly to requests for supplemental information required for the evaluation of the bid.

5.13 **Engagement Terms and Conditions**

- i) The effective date of the engagement will be in accordance with the execution of the Service and Confidentiality (S&C) Agreement.
- ii) The Bidder shall be liable to indemnify BIRAC in all respects and meet and pay off the litigation expenses and all the liabilities, including damages, sums etc., arising as a consequence of negligence, deficiencies, mistakes, lapses, delays etc., in the execution of the work and the services provided.
- iii) **Letter of Award (LOA):** On acceptance of the Bid for awarding the contract, BIRAC will issue a Letter of Award “LOA” to the successful bidder in writing. Such a successful bidder will need to execute a “Service and Confidentiality Agreement” (**enclosed as**

Annexure - VIII along with associated documents such as Letter of Authorization (LoA) or Board Resolution (BoR). After execution of the Agreement, no variation in or modification of any of the terms of the Agreement shall be made except by written amendment signed by the parties. The engagement of the bidder shall be governed by the terms and conditions of the “Service and Confidentiality Agreement”.

iv) **Payment Terms**

- a) The bills for the services (of preapproved quoted rates) shall be submitted by the agency at the earliest after undertaking the services. The payment will be made after the submission of the Invoice, along with the report of the work done during the quarter and any other supporting documents as desired by BIRAC. This shall be scrutinized and checked before passing the bills for payment. The payments for all undisputed bills shall be made by BIRAC after scrutiny of the bills normally within 15 working days from the date of submission of original bills and related supporting documents to BIRAC.
- b) Income Tax as per statutory provision shall be deducted from the bills and remitted to Income Tax authorities by Accounts Department of BIRAC. A TDS certificate shall be issued by BIRAC to the agency for such deductions.
- c) BIRAC shall make timely payments through Electronic Payment Mechanism (viz NEFT/ RTGS /ECS). Bank details have to be provided by the agency
- d) BIRAC shall not be liable for any consequences, whatsoever, in case there is a delay in making payments for any reasons resting with agency. Further, no interest shall be paid on such delayed payments.

5.14 **Abnormal Rates**

The bidder is expected to quote rate after careful analysis of cost involved considering all specifications and conditions of contract. In case it is noticed that the rates quoted by the bidder are unusually high or unusually low, it will be a sufficient ground for rejection of the tender unless the reasonableness of the rates is convincing. For scrutiny, the analysis for such rates is to be furnished by the bidder on demand.

5.15 **Disclaimer**

- a. BIRAC shall not be responsible for any late receipt of applications for any reasons whatsoever.
- b. BIRAC reserves the right to reject all applications without assigning any reasons thereof.
- c. To relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the BIRAC without assigning any reasons thereof.
- d. To include any other item in the Scope of work at any time after consultation with bidders or otherwise.
- e. BIRAC reserves the right to reject all the RFPs without assigning any reasons.

5.16 **Applicable Laws and Jurisdictions**

All the disputes or differences regarding the bid/contract shall be governed in accordance with the Laws applicable in India and subject to the exclusive jurisdiction of the courts situated in New Delhi, India.

5.17 Special Considerations For MSME/Start-Ups

If the bidding entity is registered under (i) Micro & Small Enterprises at District Industry centre or Khadi and Village Industry Board or Coir Board or National Small Industry Corporation or Directorate of Handicrafts and Handlooms or any other body specified under “Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012” & (ii) Start-Ups registered under DIPP (as per G.S.R. 501(E)) it will be exempted from the prior experience & financial criteria.

6.0 Evaluation Methodology

- 6.1 **Opening of Bids by BIRAC:** BIRAC will open the Bids on the stipulated date and time as given in the schedule. Authorized representative of the bidder is requested to attend the bid opening process.
- 6.2 Bids with Covering Letter (*Annexure - I*) and Authorization Letter (*Annexure - II*) shall only be considered for Pre- Qualification Criteria (PQC).
- 6.3 The bids shall be verified based on the documents submitted for PQC. Checklist provided at *Annexure - III* is required to be mandatorily filled. Those bids which satisfy the PQC will be considered for Technical Evaluation Criteria (TEC).
- 6.4 Each bidder shall be assigned scores under each parameter as given in the Technical Evaluation Criteria [TEC] wherein marking will be done by the Committee on the basis of presentation and TEC Documents. Checklist provided at *Annexure - IV* is required to be mandatorily filled.
- 6.5 The bids obtaining the highest total score in Technical Evaluation Criteria will be ranked as H-1 followed by the bids securing lesser marks as H-2, H-3 etc.
- 6.6 BIRAC reserves the right to decide the number of firms to be invited for empanelment and execution of agreement thereafter.

7.0 Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

S. No.	Eligibility Criteria	Supporting Documents
1	The bidder must be a legal entity registered as Company/LLP/Society/partnership/proprietorship/Academic Institute/Research Organization under respective acts in India.	Self-attested copy of registration of legal entity such as Company Incorporation Certificate from ROC/Partnership deed/ etc.
2	The bidder must have a mandate/bylaws/MoA including regulatory and policy work	Self-attested Copy of mandate/bylaws/MoA including regulatory and policy work
3	The bidder must be registered in India with taxation and other administrative authorities	Self-attested Copy of GST Registration or GST exemption certificate/ PAN Card
4	The bidder should have a Registered office in India	Electricity/Telephone Bill or any other supporting document stating the address duly certified by the Owner/Authorized Representative of the Company
5	The bidder should have provided similar services in the areas of BioPharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc during five years out of last seven years [2017-18, 2018-19, 2019-20, 2020-21, 2021-22, 2022-23 & 2023-24] to National and International Government and /or private bodies.	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.
6	The bidder has to have profit/surplus and should not have incurred loss during five years out of last seven years [2017-18, 2018-19, 2019-20, 2020-21, 2021-22, 2022-23 & 2023-24]	Certificate with UDIN number from the Organization/Audited Balance sheets for last three financial years, Income Tax return
7	The bidder should not have been blacklisted by any Central /State Government/Public Sector Undertaking, Govt. of India	Undertaking on the Letter Head of the Bidder duly signed & Stamped by Authorized Signatory (As per Annexure - V)
8	The bidder should not be involved in any major litigation that may have an impact of affecting or compromising the delivery of services as required under this Bid and in the execution of agreement.	Undertaking on Bidder's Letter Head, duly signed and stamped by the Authorized Signatory (As per Annexure - VI)
9	The bidder should not have pre-exited or terminated any contract with or by BIRAC in last 05 years as on the date of submission.	Undertaking on Bidder's Letter Head, duly signed and stamped by the Authorized Signatory (As per Annexure - VII)

Note:

- 1. Documentary Evidences are mandatory to be submitted along with the formats.**

6.0 Technical Evaluation Criteria

For Category 1: Regulatory and Policy Research

S. No.	Technical Evaluation Criteria	Maximum Score	Indicative Supporting Documents
1.	Bidder should have conducted similar kind of Regulatory or Policy studies in Bio-Pharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc in atleast three different organizations.	15	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.
2.	Bidder should have publications including regulatory and policy reports, data driven white papers and/or research articles in targeted areas.	15	Study reports, publications, position papers in targeted areas
3.	The bidder should have subscription to the relevant econometrics and statistical tools and databases for collecting and analyzing the data	15	Self-attested List the tools with their subscription invoices
4.	Bidder should have professional Competence well-equipped 'in-house' team to perform the work.	15	Resume of atleast three in-house team members working in the regulatory and policy area as mentioned in the scope of work
5.	Technical Presentation	40	-
Total		100	

For Category 2: Regulatory & Policy Support Engagement

S. No.	Technical Evaluation Criteria	Maximum Score	Indicative Supporting Documents
1.	Bidder should have developed content and structure of Regulatory or Policy events including training modules, educational material, event material/course outline in the area of in Bio-Pharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc in atleast three different organizations.	15	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.
2.	Bidder should have handled branding and administrative support for Pre, during and post event including handling online registrations, payment gateways, developing a webpage and creating promotional content for the event.	15	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.
3.	Bidder should be a member of atleast one national and/or international regulatory or policy networks and/or related industry associations.	10	Membership certificate
4.	Number of workshops/ conference/ trainings/ consultation meetings in the area have been conducted and list out the consultations provided to the government and PSUs in the area	10	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.
5.	Bidder should have professional Competence well-equipped 'in-house' team to perform the work.	10	Resume of atleast three in-house team members working in the regulatory and policy area as mentioned in the scope of work
6.	Technical Presentation	40	-
Total		100	

Note:

1. Documentary Evidences are mandatory to be submitted along with the formats.

Annexure - I

Covering Letter

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
Biotechnology Industry Research Assistance Council (BIRAC)
5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

Dear Sir / Madam,

This has reference to your above-mentioned Request for Empanelment of Agencies in Regulatory and Policy Domains at Biotechnology Industry Research Assistance Council (BIRAC)

It is hereby confirmed and declared that M/s _____
is submitting the bid for the following Category (Please tick the Category):

- ☐ **Category 1: Regulatory and Policy Research**
- ☐ **Category 2: Regulatory & Policy Support Engagement**

Please note: Separate bids are to be submitted for the above two categories.

Signature of Authorizing Authority

Name of Authorizing Authority & Designation:

Company Seal:

Annexure - II

Authorization Letter

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
Biotechnology Industry Research Assistance Council (BIRAC)
5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

Subject: Letter for Authorized Signatory

Dear Sir / Madam,

This has reference to your above-mentioned Request for Empanelment of Agencies in Regulatory and Policy Domains at Biotechnology Industry Research Assistance Council (BIRAC).

Mr./Miss/Mrs. _____ is hereby authorized to submit the bid & attend opening
of the above bid No. _____ on behalf of M/s
_____ (Agency Name).

The specimen signature is attested below:

Name: _____

(Specimen Signature of Representative) _____

Signature of Authorizing Authority

Name of Authorizing Authority & Designation:

Company Seal:

Note: Permission for entry to the hall where bids are to be opened may be refused in case authorization as prescribed above is not received.

Annexure - III**PQC Covering Letter**

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
 Biotechnology Industry Research Assistance Council (BIRAC)
 5th Floor, NSIC Business Park, NSIC Bhawan,
 Okhla Industrial Estate, New Delhi – 110020

**Subject: Request for Empanelment of Agencies in Regulatory and Policy Domains at
 Biotechnology Industry Research Assistance Council (BIRAC)**

Sir/Madam,

The undersigned having read and examined in detail all the Bid documents pertaining to your assignment; do hereby express the interest to do the work as specified in the scope of work.

Sl. No.	Description	Response
1	Name of the Bidder	
2	Address	
3	Name, designation & address of the person to whom all references shall be made	
4	Telephone No. (with STD code)	
5	Mobile No. of the contact person	
6	Email ID of the contact person	

The following documents are enclosed:

1. Covering Letter (As per **Annexure - I**)
2. Authorization Letter (As per **Annexure - II**)
3. Pre-qualification criteria as per the details given below:

S. No.	Pre-Qualification Criteria	Supporting Documents Required	Type of Document Submitted	Page number of the supporting document
1	The bidder must be a legal entity registered as Company/LLP/Society/partnership/proprietorship/Academic Institute/Research Organization under respective acts in India.	Self-attested copy of registration of legal entity such as Company Incorporation Certificate from ROC/Partnership deed/ etc.		
2	The bidder must have a mandate/bylaws/MoA including regulatory and policy work	Self-attested Copy of mandate/bylaws/MoA including regulatory and policy work		
3	The bidder must be registered in India with taxation and other administrative authorities	Self-attested Copy of GST Registration or GST exemption certificate/ PAN Card		
4	The bidder should have a Registered office in India	Electricity/Telephone Bill or any other supporting document stating the address duly certified by the Owner/Authorized Representative of the Company		
5	The bidder should have provided similar services in the areas of BioPharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc during five years out of last seven years [2017-18, 2018-19, 2019-20, 2020-21, 2021-22, 2022-23 & 2023-24] to National and International Government and /or private bodies.	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.		
6	The bidder has to have profit/surplus and should not have incurred loss during five years out of last seven years [2017-18, 2018-19, 2019-20, 2020-21, 2021-22, 2022-23 & 2023-24]	Certificate with UDIN number from the Organization/Audited Balance sheets for last three financial years, Income Tax return		
7	The bidder should not have been blacklisted by any Central /State Government/Public Sector Undertaking, Govt. of India	Undertaking on the Letter Head of the Bidder duly signed & Stamped by Authorized Signatory (As per Annexure - V)		
8	The bidder should not be involved in any major litigation that may have an impact of affecting or compromising the delivery of services as required under this Bid and in the execution of agreement.	Undertaking on Bidder's Letter Head, duly signed and stamped by the Authorized Signatory (As per Annexure - VI)		
9	The bidder should not have pre-exited or terminated any contract with or by BIRAC in last 05 years as on the date of submission.	Undertaking on Bidder's Letter Head, duly signed and stamped by the Authorized Signatory (As per Annexure - VII)		

I/we hereby declare that my/our Bid is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)

Name: _____

Designation: _____

Seal : _____

Date : _____

Place : _____

Annexure - IV

Technical Evaluation Criteria TEC
(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
 Biotechnology Industry Research Assistance Council (BIRAC)
 5th Floor, NSIC Business Park, NSIC Bhawan,
 Okhla Industrial Estate, New Delhi – 110020

Subject: Request for Empanelment of Agencies in Regulatory and Policy Domains at Biotechnology Industry Research Assistance Council (BIRAC)

For Category 1: Regulatory and Policy Research

S. No.	Technical Evaluation Criteria	Indicative Supporting Documents	Type of Document submitted	Page number of the supporting document
1.	Bidder should have conducted similar kind of Regulatory or Policy studies in Bio-Pharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc in atleast three different organizations.	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.		
2.	Bidder should have publications including regulatory and policy reports, data driven white papers and/or research articles in targeted areas.	Study reports, publications, position papers in targeted areas		
3.	The bidder should have subscription to the relevant econometrics and statistical tools and databases for collecting and analyzing the data	Self-attested List the tools with their subscription invoices		
4.	Bidder should have professional Competence well-equipped 'in-house' team to perform the work.	Resume of atleast three in-house team members working in the regulatory and policy area as mentioned in the scope of work		
5.	Technical Presentation	-		

For Category 2: Regulatory & Policy Support Engagement

S. No.	Technical Evaluation Criteria	Indicative Supporting Documents	Type of Document submitted	Page number of the supporting document
1.	Bidder should have developed content and structure of Regulatory or Policy events including training modules, educational material, event material/course outline in the area of in Bio-Pharma, Pharma, Agritech, Medtech, Food and Nutrition, Energy, Environment etc in atleast three different organizations.	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.		
2.	Bidder should have handled branding and administrative support for Pre, during and post event including handling online registrations, payment gateways, developing a webpage and creating promotional content for the event.	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.		
3.	Bidder should be a member of atleast one national and/or international regulatory or policy networks and/or related industry associations.	Membership certificate		
4.	Number of workshops/ conference/ trainings/ consultation meetings in the area have been conducted and list out the consultations provided to the government and PSUs in the area	Self-attested Copy of the work order arranged in chronological order i.e. latest first and letter of successful completion from the client.		
5.	Bidder should have professional Competence well-equipped 'in-house' team to perform the work.	Resume of atleast three in-house team members working in the regulatory and policy area as mentioned in the scope of work		
6.	Technical Presentation	-		

I/we hereby declare that my/our Bid is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)

Name : _____

Designation : _____

Seal : _____

Date : _____

Place : _____

UNDERTAKING WITH REGARD TO BLACKLISTING

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
Biotechnology Industry Research Assistance Council (BIRAC)
5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

Subject: Undertaking regarding Blacklisting / Non-Debarment

It is hereby confirmed and declared that M/s_____ is not blacklisted/debarred by any Government Department/Public Sector Undertaking/Private Sector/or any other agency for which works/assignments/services have been executed / undertaken.

(Signature of the Authorized signatory)

Name: _____

Designation: _____

Seal: _____

Date: _____

Place: _____

UNDERTAKING WITH REGARD to NON-LITIGATION

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
Biotechnology Industry Research Assistance Council (BIRAC)
5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

Subject: Undertaking regarding Litigation

It is hereby confirmed and declared that M/s_____, does not have any litigation / arbitration history with any Government department/ Public Sector Undertaking/ Private Sector/ or any other agency for which works/assignments/services have been executed/undertaken.

(Signature of the Authorized signatory)

Name: _____

Designation: _____

Seal: _____

Date: _____

Place: _____

UNDERTAKING WITH REGARD to PRE-EXIT OR TERMINATION

(To be submitted on Agency's Letter Head)

Ref. No. BIRAC/HR&A/007/2025/ENQ-50

To,

The Head-HR & Administration,
Biotechnology Industry Research Assistance Council (BIRAC)
5th Floor, NSIC Business Park, NSIC Bhawan,
Okhla Industrial Estate, New Delhi – 110020

Subject: Undertaking regarding Pre-exit or termination

It is hereby confirmed and declared that M/s_____, has not been pre-exited or terminated any contract with or by BIRAC in last 05 years as on the date of submission.

(Signature of the Authorized signatory)

Name : _____

Designation : _____

Seal : _____

Date : _____

Place : _____

Annexure - VIII

Draft template

Service and Confidentiality Agreement

This Agreement is made on this _____ day of _____, 2025 at New Delhi BY and BETWEEN **Biotechnology Industry Research Assistance Council**, a Government of India Enterprise having its office at **5th Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020** hereinafter referred to as “**BIRAC**” (which expression shall wherever the context so admits include its successors and assignees) of the **First Part**

AND

_____ a company registered under the Companies Act 2013, having its Registered Office at _____, hereinafter referred to as the “**Agency**” through its authorised representative [name], [Designation], duly authorized by the agency vide its Letter of Authorization (LoA)/ Board Resolution (BoR) No.____ dated____ (which expression shall wherever the context so admits include its employees, administrators and permitted assignees) of the **Second Part**

WHEREAS all the parts are hereinafter referred to as “Parties”;

All Annexure to this Agreement and Tender Document [reference No._____] shall be integral part of this Agreement.

WHEREAS BIRAC desires to engage the Agency and the Agency hereby agrees to provide the same governed by below mentioned terms and conditions and as per the BID documents.

NOW THEREFORE, the parties hereby agree to be bound by the provisions set out in this agreement.

1. Interpretation

- i. Confidential Information: “Confidential Information” means all information (whether in oral, written or electronic form) relating to BIRAC, matters related to BIRAC’s corporate affairs, minutes of the meeting(s) or other agnate materials including any notes or summaries derived from those materials of the Disclosing Party and confidential information received by the Disclosing Party from third parties, but excludes any information that: (1) was lawfully in the possession of the Recipient before receiving it from the Disclosing Party; (2) is provided in good faith to the Recipient by a third party without breaching any rights of the Disclosing Party or any other party; (3) is or becomes generally available to, or accessible by, the public through no fault of the Recipient; (4) is independently developed by the Recipient without use of the disclosed Confidential Information or (5) is required by public authority, by law or decree.
- ii. Words importing the singular numbers shall include the plural number and vice versa.

2. Headings and subheadings are for convenience only and shall not be deemed to be a part of this Agreement.

3. *Terms of Empanelment*

- i. The empanelment shall be effective from the ____ day of ____ 2025 (Effective Date).
- ii. The empanelment shall be effective for an initial period of 03 [Three] Years thereafter can be extended up to another 2 (two) years based on the performance of the agency on mutually agreed Terms & Conditions.
- iii. BIRAC will not retain any control for direct supervision of the contracted services and execution of this Contract does not create any liability, explicit or implicit, on BIRAC in respect of the manpower engaged.
- iv. The rights and remedies herein provided are cumulative with, and not exclusive of, any rights or remedies provided by law.
- v. **The Agency shall be entitled to the approved quoted fees upon submission of proper Invoices in accordance with the then-regular procedures of the BIRAC.**
- vi. BIRAC reserves the right to assign the tasks to any of the agency. BIRAC also reserves the right to award the work to any other agency, not necessarily with BIRAC.
- vii. This does not constitute and will not be deemed to constitute an exclusive commitment/ arrangement between BIRAC and the Agency.

4. *Responsibilities of the Agency*

- i. Discharge the duties, responsibilities and execute activities strictly in furtherance of the BID document, Scope of Work as given in the BID document as annexed as ***Annexure***

- ii. Ensure compliance with legal provisions related to this Contract. The Agency shall obtain all requisite license and approval at his cost from the appropriate authority for executing this contract work and submit copy of such license and approval to BIRAC.
- iii. Deploy any workforce which will exclusively be on Agency's pay roll.
- iv. Ensure proper behavior of the work force provided for the event. The Agency will prevent the work force from taking part in any direct or indirect association with a person or persons engaged in any antisocial activities, demonstrations, riots of agitation, which may in any way be detrimental or prejudicial to the occupants of land / properties in the neighborhood.
- v. Keep the BIRAC and its employees etc., harmless and indemnified from any consequential claims, actions, suits, proceedings, losses or damages on any ground whatsoever.
- vi. Take disciplinary action against any worker/staff engaged by him.
- vii. Undertake to indemnify the BIRAC against all claims which may arise under the noted acts:

- a The Shops and Establishment Act.
 - b The Workman's compensation Act.
 - c The payment of Wages Act.
 - d The Contract labor (Regulation and Abolition) Act. 1970 and the rules framed thereunder.
 - e Family Pension Scheme.
 - f Inter-state Migrant Workmen (Regulation of employment and condition of Service) Act, 1979.
 - g Any other Statutory Act/Law/Regulation made applicable during the pendency of the contract.
- viii. Be solely responsible for determining all matters of detail as to the manner in which a specific assignment is done with an objectively acceptable quality.
- ix. Undertake necessary liaison work as may be required from time to time with the officials of the concerned departments.
- x. Comply to the best of the technical /scientific knowledge, statutory, regulatory and safety guidelines established by the Government of India, any statutory authority and BIRAC while performing the services.
- xi. Take reasonable measures to protect the secrecy and avoid disclosure and unauthorized use of the Confidential Information of the disclosing party including discussion of the Confidential Information in any public forum which includes formal and informal discussions.
- xii. Comply with all prevailing laws, rules and regulations and shall not indulge in any act, which constitutes an offence or a corrupt practice under the Indian laws.
- xiii. Practice Chinese wall or Firewall policy within to deal with contrary interests or with confidential information.
- xiv. Submit any other documentary evidence as & when called by the BIRAC in connection with this Contract.

5. *Payment Terms*

- a. The bills for the services (of preapproved quoted rates) shall be submitted by the agency at the earliest after undertaking the services. The payment will be made after the submission of the Invoice, along with the report of the work done during the quarter and any other supporting documents as desired by BIRAC. This shall be scrutinized and checked before passing the bills for payment. The payments for all undisputed bills shall be made by BIRAC after scrutiny of the bills normally within 15 working days from the date of submission of original bills and related supporting documents to BIRAC.
- b. Income Tax as per statutory provision shall be deducted from the bills and remitted to Income Tax authorities by Accounts Department of BIRAC. A TDS certificate shall be issued by BIRAC to the Agency for such deductions.

- c. BIRAC shall make timely payments through Electronic Payment Mechanism (viz NEFT/ RTGS /ECS). Bank details have to be provided by the Agency.
- d. BIRAC shall not be liable for any consequences, whatsoever, in case there is a delay in making payments for any reasons resting with Agency. Further, no interest shall be paid on such delayed payments.

6. *Withholding of Payment*

BIRAC reserves the right to recover from the bills of the Agency the amount due to BIRAC against any losses and damages, including Liquidated Damages or as a result of any claims/compensation or due to any statutory imposition, etc., without any notice. BIRAC also reserves the right to withhold any payment to safeguard the interest of BIRAC against any dues for which the decision of the company shall be final. In case of any legal disputes, withheld payments shall not be released till the dispute is settled. No interest shall be payable in case of such withheld amounts.

In order to protect BIRAC, it may withhold the whole or any part of the amount due to the agency on account of evidence subsequently discovered in respect of the following:

- i. For non-completion of contracted work to BIRAC's satisfaction.
- ii. Agency's indebtedness arising out of execution of contract
- iii. All claims against Agency for Liquidated damages.
- iv. Any failure by the Agency to fully reimburse BIRAC under of indemnification provisions of this Contract. If, during the process of the Agency shall allow any indebtedness to accrue of which BIRAC may be primarily or contingently liable or ultimately responsible and agency shall, within five days after demand is made by the BIRAC, fail to pay and discharge such indebtedness, then BIRAC may during the period for which indebtedness shall remain unpaid, withhold from the amounts due to Agency's a sum equal to the amount such unpaid indebtedness. When all the above grounds for withholding payments shall be removed, payment shall thereafter be made for amounts so withheld.
- v. Garnishee order issued by a Court of Law in India.
- vi. Income-tax deductible at source according to law prevalent from time to time in the country.
- vii. Any obligation of Agency which by any law prevalent from time to time to be discharged by the BIRAC in the event of Agency's failure to adhere to such laws.

7. *Confidentiality*

The Parties, undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the Confidential Information and data exchanged/generated from the Process under this Contract for any purpose other than in accordance with this Contract. It shall be the responsibility of both the Parties to ensure maintenance of such confidentiality in respect of their behalf and on behalf of their employees, representatives and associates involved in related activities. Thus, obligation under this Contract will commence on the Effective Date and will subsist till three years after completion/termination or till such time the confidential information falls into the public domain whichever is earlier.

8. Return of Materials

Upon the conclusion of the task the agency undertakes to return or destroy materials containing Confidential Information in physical form handed over by the BIRAC in relation to the services or which was generated by the agency in the course of providing the services.

9. Waiver and Assignment

Any waiver by the BIRAC of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of the same or any other provision hereof. The agency shall not have the right to assign the rights or obligations under this Agreement without the prior written consent of BIRAC.

10. Effect of this Agreement

- i. The duty of secrecy under this agreement will commence on the Effective Date and will subsist till three years after the completion of the agreement.
- ii. This Agreement may be executed in two or more counterparts, each of which shall constitute an original and all of which shall be deemed a single agreement.
- iii. The rights and remedies herein provided are cumulative with, and not exclusive of, any rights or remedies provided by law.

11. Dispute Resolution

In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this Contract, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation.

If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this Contract or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived therefrom dispute shall be submitted for arbitration to with the sole arbitrator under the provisions of the New Delhi International Arbitration Centre Act, 2019. The award made in pursuance thereof shall be binding on the Parties. The venue/seat of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the Contract expiring or ceasing to exist or being terminated.

12. Notice

Any notices, consents, objections, demands, requests or other communications required or permitted to be given pursuant to this Agreement shall be in writing, and shall be sent by registered post, return receipt requested, to the addresses of the parties set forth in the heading to this Agreement. Either party may designate, by notice, a change of address hereunder.

13. Severability

If any of the provisions of this Agreement are found to be unenforceable, the remainder shall be enforced as fully as possible and the unenforceable provision(s) shall be deemed modified to the limited extent required to permit enforcement of the Agreement as a whole.

14. Governing Law and Jurisdiction

This Agreement shall be construed in accordance with and governed for all purposes by the laws of India. All the disputes or differences regarding the bid/contract shall be subject to the exclusive jurisdiction of the courts situated in New Delhi, India.

15. Amendments or Waiver

No amendment or waiver of this Agreement is binding unless agreed to in writing by the parties.

16. No other Relationship

The Agency agrees that all Services will be rendered as an independent Agency and that this Agreement does not create an employer-employee relationship or business partnership between the parties.

WHEREFORE, the Parties hereto through its duly authorized representatives have signed this Agreement on the day, month and year mentioned hereinbefore.

For Agency Duly authorized under the Letter of Authorization (LoA)/ Board Resolution No. ____ dated ____		For BIRAC	
Signature		Signature	
Name:		Name:	
Designation: Director		Designation: Director	
Date.....		Date.....	
WITNESS		WITNESS	
Signed		Signed	
Name:		Name:	
Complete Address:		Complete Address:	