

Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL)
OPV Plant, Chola, Bulandshahr - 203203, U. P.

Sub: NIT for selection of Biopharma consultant for setting up Pilot Scale GMP compliant Manufacturing Facility for production of clinical grade bacterial vaccine

BIBCOL invites sealed bid in two parts from eligible and experienced Biopharmaceutical Consultants for providing consultancy for setting up of bacterial vaccine pilot plant at its Chola (Bulandshahr) factory campus.

Back Ground:

BIBCOL is a central PSU under administrative control of Department of Biotechnology, Ministry of Science and Technology, Government of India and is located at village Chola of Bulandshahr district of Uttar Pradesh, 70 Km from Delhi. Currently BIBCOL is engaged in formulation of oral polio vaccine, dispersible zinc tablets and diarrhoea treatment kits. BIBCOL has been in oral polio vaccine segment since 1996 and has contributed significantly in polio eradication from the country by formulating and supply of billions of doses of oral polio vaccine to Ministry of Health & Family Welfare, Government of India.

Now BIBCOL decided to diversification into bacterial vaccine production with the help of technology provider of international repute and is looking for a consultant who can make assessment of existing infrastructure, design the GMP pilot scale facility for bacterial vaccine production within given existing space and budget and prepare tender document for modification of existing infrastructure, estimation of BOQ and cost, tender document preparation for turnkey contract (civil, electrical, mechanical, clean rooms, HVAC system, water purification system, BMS, waste disposal system etc), invitation of bids, evaluation, selection of turnkey contractor, project monitoring, regulatory clearances, certifying the contractors work , bill check and recommendation of payment, facility validation, pre clinical tox study. The work will involve liaison with technology provider, client, vendors, and regulatory authorities.

BIBCOL has sufficient excess land and utilities like power, water, HVAC plant with spare chilled and hot water, black steam etc which can be utilized for diversification. It has also earmarked an area in existing building for establishment of manufacturing and downstream processing of vaccine. The conceptual lay out, process flow and manufacturing technique, list of equipment, budget, timelines are available. This space so developed shall be used manufacturing of bacterial vaccine till inactivation process. It is proposed that the fill finish shall be done in existing facility presently being used for fill finish of other vaccine, on campaign basis.

1.0 **Scope of work:**

The consultant shall have following scope of work (however, all or part of scope of work may be allotted):

1.1 Developing and designing the lay out:

An existing area at third floor of building has been earmarked and conceptual layout is available and based on process flow and manufacturing method, man material movement, air flow, and application of GMP concept, the consultant shall design and prepare the detailed layout. Manufacturing technique, process flow, equipment list and capacity shall be provided by the client.

1.2 Liaison with client, technology provider:

Consultant shall be required to interact with client and technology provider for proper execution of work. Meetings shall be conducted at regular intervals for monitoring the progress of project and consultant shall prepare the monthly periodical progress reports and submit to client. Client shall facilitate the meetings.

1.3 Preparation of Tender Document for facility

The consultant shall prepare tender document for turnkey execution of facility which will involve civil, electrical, mechanical, clean rooms, HVAC system, BMS, access control system, fire fighting system, waste treatment and disposal. The process and quality control equipment shall not be part of this work. Based on the layout it may involve demolition of part civil structure. The scope shall include bill of quantities of various items, approved brands of various items, specifications, capacities, quality parameters, design , layout of various systems like HVAC, clean rooms, ducting, piping, equipment positioning, testing methods, execution, and validations (IQ, OQ, and PQ). It will summarise the projected total cost, scheduling of various work and timelines. It will have various drawings of process flow, man material flow, waste flow, air flow, AHU zoning, area classifications, room matrix, doors, windows, access control points, emergency exits etc. Consultant shall prepare the tender document in consultation with client and or technology provider. Tender shall be essentially in two parts technical and price bid. Various other terms and conditions like qualification criteria shall be included in the tender for clear cut understanding of scope and type of work.

1.4 Tender related assistance:

The execution of work shall be based on the tender document. After approval of tender document the consultant shall invite the bids from prospective turnkey executors having relevant experience in the field. The bids shall be invited at the place of client. On the due date, the bids shall be opened in presence of client, consultant and bidders. The bids shall be handed over to consultant for technical evaluation and recommendation. The price bids of

successful bidders shall be opened in the presence of client, consultant and bidders. The job shall be awarded to technically qualified and lowest bidder. BIBCOL has right to agree or disagree with the recommendations of consultant.

1.5 Project Management:

The consultant shall monitor, supervise the work of turnkey contractor, certify the quality and quantity of work and check the bills of contractor, recommend the running payments. Consultant will also check the DQ, IQ, OQ and PQ of various systems of facility. For project management consultant shall deploy a full time Project Manager or team at site of work for day to day work.

1.6 Regulatory work:

Consultant shall advise client about various regulatory clearances for setting up of facility and shall liaise with relevant authorities, and will help client in dossier preparation for regulatory clearances.

1.7 Assistance in Equipment Purchase:

The consultant shall finalize the list of equipment to be purchased for the project like autoclaves, DHS, WFI, pure steam generator, distribution piping, process and QC equipment like Fermentor, TFF system, LAFs, Bio safety hoods, pressure vessels, refrigerators, spectrophotometer, ELISA reader etc with detailed specifications, make, and capacity in consultation with technology provider/client. The work includes DQ, preparation of tender documents, invitation of NIT on behalf of client, finalization of vendors, installation, commissioning including checking of IQ, OQ, PQ and certifying the completion of project.

1.8 Preclinical tox study

Consultant shall interact with drugs regulatory authorities and may seek exemption of pre clinical study as the product is well established and has been in use in the country.

In case there is no exemption, in addition to consultation for setting up of facility at pilot scale, the consultant shall identify the preclinical study service provider for preclinical study of the product manufactured by client at its renovated facility. The selected service provider must be authorized to conduct the study and the outcome report must be acceptable to drug authorities. Proper tendering process shall be followed for selection of service provider.

1.9 **Work Completion:**

Consultant shall certify that the facility has been completed as per tender and all validation documents have been prepared and completed as per scope of work and meets the requirement of GMP and facility is ready for production of clinical grade bacterial vaccine.

2.0 Documents to be submitted with Technical Bid:

- 2.1 Detail about organization and its main activities.
- 2.2 Organization structure
- 2.3 Three years balance sheet and P&L accounts.
- 2.4 Client list related to the work, along with copies of work orders.
- 2.5 List of manpower with qualification and experience (field specific).
- 2.6 Description of proposed plan for execution of project with time lines.
- 2.7 Registration certificate of organization
- 2.8 GST and PAN details
- 2.9 Any other relevant information.
- 2.10 EMD: EMD of Rs 75,000/- in the shape of DD in favour of BIBCOL to be submitted along with the technical bid. Without EMD, the bid shall not be accepted. EMD shall be adjusted against performance security of successful bidder, and the EMD of unsuccessful bidder shall be refunded or returned within one month of award of order to successful bidder. In any case, the EMD of unsuccessful bidder shall be returned within three months of receipt of EMD with tender.

3.0 Terms and Conditions:

3.1 Eligibility criteria:

Only those bidders shall be eligible who fulfil at least three of following criteria (fulfilment of condition (ii) is essential):

- (i) The firm should have conducted feasibility study in vaccine or bio similar space.
- (ii) Should have carried out conceptual design, detailed design and engineering facility commissioning as per cGMP guidelines of Schedule M, USFDA, MHRA, WHO cGMP, TGA etc.
- (iii) Quality management system design and implementation.
- (iv) Manpower training and development.
- (v) Audit of firms for gap analysis, regulatory compliances.
- (vi) One member of core team should have been enlisted by WHO.

3.2 The bidder is required to submit the tender by 3.00 p.m. on 28-06- 2019.

3.3 The tender shall be submitted in sealed envelope with clearly super scribing on top of envelop, "Bid for Biopharmaceutical Consultant" to be opened on 28-06-2019 at 3.30 p.m." Tenders submitted by electronic mode or other modes shall not be accepted.

- 3.4 Bidders are advised to include all relevant documents as mentioned above to prove their experience and expertise in the project.
- 3.5 BIBCOL shall not be responsible for any expense incurred by the bidder in connection with the preparation of this bid.
- 3.6 The selected consultant shall sign a non disclosure agreement with client before start of work.
- 3.7 The selected consultant shall sign an agreement with client for execution of work and shall adhere to the agreed timelines for execution of work. The various activities shall be having timelines within overall project completion time.
- 3.8 **Performance Security:**
The selected consultant shall submit the performance security in the shape of DD or payment to the bank account of client @ 10% of total consultancy charges as arrived at S. No. 1 of price bid. Consultant may also submit the bank guarantee in place of DD.
- 3.9 BIBCOL reserves right to cancel or reject any or all tenders without assigning any reason thereof.
- 3.10 BIBCOL reserves the right to deal with the proposal in any manner without assigning any reason for the same.
- 3.11 BIBCOL may invite the bidders, if required, to make a presentation for assessing the capabilities and expertise.
- 3.12 The Price bid shall be as per format (Form -1) and with item wise rates and total amount. Conditional price bid shall not be accepted.
- 3.13 **Schedule of Payment:**
Consultant shall be paid the consultancy charges every month in proportion to the value of work done which shall be considered as adhoc payment and final payment payable shall be calculated with respect to the project cost and maximum payable as per agreed consultancy charges and project management charges on monthly basis, within 15 days of completion of calendar month.
- 3.14 **Dispute:**
If any dispute arises between the parties, the concerned party may submit its concern or disputes to the Managing Director BIBCOL in writing and the decision of Managing Director BIBCOL shall be communicated to the party and if not satisfied the party may prefer the arbitration as per arbitration act.
- 3.15 The two bids "Technical & Commercial" and "Price bid" shall be submitted in two separate envelops with clearly captioned on the top of envelop as "Technical & Commercial Bid" and "Price Bid" respectively. Two sealed envelopes shall be kept in a separate envelop captioned on the top of envelop as, "Bid for Biopharmaceutical Consultant", to be opened on 28-06-2019 at 3.30 p.m.

Interested parties qualifying above conditions may submit their bid/tender with the necessary documents and EMD by post or courier (preferably DTDC-PIN Code 203001) to the below mentioned address on or before 3.00 p.m. on 28-06-2019:

Associate Vice President (Purchase)
OPV Plant, Chola, Bulandshahr-203203 (U P)
Ph: 9458096106
Email: sksbibcol@rediffmail.com

Form-1

(Price Bid)

NIT for selection of Biopharma consultant for setting up Pilot Scale GMP compliant Manufacturing Facility for production of clinical grade bacterial vaccine

S. No.	Description	Rate	Remark
1	Providing consultancy for setting up of pilot scale facility for production of bacterial vaccine as per user requirement which includes study of current infrastructure,		Rate must be in terms of percentage of total cost of facility (Estimated cost

	design, drawings, layout, cost estimation, preparing tender document, tender related assistance, regulatory work, identification of service provider for pre clinical tax study as defined in the scope of work under 1.1, 1.2, 1.3, 1.4, 1.6, 1.7, 1.8 and 1.9		is Rs 10 crore and estimated project completion time is 12 months)
2	Project Management service as defined in the scope of work at 1.5		Rate must be in terms of fee per month (Estimated time duration is 10 months)
3	Service tax		Rate must be in terms of percentage of value of work and in line with rates applicable as per GST tariff
4	Any other charges, if required		Charges, if any must be clearly written against the item for which being charged