

भारतसरकार
वित्तमंत्रालय
राजस्वविभाग
कार्यालय महाप्रबन्धक,
शासकीय अफीम एवं क्षारोदकारखाना
नीमच.458441 (म.प्र.)



GOVERNMENT OF INDIA
Ministry of Finance
Department of Revenue,
Office of the General Manager,
Govt. Opium & Alkaloid Works,
Neemuch-458441 (M.P.)

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F.No: R&D/124/GMP/CERT/21-22

Dt. 06-11-2023

**EXPRESSION OF INTEREST (EOI) CUM REQUEST FOR PROPOSAL
(RFP) APPOINTMENT OF CONSULTANT FOR IMPLEMENTATION OF
cGMP STANDARDS AT GOAW, NEEMUCH, M.P**

TENDERING SCHEDULE

1	EOI cum RFP document available on website for download	:	07-11-2023, 17.00 Hrs.
2	Pre-bid Meeting	:	16-11-2023, 11.00 A.M
3	EOI cum RFP Submission due date	:	28-11-2023, 17.00 Hrs..
4	Opening of Technical Proposal	:	30-11-2023, 11.00 A.M
5	Opening of Financial Proposal	:	Will be communicated in due course of time

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SECTION- I

INVITING EXPRESSION OF INTEREST (EOI) CUM REQUEST FOR PROPOSAL (RFP)

Implementation of cGMP Standards:

GOAW, Neemuch is engaged in production of various Alkaloids namely Codeine phosphate, Noscopine, Thebaine etc. The manufacturing facility was setup in the year 1976. Production capacity of GOAW has approximately 25.00 MT of Alkaloids and its average turnover for the last three years is approximately Rs. 137 crores.

"Expression of Interest Cum Request for proposal" is invited from renowned Consultant within India, having the requisite expertise and experience for providing consultancy to undertake design, supervision and implementation of cGMP as per schedule "M" of Drugs & Cosmetics Act, 1940, at Govt. Opium and Alkaloid Works (GOAW), Neemuch, M.P. The details regarding the scope of work etc. are available below and are placed alongside with this notice in the website www.goaf.gov.in and the Government e-procurement portal <https://eprocure.gov.in/eprocure/app>. Interested and eligible Consultant (Corporation/Company/Firm) may submit their "EOI cum RFP" with all relevant details and supporting documents as mentioned below on or before 28-11-2023. For any clarification Shri M.K.Kishore, Chemical Engineer (Chairman), GOAW, Neemuch may be contacted at the office or on telephone number (07423 220199) or Mobile number 9893131371.

Eligibility (Pre-Qualification) Criteria:

The Consultant shall be of single entity and should have been in the field of establishing of c-GMP-Compliant Facility. The Consultant shall be a registered in India as required by the Law with minimum three years of operation up to 31-03-2023.

Documents/ Evidence shall be submitted by the consultant in support of the following criteria:

- a. The consultant should have undertaken cGMP projects pertaining to pharmaceutical industries for atleast three years ending 31-03-2023 costing not less than Rs.27,50,000/-each for three similar works or Rs. 34,00,000/-each for two similar works or Rs. 54,50,000/-for one similar work, indicating number of assignments handed by them successfully similar to the areas mentioned in the scope of work of EOI cum RFP. (Document evidence of work order/performance certificate or etc may be submitted)
- b. The average annual financial turnover of the bidders during last three years ending on 31.03.2023 should not be less than Rs. 55,00,000/-

(Rupees Fifty five lacs only). (Financial statement i.e. Balance Sheet and Profit & Loss amount certified by CA be submitted)

c. Firm should have following In-house (on roll) key personnels:

(1) GMP Expert/ Team leader:

- (i) Qualification: Graduate/Diploma in Mechanical/ Chemical/Pharmacy or M.Sc in chemistry or equivalent.
- (ii) Experience: Must have minimum 07 years experience in the field of implementation of cGMP norms as per Schedule M of Drugs & Cosmetics act/ WHO-GMP/ USFDA/ EUFDA etc.

(2) Mechanical/ Chemical/ HVAC Engineer:

- (i) Qualification: Graduate/Diploma in Mechanical/ Chemical/Pharmacy or equivalent.
- (ii) Experience: Must have minimum 07 years experience in the field of installation and commissioning of HVAC system in GMP implemented pharmaceutical plant.

(3) Technical incharge:

- (i) Qualification: Graduate/Diploma in Mechanical/ Chemical/Pharmacy/ M.Sc or equivalent.
- (ii) Experience: Must have minimum 07 years experience in the field of concept design, feasibility study, capacity designing, machinery selection, and installation and trial batches in GMP implemented Pharmaceutical plants.

(4) Quality control/ Quality Assurance personnel:

- (i) Qualification: B.Tech (chemical)/B.Pharmacy/M.Pharmacy or M.Sc in chemistry or equivalent.
- (ii) Experience: Must have minimum 07 years experience in the field of Quality control laboratory/ Quality assurance department in any GMP implemented pharmaceutical plant etc.

(Documentary evidence in support of experience shall be submitted)

d. The Consultants should submit MSME for exemption from payment of Earnest Money Deposit (EMD).

e. The Consultants should not have been blacklisted, debarred or expelled by Union Government/ State Government/ PSU's etc during last three years. (Attached as annexure-B)



(M.K.KISHORE)
CHEMICAL ENGINEER
Govt. Opium & Alkaloid Works,
Neemuch - 458 441 (M.P.)

LETTER OF INVITATION FOR EOI CUM RFP

Ref. No.:

Dated: / /

..... [Contact Person & Designation]

..... [Name of Consultant & Address]

Dear Mr. /Ms. _____

1. This EOI cum RFP is for Implementation of cGMP standards as prescribed under the Drugs and Cosmetics Act 1940, at their manufacturing facility Government Opium and Alkaloid Works (GOAW), Neemuch – 458 441 (MP) .

2. The Background Information and Terms of Reference (TOR) for the Consulting services are provided in Section 5 of the EOI cum RFP.

3. The EOI CUM RFP includes the following documents:

Section 1	Letter of Invitation
Section 2	Instructions to Consultant including Data Sheet, integrity Pact and Evaluation Criteria
Section 3	Technical Proposal Standard Forms
Section 4	Financial Proposal Standard Forms
Section 5	Terms of Reference
Annexure I	Evaluation Criteria
Annexure II	Format for submission of Technical Proposal.
Annexure III	Format for submission for Financial Proposal.
Annexure IV	List of Major Works planned and proposed in upcoming shutdown work

Yours sincerely,

(Authorized Signatory)

INSTRUCTIONS TO CONSULTANT

1. INTRODUCTION

General

- 1.1** The Consultant having experience and expertise of providing the cGMP Norms are invited to submit their EOI cum RFP for pre-qualification (technical) and financial proposals for the above consultancy services.

The selection will be through a competitive bidding which will be single submission and have 2 stages of evaluation process viz., Technical and financial proposal evaluation.

a) Stage-I: The Consultant fulfilling the eligibility criteria will be evaluated and deemed to be technically qualified.

b) Stage-II: The financial proposals of the Consultants which are technically qualified shall be opened and evaluated.

Selection of the consultant by the GOAW, Neemuch will be through least cost system (LCS). Selection will be made from Consultant responding to this RFP.

- 1.2** Consultant should familiarize themselves with local conditions and take those into account in preparing their Proposals. To have an idea of the assignment and local conditions, Consultant are advised to visit GOAW, Neemuch. The Consultant's representatives may contact the Consultancy Evaluation Committee (CEC) member named in the Data Sheet for this purpose.
- 1.3** Consultant shall bear all costs associated with the preparation and take into account all prevailing conditions including those like machineries and buildings before submission of their Proposals.
- 1.4** The GOAW, Neemuch is not bound to accept any Proposal and reserves the right to annul the selection process at any time prior to contract award, without incurring any liability to the Consultant.
- 1.5** In preparing their Proposals, Consultant are expected to examine in detail the documents comprising the EOI cum RFP. Material deficiencies in providing the information requested may result in rejection of a Proposal.

Validity of EOI cum RFP

- 1.6** EOI cum RFP shall remain valid as per sl. No. 9 of Data sheet.

Earnest Money Deposit

- 1.7 Earnest money/Bid security deposit of Rs.2,70,000/- (Rs. Two Lacs Seventy Thousand Only) in the form of DD from any nationalized bank drawn in favour of "ACAO, Govt. Opium & Alkaloid Works", payable at Neemuch (M.P.) must be accompanied with technical bid cover valid for 6 months from the date set for opening of technical bid. Tender not accompanied with the prescribed EMD shall not be considered at all. The EMD of successful bidder will be released after receiving bank guarantee.
- 1.8 The EMD of all unsuccessful bidder/tenderers will be returned without interest after the award of contract.
- 1.9 The successful bidder will be required to furnish Bank Guarantee of Five percent (5%) of the contract value within 15 days of award of the contract. The bank guarantee of successful bidder will be considered as performance security and released after six months of successful implementation of entire work related to cGMP standards (date of receiving GMP certificate) as mentioned in TOR and GC laid down by GOAW.
- 1.10 No interest on the earnest money deposit shall be paid.

2. CLARIFICATIONS AND AMENDMENTS TO RFP DOCUMENTS

2.1 Consultant may request a clarification of any of the EOI cum RFP documents up to Twelve(12) days prior to the Proposal submission date (but prior to pre bid meeting) indicated in the Data Sheet. Any request for clarification must be sent in writing to the Mail indicated in the Data Sheet (gmgoaw-nmh@gov.in). These would be clarified at the pre-bid meeting without identifying its source.

Pre-bid meeting

- 2.2 The bidder or his official representative is invited to attend the pre-bid meeting, which will take place on the appropriate time and place as indicated in data sheet.
- 2.3 The purpose of the meeting will be to clarify issues and to answer questions on any matter related to the EOI cum RFP that may be raised at that stage including the clarifications requested under 2.1 above.
- 2.4 Non-attendance at the pre-bid meeting will not be a cause for disqualification of a bidder.

Amendment to EOI CUM RFP

- 2.5 Any time before the submission of Proposals, the GOAW may, whether on its own initiative, or in response to a clarification requested by the consultant in response to queries raised at the pre-bid meeting, amend the EOI cum RFP by issuing an addendum.

3. PREPARATION OF THE PROPOSAL

3.1 The Proposal will consist of two components

- (i) The Technical Proposal, and
- (ii) The Financial Proposal

3.2 All related correspondence exchanged by the Consultant would also form part of the Proposal.

3.3 The Technical & Financial Proposals should include separate for each (formats at Annexure II and III) signed by person(s) with full authorization to make legally binding contractual (including financial) commitments on behalf of the consultant. The letter should specify all association arrangements, and certify that each associated Consultant will perform its designated tasks under the assignment if the lead Consultant is awarded the contract.

3.4 The Technical Proposal should clearly demonstrate the Consultant's understanding of the assignment requirements and capability and approach for carrying out the tasks set forth in the TOR.

4. TECHNICAL PROPOSAL

General

The Technical Proposal shall not include any financial information and any such Proposals containing financial information shall be declared non-responsive.

Technical Proposal Format and Content

4.1 The Technical Proposal shall contain information indicated in the following subparagraphs from (i) to (ix) using the Standard Technical Proposal Forms (Section 3). The Consultant must provide such information.

- (i) A brief description of the organization and outline of recent experience, (last 7 years) of the Consultant and of a similar nature is required in Form TECH-1. For each assignment, the outline should indicate inter alia, the assignment, approximate value of services, and the extent of Consultant's involvement. Information should be provided only for those assignments for which the Consultant was legally contracted by the GOAW or as one of the major participating Consultant within an association. Assignments completed by individual experts working privately or through other consultant cannot be claimed as the experience of the Consultant, but can be claimed by the individuals themselves in their CVs. Consultant should be prepared to substantiate the claimed experience if so requested by the GOAW.
- (ii) A concise, complete, and logical description of how the Consultant's team will carry out the services to meet all requirements of the TOR in form TECH-2 supported by form TECH-3.

- (iii) Comments, if any, on the TOR (to be given in Form TECH – 2) to improve performance in carrying out the assignment. Innovativeness will be appreciated, including workable suggestions that could improve the quality/effectiveness of the assignment. In this regard, unless the Consultant clearly states otherwise, it will be assumed by the GOAW, Neemuch that work required to implement any such improvements, are included in the inputs shown on the Consultant's Staffing Schedule (Form TECH- 4, Section – 3).
- (iv) A work plan showing in graphical format (bar chart) the timing of major activities, anticipated coordination meetings, and deliverables such as reports required under the TOR (Section – 5).
- (v) A Staffing Schedule (Form TECH-4, Section - 3) indicating clearly the estimated duration in terms of person and the proposed timing of each input for each nominated expert using the format shown in Form TECH – 4. The schedule shall also indicate when main office experts are working at the site office and when they are working at locations away from the site office.
- (vi) The name, age, background employment record, and professional experience of each nominated expert, with particular reference to the type of experience required for the assignment should be presented in the CV format shown in Form TECH-5. A summary should be given in Form TECH – 6.
- (vii) Only one CV may be submitted for each position.
- (viii) The GOAW requires that each expert confirm that the content of his/her Curriculum Vitae (CV) is correct and the experts themselves should sign the certification of the CV. However, in particular cases, the CEC may accept a senior officer of the Consultant signing the CVs on behalf of the experts.
- (ix) A zero rating will be given to a nominated expert if
 - (a) The CV is not signed in accordance with Sub-Clause 4.1 (viii) requirements.
 - (b) The expert is a current employee of Government of India/ any State Government /Union Territory.

As a checklist to ensure all these requirements have been complied with, Consultant are required to complete the "Summary of Information on Proposed Experts", Form TECH-6.

5. FINANCIAL PROPOSAL

- 5.1** All information provided in the Consultant' Financial Proposal will be treated as confidential unless otherwise specified. The Financial Proposal should cover all costs associated with the assignment, including Office accommodation, transportation (mobilization, demobilization, local), equipments (vehicles, office equipment, furniture and supplies), and preparation of reports in requisite number of copies.

- 5.2 The Financial Proposal must be uploaded using the format shown in Section 4. The Financial Proposal requires completion of one form namely form FIN-1. The consultant should submit financial bid on lump sum basis only (not in percentage) covering the entire work. This amount is to be filled up at form FIN-1, and should include tax component if any.
- 5.3 Amounts payable to the Consultant by the GOAW, Neemuch may be subject to local taxes. It is the responsibility of the Consultant to determine the estimated taxes payable and take such amounts into account, as applicable. **All such taxes shall be deemed to be included in the Consultant's Financial Proposal.**

6. SUBMISSIONS, RECEIPT AND OPENING OF PROPOSALS

- 6.1 The original Proposal (both Technical and Financial Proposals) shall contain no interlineations or over writing.
- 6.2 Proposals must be uploaded on or before the time and date stated in the Data Sheet or any new date established by GOAW, Neemuch according to provisions of Sub-Clause 2.5.

7. PROPOSAL EVALUATION

General

- 7.1 From the time the Proposals are opened to the time the contract is awarded, the Consultant should not contact the GOAW, Neemuch on any matter related to its Technical and/or Financial Proposal. Any effort by a Consultant to influence the GOAW, Neemuch in examination, evaluation, ranking of Proposals or recommendation for award of contract shall result in rejection of the Consultant's Proposal.

Evaluation of Technical Proposals

- 7.2 Consultant Evaluation Committee (CEC) in GOAW, Neemuch will be responsible for evaluation and ranking of Proposals received.
- 7.3 The CEC evaluates and ranks the Technical Proposals on the basis of Proposal's responsiveness to the TOR using the evaluation criteria and points system specified in the Annexure-I. Each Technical Proposal will receive a technical score. A Proposal shall be rejected if it does not achieve the minimum technical mark of 75 out of the maximum of 100 points.
- 7.4 Technical Proposal may not be considered for evaluation in any of the following cases:
- (i) The Technical Proposal was submitted in the wrong format; or
 - (ii) The Technical Proposal included details of costs of the services, i.e., financial matters; or

- (iii) The Technical Proposal uploaded after the closing of submission date and time as specified in the Data Sheet.

7.5 After the technical evaluation is completed, the GOAW shall notify Consultant whose Proposals did not meet the minimum qualifying technical mark or Consultant whose Technical Proposals were considered non-responsive to the EOI cum RFP requirements, indicating that their Financial Proposals will be unopened after completion of the selection process. The GOAW shall simultaneously notify, in writing to the Consultant whose Technical Proposals received a mark of 75 or higher, Financial Proposals will be opened.

8. Evaluation of Financial Proposals

8.1 The CEC of GOAW, Neemuch will subsequently review the detailed contents of each Financial Proposal. During the examination of Financial Proposal the GOAW, Neemuch staff and any other person involved in the evaluation process will not be permitted to seek clarification or additional information from any Consultant who had submitted Financial Proposal.

8.2 The commercial terms in each Financial Proposal will be checked for compliance with the requirements set forth in the Annexure-II.

9. SELECTION OF CONSULTANT

Selection of the Consultant will be done on the basis of Least Cost system (LCS), there is no weight age for Technical score in the final evaluation, the financial proposals will be ranked in terms of their total evaluated cost. The least cost proposal will be ranked as L-1 and the next higher and so on will be ranked as L-2, L-3 etc. The least cost proposal (L-1) will be considered for award of contract. Negotiations will be carried out as per the guidelines.

10. NEGOTIATIONS

10.1 Negotiations are not an essential part of the selection process. In many cases, however, it is felt necessary to conduct negotiations with the selected consultant. Negotiations shall include discussions of the TOR, the methodology, staffing and any special conditions of the contract. These discussions shall not substantially alter the original TOR or the terms of the contract, lest the quality of the final product, its cost, and the relevance of the initial evaluation be affected.

10.2 Financial negotiations shall only be carried out if due to negotiations as mentioned in para 10.1 above, there is any change in scope of work which has any financial bearing on the final prices or of the costs/cost elements quoted are not found to be reasonable. In such negotiations, the selected Consultant may also be asked to justify and demonstrate that the prices proposed in the contract are not out of line with the rates being charged by the consultant for other similar assignments. However, in no case such financial negotiation should result into increase in the financial cost as originally quoted by the consultant and on which basis the consultant has been called for the negotiations.

10.3 If the negotiations with the selected consultant fail, the employer shall cancel the bidding procedure and re-invite the bids.

11. CONFIDENTIALITY

Information for the evaluation and till awarding of contract will be kept confidential by both the parties.

12. AWARD OF CONTRACT

The GOAW, Neemuch shall award the contract to the selected Consultant and promptly notify the other Consultant who submitted Proposals, that they were unsuccessful. The GOAW, Neemuch will return the unopened Financial Proposals to the unsuccessful Consultant.

13. CONTRACT COMMENCEMENT DATE:

The Data Sheet indicates the anticipated date for the commencement of the Contract services.

14. LATE BIDS:

Bids received after the specified date and time will not be considered under any circumstances.

15. RIGHT TO REJECT:

The Govt. Opium & Alkaloid Works, Neemuch will have the right to reject any or all proposals without assigning any reason and may re-invite fresh proposals.

16. Location:

Rates should be quoted for Neemuch basis. Neemuch is located 135 km from Ratlam (M.P.) and 55 kms from Chittorgarh (Raj.)

17. Definitions:

Unless the context otherwise requires, the following term whenever used in this Agreement have following meanings

- "CMC" Means Consultancy monitoring committee.
- "CEC" Means Consultancy evaluation committee.
- "TOR" Means Terms of reference
- "GC" Means General Conditions.
- "IEM" Means Independent external monitor.

DECLARATION FOR NOT BLACK LISTED

To,

The General Manager,
GOAW, Neemuch, m.p.

**Subject : EOI cum RFP for Appointment of Consultant for establishment of cGMP
Compliant at GOAW, Neemuch, M.P.**

Ref. :R&D/124/GMP/CERT/2021-22

Dear Sir/ Madam,

I / We hereby confirm that our organization has not
been banned or black listed by any government organization/Financial institution/Court
/Public sector Unit /Central Government.

In case the above statement made by us are found to be false or incorrect, you have
right to reject our bid at any stage including forfeiture of PBG and / or cancel the award
of contract

Signature of Authorized Representative
with Seal

Place :

Name :

Date :

Designation :

Integrity Pact

(To be executed on stamp paper and submitted along with technical bid/tender documents. To be signed by the bidder and Govt. Opium and Alkaloid Works, Neemuch.)

Govt. Opium & Alkaloid Works, (GOAW) Neemuch hereinafter referred to as "The Principal".

AND

_____ hereinafter referred to as "The Bidder/Consultant".

PREAMBLE

The Principal intends to award, under laid down organizational procedures, contract/s for engagement of Consultant to implement GMP Norms. The Principal values full compliance with all relevant laws of the land, rules, regulations, economic use of and of fairness/transparency in its relations with its Bidder and/or Consultant).

In order to achieve these goals, the Principal will appoint an Independent External Monitor (IEM), who will monitor the tender process and the execution of the contract for compliance with the principles mentioned above.

Section 1: Commitments of the Principal.

1. The Principal commits itself to take all measures necessary to prevent corruption and to observe the following principles:-
 - a) No employee of the Principal, personally or through family members, will in connection with the tender for, or the execution of a contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the personal is not legally entitled.
 - b) The Principal will during the tender process treat all Bidders with equity and reason. The Principal will in particular, before and during the tender process, provide to all Bidders the same information and will not provide to any Bidder confidential/additional information through which the Bidder could obtain an advantage in relation to the process or the contract execution.
 - c) The Principal will exclude from the process all known prejudiced

persons.

2. If the Principal obtains information on the conduct of any of its employees which is a criminal offence under the IPC/PC Act, or if there be a substantive suspicion in this regard, the Principal will inform the Chief Vigilance Officer and in addition can initiate disciplinary actions.

Section 2: Commitments of the Bidder/Consultant

1. The Bidder/Consultant commit himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the tender process and during the contract execution.
 - a. The Bidder/ Consultant will not, directly or through any other persons or firm, offer promise or give to any of the Principal's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which he/she is not legally entitled to, in order to obtain in exchange any advantage or during the execution of the contract.
 - b. The Bidder / Consultant will not enter with other Bidders into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non submission of bids or any other actions to restrict competitiveness or to introduce cartelization in the bidding process.
 - c. The Bidder /Consultant will not commit any offence under the relevant IPC/PC Act; further the Bidder/Consultant will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or documents provided by the Principal as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.
 - d. The Bidder / Consultant of foreign origin shall disclose the name and address of the Agents/representatives in India, if any. Similarly, the bidder/ Consultant of Indian Nationality shall furnish the name and address of the foreign principals, if any. All the payments made to the India agent/representative have to be in Indian Rupees only.
 - e. The Bidder /Consultant will, when presenting his bid, disclose any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the contract.
 - f. The Bidder/ Consultant who have signed the Integrity Pact shall not approach the courts while representing the matter to IEMs and shall wait for their decision on the matter.

2. The Bidder/ Consultant will not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3: Disqualification from tender process and exclusion from future contract

If the Bidder/ Consultant before award or during execution has committed a transgression through a violation of Section 2 above or in any other form such as to put his reliability or credibility in question, the Principal is entitled to disqualify the Bidder/ Consultant from the tender process or to terminate the contract, if / Consultant already signed, for such reasons.

Section 4: Compensation for Damages

1. If the Principal has disqualified the Bidder(s) from the tender process prior to the award according to Section 3, the Principal is entitled to demand and recover the damages equivalent to Earnest Money Deposit/Bid Security.
2. If the Principal has terminated the contract according to Section 3, or if the Principal is entitled to terminate the contract according to Section 3, The Principal shall be entitled to demand and recover from the Contractor liquidated damages of the Contract value or the amount equivalent to Performance Bank Guarantee.

Section 5: Previous Transgression

1. The Bidder declares that no previous transgressions occurred in the last three years with any other company in any country conforming to the TII's anti corruption approach or with any other public sector enterprise in India that could justify his exclusion from the tender process.
2. If the bidder makes incorrect statement on this subject, he can be disqualified from the tender process and appropriate action can be taken including termination of the contract, if already awarded, for such reason

Section 6: Equal treatment of all Bidders / Consultants / Sub Consultant

1. In case of sub consulting, the Principal Consultant shall take the responsibility of adoption of Integrity Pact by the Sub – Consultant.
2. The Principal will enter into agreements with the identical conditions as this one with all bidders and / Consultants.
3. The Principal will disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7: Criminal charges against violation Bidder(s) // Consultant (s)/ Sub-Consultant (s).

If the Principal obtains knowledge of conduct of a Bidder(s)/ / Consultant(s) which constitutes corruption, or if the Principal has substantive suspicion in this regard, the Principal will inform the same to the Chief Vigilance Officer.

Section 8: Independent External Monitor/Monitors

1. The Principal appoints competent and credible Independent External Monitor for this Pact after approval of Central Vigilance Commission. The task of the Monitor is to review independently and objectively, whether and to what extent the parties comply with the obligations under this agreement.
2. The Monitor is not subject to instructions by the representatives of the parties and performs his functions neutrally and independently. The Monitor will have access to all contract documents, whenever required. It will be obligatory for him to treat the information and documents of bidders/contractors as confidential. He reports to the Chief Controller of Factories, New Delhi.
3. The Bidder(s) / Consultant (s) accepts that the Monitor has the right to access without restriction to all project documentation of the Principal including that provided by the Consultant. The Consultant will also grant the Monitor, upon his request and demonstration of a valid interest, unrestricted and unconditional access to his project documentation. The same is applicable to Sub Consultant.
4. The Monitor is under contractual obligation to treat the information and documents of the Bidder(s)/ / Consultant (s)/Sub Consultant (s) with confidentiality. The Monitor has also signed declarations on "Non – Disclosure of Confidential Information" and of "Absence of Conflict of Interest" In case of any conflict of interest arising at a later date; the IEM shall inform Chief Controller of Factories, New Delhi and recuse himself/herself from the case.
5. The Principal will provide to the Monitor sufficient information about all meetings among the parties related to the Project provided such meetings could have an impact on the contractual relations between the Principal and the Consultant. The parties offer to the Monitor the option to participate in such meetings.
6. As soon as the Monitor notices, or believes to notice, a violation of this agreement, he will so inform the Management of the Principal and request the Management to discontinue or take corrective action, or to take other relevant action. The monitor can in this regard submit non-binding recommendations. Beyond this, the Monitor has no right to demand from the parties that they act in a specific manner, refrain from action or tolerate action.
7. The Monitor will submit a written report to the Chief Controller of

Factories, New Delhi within 8 to 10 weeks from the date of reference or intimation to him by the Principal and, should the occasion arise, submit proposals for correcting problematic situations.

8. If the Monitor has reported to the Chief Controller of Factories, New Delhi, a substantiated suspicion of an offence under relevant IPC/PC Act, and the Chief Controller of Factories, New Delhi has not, within the reasonable time taken visible action to proceed against such offence or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Central Vigilance Commissioner.
9. The word "Monitor" word include both singular and plural.

Section 10: Pact Duration

This pact begins when both parties have legally signed it. It expires for the Consultant 12 months after the last payment under the contract, and for all other Bidder 6 months after the contract has been awarded.

If any claim is made/lodged during this time, the same shall be binding and continue to be valid despite the lapse of this pact as specified above, unless it is discharged/determined by Chief Controller of Factories, New Delhi.

Section 11: Other Provisions

1. This agreement is subject to Indian Law. Place of performance and jurisdiction is the registered office of the Principal i.e. GOAW Neemuch.
2. Changes and supplements as well as termination notices need to be made in writing. Side agreements have not been made.
3. If the Consultant is a partnership or a consortium, this agreement must be signed by all partners or consortium members.
4. Should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties will strive to come to an agreement to their original intentions.
5. Issues like Warranty/Guarantee etc. shall be outside the purview of the IEMs.
6. In the event of any contradiction between the Integrity Pact and its Annexure, the clause in the Integrity Pact will prevail.

(For & on behalf of the Principal)
(Office Seal)

Place

Date

(For & on behalf of Bidder/Consultant)
(Office Seal)

Place

Date

Witness 1:
(Name & Address)

Witness 1:
(Name &Address)

Witness 2:
(Name & Address)

Witness 2:
(Name &Address)

DATA SHEET

Information to Consultant

S.NO.	Particulars	Details
1.	The name of client is	The General Manager, Govt. Opium & Alkaloid Works, Neemuch- 458441 (M.P.).
2.	Method of selection	Two Stage Bidding System
3.	Technical and Financial bids requested separately	Yes, both in separately.
4.	Name of Assignment	Implementation of cGMP in GOAW, Neemuch.
5.	Amount of EMD to be submitted with bid	Rs. 2,70,000/- (Rs. two lacks seventy thousand only) in the form of D.D. in favour of "ACAO, Govt. Opium & Alkaloid Works", payable at Neemuch (M.P.)
6.	Description of assignment/scope	Kindly refer to scope of work
7.	Contact person (Chairman of CEC)	(i) M.K. Kishore, Chemical Engineer, GOAW, Neemuch-458441, MP. Ph. 9893131371.& 07423 220199
8.	Period of contract	As mentioned in EOI cum RFP
9.	Validity of proposal	Proposal must remain valid for 120 calendar days from the date of submission of the proposal
10.	Mail ID to which any queries is to be sent	gmgoaw-nmh@gov.in
11.	Commencement of Assignment	The Assignment shall commence within 15 days of issue of LOA as referred to in clause 2.3 of the General conditions of agreement.
12.	Submission date of proposal	28-11-2023, 17.00HRS.
13.	Date and time of opening the Technical bid	30-11-2023, 11.00 A.M
14.	Date and time of opening the Financial bid	Will be communicated in due course of time
15.	Other Documents to be attached	These are mentioned in the Prequalification criteria and elsewhere in this EOI cum RFP.
16.	Place of submission	The General Manager, Govt. Opium & Alkaloid Works, Neemuch- 458441 (MP.).
17.	Date of pre-bid meeting	16-11-2023, 11.00 A.M

ANNEXURE – I

Evaluation Criteria of Technical Proposal

Sr No	Item	Criteria/ Mark	Max Mark
1.0	Technical Experience of Consultant		
	1.1. Number of years' (Format TECH-1)		
	3 years and above but less than 5 years' experience	08	10
	5 years and above but less than 7 years' experience	09	
	7 years and above experience	10	
	1.2. Number of Projects i.e. Established GMP-compliant facility of having Project cost equivalent to Rs.54.5 Lakh X1 Work OR Rs.34 Lakh X 2 Work OR Rs.27.5 Lakh X 3 Works in the last 7years with recommendation letter		30
	One Project	20	
	Two Projects	25	
	Three or More Projects	30	
2.0	Financial Strength: Average Annual Turnover in Last Three years (2020-21, 2021-22 & 2022-23) – Financial statement i.e. Balance sheet and Profit & Loss Account certified by CA shall be submitted.		10
	Above Rs.55lakhs and Up to Rs. 65 lakhs	06	
	Above Rs.65 lakhs and Up to Rs. 75 lakhs	08	
	Above Rs. 75 lakhs	10	
3.0	In house Key Personnel as on date (Format TECH-3 & TECH-5)		
	2.1. Mechanical / HVAC Engineer – 1 No.		20
	Graduate / Diploma in Mechanical/Chemical /HVAC engineering with min 07 year experience	05	
	2.2. Team Leader/Specialist – 1 No.		
	Graduate/Diploma in Mechanical/ Electrical/ Chemical Engineering with min 07 year experience	06	
	2.3. Technical incharge – 1 No.		
	Graduatein Mechanical/Chemical/Pharmacy/ M.Sc or equivalent with min 7 year experience	05	
	2.4. QC/QA Personnel – 1 No.		
	Graduatein Chemical Engineering/B.Pharmacy/M.Pharmacy/ M.Scwith min 7 year experience	04	
4.0	Presentation- Consultant quality of executed works, company profile, methodology to complete the prospective work if assigned. (Tech-1 & Tech-2)		30
	* Technical knowledge and understanding of GMP Compliant Facility along with proven Facilities Design Expertise as per national and international regulatory requirements (WHO, USFDA, EUFDA) , (15M)		
	* Methodology to complete the work assignment as per given scope and taken approval from authorities i.e. GMPetc(15 M)		
TOTAL MARKS			100

The procurement entity will short list all the Consultant who secure the minimum required marks is 75.

SEAL & SIGN OF THE CONSULANT

SECTION 3

TECHNICAL PROPOSAL STANDARD FORMS

CONTENTS

FORM		TITLE
Annexure II	:	Format of Covering Letter
Form TECH-1	:	Major Works during last seven years
Form TECH-2	:	Approach paper on Methodology and Comments on TOR.
Form TECH-3	:	Composition of Team Personnel and Task Assignment.
Form TECH-4	:	Staffing Schedule
Form TECH-5	:	Curriculum Vitae (CV) format to be submitted with the proposal
Form TECH-6	:	Summary of information on proposed experts

ANNEXURE II

FORMAT OF COVER LETTER TO TECHNICAL PROPOSAL

(To be printed on letterhead of consultant)

To

Sir,

Subject: Engagement of consultant for implementation of cGMP as per Schedule M of Drugs and Cosmetics Act 1940, at Government Opium and Alkaloid Works (GOAW), Neemuch.

Regarding Technical Proposal

1. I/We the undersigned, offer to provide the consulting services of the above Project Ref. No. in accordance with your request for proposal dated []. I/We am/are hereby submitting my/our proposal, which includes this technical proposal, and a financial proposal sealed under separate envelopes. EMD furnished in the form of a demand draft from the [Name of the bank, branch] is also enclosed. The bid DD is valid up to [Date].
2. If negotiations are held during the period of validity of the proposal, i.e. before [Date], I/We undertake to negotiate on the basis of the proposed staff. My/Our proposal is binding upon me/us and subject to modifications resulting from contract negotiations.
3. I/We understand that you are not bound to accept any proposal you receive.

Yours faithfully,

Encls:

Signature.....

Full Name.....

Designation.....

Address.....

.....

(Authorized Representative)

FORM TECH-1

**MAJOR WORK PERFORMED DURING LAST SEVEN YEARS THAT BEST
ILLUSTRATES QUALIFICATIONS**

**Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch**

Please provide information on each reference assignment for which your organization was legally contracted as a corporate entity or as one of the major companies within a consortium.

Project Name:		Field of Professional Service Provided by your organization:	
Project Location:		Professional Staff Provided by your Consultancy: No. of Staff :	
Name of Employer:		No. of Person- Months:	
Start Date (Month/Year):	Completion Date: (Month/Year)	Approx. Value of Services: (Rs)	
Name of Associated Consultants (S), if any:		No. of Person-Months of Professional Staff Provided by Associated Consultant(S):	
Name of Senior Staff (Project Director/Coordinator, Team Leader) Involved and Functions Performed:			
Detailed Narrative Description of Project:			
Brief note on technical knowledge and understanding of GMP Compliant Facility along with proven Facilities Design Expertise as per national and international regulatory requirements (WHO, USFDA, EUFDA) Brief note on the same should include details of one or more projects and provide the proof of certification (any one from WHO/USFDA/EUFDA) and validation of the project completed (Work order and Performance certificate)			
Detailed Description of Actual Services Provided by your Company:			
Consultant's Name and signature of Authorized Representative:			

FORM TECH-2

APPROACH PAPER ON METHODOLOGY
PROPOSED FOR PERFORMING THE ASSIGNMENT AND COMMENTS ON TOR

Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch

S.No	Name of the consultant	Consultant understanding of TOR	Work plan & Methodology	Organization and staffing for the proposed assignment	Total marks awarded

Note: Understanding of TOR, Work plan and methodology, Organization and staffing are to be submitted in separate sheet.

FORM TECH-3

**COMPOSITION OF THE TEAM PERSONNEL AND THE TASK, WHICH WOULD BE
ASSIGNED TO EACH TEAM MEMBER**

**Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch**

(A) Office Based Experts

S.No.	Name	Position	Task Assigned
-------	------	----------	------------------

1.

2.

(B) Site Base Experts

S.No.	Name	Position	Task Assigned
-------	------	----------	------------------

1.

2.

FORM TECH-4

STAFFING SCHEDULE

**Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch**

Name of location	Position	Month												Total no. of days
1	2	3												4
		J	F	M	A	M	J	J	A	S	O	N	D	
Office														
Site														
	Total													

Note: In column no. 3 please fill number of Days to be spent at each site in each month.

FORM TECH-5

**CURRICULUM VITAE (CV) FORMAT TO BE SUBMITTED WITH THE PROPOSAL
ONE FOR EACH EXPERT (ONLY ONE CANDIDATE SHOULD BE NOMINATED FOR
EACH POSITION)**

**Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch**

1.	PROPOSED POSITION FOR THE PROJECT	:	
2	NAME	:	
3	DATE OF BIRTH	:	
4	NATIONALITY	:	
5	PERSONAL ADDRESS	:	
	TELEPHONE NO	:	
	FAX NO.	:	
	E-MAIL ADDRESS	:	
6.	EDUCATION (The years in which various qualification were obtained must be stated).	:	
7	OTHER TRAINING	:	
8	LANGUAGE & DEGREE OF PROFICIENCY (Indicate proficiency in speaking reading and writing of each language by excellent, good, fair or poor).	:	
9	MEMBERSHIP IN PROFESSIONAL BODIES	:	
10	Work Experience (Years) and relevant documentary evidences for same.	:	

FORM TECH-6

SUMMARY OF INFORMATION ON PROPOSED EXPERT

**Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch**

Family Name First Name	Proposed Position for The Project	Consultant (acronym)	Employment Status with Consultant (full time Regular staff or other)	Education /Degree (Year /Institution)	No. of years of relevant Project Experience	Ex-Govt. Staff (Yes/No.)	CV Signature (By Expert/By other)
Example R.Ramesh	Resident Engineer	ABC	Other	B.Tech/BE Engineering (1975/University XYZ)	20 yrs.	No.	By Expert.

SECTION-4

ANNEXURE III

FORMAT OF COVER LETTER TO FINANCIAL PROPOSAL

(To be printed on letterhead of consultant)

To:

Sir,

**Subject: Engagement of consultant for implementation of cGMP standards at
GOAW, Neemuch.**

Regarding Financial Proposal

1. I/We the undersigned, offer to provide consulting services for the above project Ref. No. _____ in accordance with your RFP dated [Date] and my/our proposal (technical and financial proposals). My/Our attached financial proposal is for the sum of [Amount in words and figures]. This amount is inclusive of all taxes, levies as per details given in form FIN-1. Our GST Registration No. is _____
2. My/Our financial proposal shall be binding upon me/us subject to the modifications resulting from Contract negotiations, up to expiration of the validity period of the proposal or the date extended by me/us i.e. [Date].
3. I/We certify that I/we have not engaged any Agents, nor I/we have paid any fee to any Agent for procuring this consulting service.
4. I/We understand that you are not bound to accept any proposal you receive.

Yours faithfully,

Signature.....

Full Name.....

Designation.....

Address.....

.....

(Authorized Representative)

Encls:

Format for financial proposal**Break up of phases & percentage of lump sum amount payable**

stage	Description of work	Payment in percentage	Amount payable in Rs.
Phase-1	Monitoring of shutdown work as mentioned in TOR	10	
Phase-2	FDA audit & Certification of Plant for cGMP, Schedule "M" on or before 31-03-2024	25	
Phase-3	Documentation, Preparation of specifications & Validation as mentioned in TOR.	30	
Phase-4	Training, batch trials & continuous six months support as mentioned in TOR.	35	

LUMP SUM CONSULTANCY FEES FOR ABOVE MENTIONED WORK:**Amount in Figures: Rs. -----****Amount in Words: Rs. -----****The above amount is inclusive of Tax and other levies, if any.****NOTE:**

- All necessary input information regarding process, quality control, PCL, stores, packing etc., shall be provided by GOAW, Neemuch to Consultant, so that the he can prepare the entire documentation.
- Consultant shall carry out all printing, binding and DTP work.
- All tender documents, and tender notice related to the works, (i.e. civil, electrical, mechanical etc.,) shall be prepared by the consultant. He shall also undertake the supervision of all the work till completion.
- All relevant office equipments like computers, printers, scanners, etc, required by the Consultant shall be arranged by him. No such facility shall be made available by GOAW, Neemuch.
- Payment shall be released only on approval of deliverables by the CMC.

Accepted
Signature of Bidder/Tenderer
With Seal, Signature, Date & Name

SECTION-5

TERMS OF REFERENCE (TOR) FOR ENGAGEMENT OF CONSULTANT FOR IMPLEMENTATION OF cGMP

1. 1 Introduction:

GOAW, Neemuch is engaged in production of various alkaloids namely Codeine phosphate, Nascopine, Thebine, etc. The manufacturing facility was setup in the year 1976. Its average turnover for the last three years is approximately Rs. 137 crores.

1.2 Purpose/Objective of the assignment:

Engagement of consultant for implementation of cGMP standards at GOAW, Neemuch as mentioned below:

- a) Project Planning, Monitoring and Supervision for implementation of cGMP standards in Alkaloid plant.
- b) Framing of guidelines, Standard Operating Procedures (SOP) and creation of Documentation, as per prescribed cGMP, USFDA, EUFDA, WHO-GMP norms and implementation thereof.
- c) Provide training to technical staff of GOAW, Neemuch in cGMP, operations, regulation, management & documentation as per prescribed professional norms in this regard.
- d) Any other related tasks but not limited to clauses (a) to (c) with respect to the project.

2. Implementation Arrangements:

- 2.1 The Consultant would be attached to Consultancy Monitoring Committee (CMC) of GOAW, Neemuch for coordination, reporting and payment purposes.
 - 2.2 The Consultant will (i) provide management advice to Consultancy Monitoring Committee on methodologies and procedures for cGMP implementation, (ii) prepare the Detailed Project Reports, works procurement, supervision of contract management and quality monitoring of works for the project.
 - 2.3 Status of all the activities entrusted to the Consultant would be reviewed through monthly meetings with CMC. Corrective actions as identified during such meetings would be required to be taken by the Consultant.
- 3.0 The consultant would be required to undertake cGMP work in the below mentioned areas at GOAW, Neemuch, M.P.**
- 3.1 (a) The GOAW, Neemuch Alkaloid plant is very old and commissioned in October 1976 and since its inception a number of changes have taken place in

the Drug Regulations. In its present form, the plant is not complying with the latest requirements of revised Schedule – M of the Drugs & Cosmetic Act & Rules. Accordingly Management of GOAW, Neemuch have completed Gap Analysis part that covered all the sections and sub sections mentioned in the Schedule –M (complete detailed report available with GOAW, Neemuch for your reference). However, consultant will undertake remaining part of Gap Analysis if any required for WHO-GMP, USFDA, EUFDA etc.

(b). The GOAW, Neemuch is going to take Alkaloid plant shut down work in the month of October 2023 for three months. In the shutdown new equipments/ machinery are being installed including AHU/HVAC. Details of shutdown work to be taken up are mentioned in Annexure-IV. Consultant to monitor shutdown work with respect to GMP compliance especially of HVAC/Clean room/classified area for finished products.

(c) All other civil work and other installations related to cGMP etc during the contract period if undertaken by GOAW would be monitored, implemented and validated by Consultant.

3.2 Following other works of GMP to be undertaken by the consultant:

a) Documentation

The consultant is required to provide complete GMP documentation including BMR/SOP/SMF etc. for each product and also provide detailed guidelines for obtaining certification from international agencies in US, UK, Europe etc.

b) Training:

The Consultant shall provide (i) formal and (ii) on the job training to GOAW, Neemuch staff. Formal training shall take the form of (i) briefings held on site at of each processing section to ensure that all employees working on each section understand their respective roles and responsibilities and (ii) one day workshops on a monthly basis in respect of all items of work covered under this project or as instructed by the CMC that seeks to address common weaknesses noted over the intervening period. Such training shall be dovetailed with other training programmes being provided by GOAW, Neemuch with particular emphasis on the checklists required to be followed. During their regular reviews, the Consultant is expected to provide on the job training on aspects such as use of checklists, performing various construction operations, setting-out of the works, quality control procedures, safety and environmental management, good contract management practices and other aspects as the implementation of cGMP dictate.

It is expected that available staff of the Consultant would be in a position to provide required level of training. However, training on some of the specialized item(s), activities could be either provided by experts from the Head Quarter of the Consultant or could be outsourced. In such cases the Consultant is required to obtain approval of the CMC in regard to the CV of the experts proposed to be deputed. Thus, the scope under this activity comprises:

(a) Prepare training need assessment of all employees and the training plan.

b) Based on the approved training plan, provide periodic on-the-job training for the employees.

c) Specifications:

All detailed specifications/ engineering drawings/designs etc related to Civil work, mechanical, electrical, fire system, utilities, Quality Control, instrumentation etc as per cGMP, USFDA, EUFDA, WHO-GMP etc to be prepared and tender documents for same be submitted to CMC.

d) Validation assistance:

1. The consultant shall help the shutdown contractor to prepare of DQ, IQ, OQ and PQ protocols for validation of entire clean room/HVAC system cGMP requirement (US-GMP, EU-GMP & Etc.).

2. Overseeing validation by contractor and third-party validation of the clean room/HVAC system as per cGMP requirements (US FDA, EUFDA & Etc.).

3. Validation sign-off.

f) Certification:

The consultant would be required to obtain compliance certificate for GOAW manufacturing facility for cGMP from the specified statutory bodies in the State.

FDA audit & Certification of Plant for Schedule "M" on or before 31-03-2024

g) Trial Batches:

After completion of modifications, up gradations and installation, consultant should provide technical guidelines to staff of GOAW, Neemuch to run three trial batches for each of the products manufactured in the plant.

h) Any other work related to compliance of cGMP, USFDA, EUFDA, WHO-GMP etc to be prepared and submitted to CMC.

i) Providing continuous support for six months after certification.

4. Staffing and Other Inputs:

4.1 The Consultant shall provide information about time duration as per Form TECH-4 against each expert as indicted in the Table below serially from 1 to 6. The time duration against each expert will be subject to change by a mutual agreement between the Consultant and GOAW.

Sl.No.	POSITION	RESPONSIBILITY
1.	Director/Project leader	Professional Degree (B.E., B.Tech., M.Sc., B.Pharm or equivalent) with at least 07 years experience in consultancy firm/corporation/ company as a Director and or chief consultant. He will look after all departments of organization. His work is to prepare concept designing of project and provide guideline to staff about implementation of project.
2.	Technical in charge	Professional Degree, (B.E., B.Tech., M.Sc., B.Pharm or equivalent) with at least 7 years experience. He shall work under director and follow instruction & guideline provided by him. He shall also prepare concept design, feasibility study, capacity designing, machinery selection, and installation and trial batches in Pharmaceutical plants.
3.	Quality Control/ Quality Assurance Person	Graduate in Chemical engineering/ B. Pharmacy, M.Sc. in Chemistry or equivalent, with at least 7 years experience in GMP certified Pharmaceutical Plant.
4.	Mechanical Engineer	Graduate/Diploma in Mechanical engineering, with at least 7 years experience. He will be responsible for all mechanical engineering related activities. He works on as per the direction given by director.

5. Facilities:

The Consultant will have to make his own arrangements for office, utilities, accommodation and transport and should include cost of all these elements in his financial bid.

6. Reports:

The Consultant will submit the following periodic reports, which will be submitted on the specific dates under the scope of work. Some of the reports would be in questionnaire form so that all required aspects are covered.

(a) Inception Report: To be submitted within three (3) weeks of the commencement of services. The report will be based on work and staffing schedules agreed during contract negotiations.

(b) Training need assessment of Engineers of the GOAW, Neemuch: The report would be based on interaction with the Engineers of the GOAW, Neemuch.

(c) Progress Report: Progress reports to be submitted by the consultant, the reports will summarize the activity wise work performed during the reported period identifying the problems encountered, and indicating the corrective action taken or recommended. The report will also summarize record of meetings with the CMC.

(d) Special Reports: Special Reports shall be prepared periodically covering:

- List of major shortcomings in field investigation, design and preparation of DPRs
- Development of specification for use of locally available material
- Procedures and methodologies regarding Contract Management, 1st tier quality Plan, deployment of Plant & Machinery with reference to project implementation Schedule, Safety of works, personnel and general public.
- Annual Quality report based on reports of SQMs
- Model maintenance management plan.
- On any other issue covered in the TOR, if required by GOAW, Neemuch

(e) Project Completion Report: To be submitted upon completion of the service (Certification of plant for schedule compliance)

7. Un- satisfactory work:

The CMC of GOAW may conduct independent quality monitoring and checking of Work carried out by the Consultant. If such checks disclose that Work carried out by the Consultant do not meet the specified requirements, the GOAW, Neemuch will not pay the Consultant fees for the affected portion.

8. Completion period:

The consultant should complete the Work awarded to him after successful bidding as per the TOR at GOAW, Neemuch on or before 31-03-2024. Further Consultant will provide full support for 6 months period after certification. This period of support will include preparation of roadmap for WHO-GMP, USFDA and EUFDA. This excludes the time required for administrative and financial approvals for procurement of goods and services by GOAW, Neemuch.

9. Payment Schedule:

The payment will be made within 30 days after submission of bill with complete supporting documents and certified by CMC.

10. Exiting from the consultancy:

The GOAW, Neemuch reserves the right to exit or foreclose the agreement without assigning any reason. In such a case, only the amount payable up to the completed phase will be paid to the Consultant as decided by CMC.

GENERAL CONDITIONS OF AGREEMENT (GC)

1. GENERAL PROVISIONS

1.1 Definitions:

Unless the context otherwise requires, the following term whenever used in this Agreement have following meanings:

- **"Applicable Law"** means the laws and any other instruments having the force of law in the India
- **"GOAW"** means the Govt. Opium & Alkaloid Works, Neemuch (MP).
- **"Agreement"** means the Agreement signed by the Parties, together with all documents/Appendices attached hereto and includes all modifications made in term of the Provisions of Clause 2.6 hereof;
- **"Authorised Representatives"** is the person named in Clause 1.7 of GC to execute the agreement and administer the contract.
- **"Bank"** means any Scheduled or Institutional bank so designated by GOAW, Neemuch for their banking transactions relating to this agreement.
- **"Consultant"** means Corporation/Company/Firm engaged for carrying out of services under this agreement;
- **"Effective Date"** means the date on which this Agreement comes into force and effect pursuant to Clause 2.1 hereof;
- **"General Manager"** means [General Manager] of GOAW, Neemuch
- **"Personnel"** means persons hired by the Consultant as employees and assigned to the performance of the Services or any part thereof;
- **"Key personnel"** means the personnel referred to in Clause 4 hereof;
- **"Services"** means the work to be performed by the Consultant pursuant to this Agreement for the purposes of the project as per the Term of Reference (TOR) (Section 5 of EOI cum RFP);
- **"Starting Date"** means the date referred to in Clause 2.3 hereof.

1.2 Relation between the Parties:

Nothing contained herein shall be construed as establishing a relation of master and servant or of agent and principal as between GOAW, Neemuch and the Consultant. The Consultant, subject to this Agreement, have complete charge of Personnel and Sub-Consultant, if any, performing the Services and shall be fully responsible for the Services performed by them or on their behalf hereunder.

1.3. Law Governing the Agreement:

This Agreement, its meaning and interpretation, and the Applicable Law shall govern the relations between the Parties.

1.4. Language & Headings:

This Agreement has been executed in English, which shall be the binding and controlling language for all matters relating to the meaning or interpretation of this agreement. The Headings shall not limit, alter or affect the meaning of this Agreement.

1.5. Notices:

1.5.1 Any notice, request or consent required or permitted to be given or made pursuant to this Agreement shall be in writing. Any such notice, request or consent shall be deemed to have been given or made when delivered in person to an authorized representative of the Party to whom the communication is addressed, or when sent by registered mail, speed post, telegram or facsimile to such Party at the addresses specified hereunder: -

GOAW, Neemuch:

Name and Address to be given Attention: -----

Phone: -----

E-mail: -----

Fax: -----

Consultant:

Name and Address to be given Attention: -----

Phone: -----

E-mail: -----

Fax: -----

1.5.2 Notice will be deemed to be effective as follows:

The notice shall be deemed to be effective in the manner and at time as specified as follows:

- (a) In the case of personal delivery, speed post or registered mail, on delivery;
- (b) In the case of telegrams and facsimiles, 24 hours following confirmed transmission.

1.6 Location:

The services shall be performed at GOAW, Neemuch, Madhya Pradesh.

1.7 Authorized Representatives:

Any action required or permitted to be taken, and any document required or permitted to be executed under this Agreement by GOAW, Neemuch or the Consultant may be taken or executed by the officials as under:

GOAW, Neemuch:

Name and Address to be given Attention: -----

Phone: -----

E-mail: -----

Fax: -----

Consultant:

Name and Address to be given Attention: -----

Phone: -----

E-mail: -----

Fax: -----

1.8 Taxes and Duties:

The Consultant and the personnel shall pay the taxes, duties, fees, levies and other impositions levied under the existing, amended or enacted laws during the life of this Agreement.

1.9 The conditions shown in EOI cum RFP, Term of Reference, Technical and Financial Bids shall form part of this Agreement.

2. COMMENCEMENTS, COMPLETION AND MODIFICATION OF AGREEMENT**2.1 Effectiveness of Agreement:**

This agreement shall come into force and become effective on the date (the "Effective Date") of notice by GOAW, Neemuch to the Consultant instructing them to begin of the services.

2.2 Termination of Agreement for Failure to Become Effective:

If this Agreement has not become effective (within two months) after the agreement has been signed by the Parties, the GOAW, Neemuch or the Consultant may, by not less than 15 days written notice to the other Party, declare this Agreement to be null and void, and in the event of such a declaration by either party, neither Party shall have any claim against the other party with respect hereto.

2.3 Commencement of Services:

The Consultant shall begin carrying out the Services within 15 days after issue of LOA, i.e. Letter of Award/ work order.

2.4 Expiration of Agreement:

Unless terminated earlier pursuant to GC Clause 2.8 hereof, the Agreement shall expire when services have been completed and all payments have been made as laid down in FORM FIN-I after the 'Effective date' as shall be specified in this Agreement.

2.5 Liability of Parties:

This agreement contains all covenants, stipulations and provisions agreed by the parties. No agent or representative of either Party has authority to make, and the parties shall be not bound by or be liable for, any statement, representation, promise or agreement not set forth herein.

2.6 Modification:

Modifications of the terms and conditions of this agreement, including any modification of the scope of the services, may only be made by written agreement between the parties. Pursuant to Clause 7.2 of this agreement hereof, however, each Party shall give due consideration to any proposals for modification made by the other Party.

2.7 Force Majeure

On the occurrence of any unforeseen event, beyond the control of either Party, directly interfering with the delivery of Services arising during the currency of the contract, such as war, hostilities, acts of the public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes, lockouts, or acts of God, the affected Party shall, within a week from the

commencement thereof, notify the same in writing to the other Party with reasonable evidence thereof. Unless otherwise directed by the General Manager, GOAW, Neemuch in writing, the contractor shall continue to perform its obligations under the contract as far as reasonably practicable and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event. If the force majeure condition(s) mentioned above be in force for 90 days or more at any time, either party shall have the option to terminate the contract on expiry of 90 days of commencement of such force majeure by giving 14 days' notice to the other party in writing. In case of such termination, no damages shall be claimed by either party against the other, save and except those which had occurred under any other clause of this contract before such termination.

2.7.2 No Breach of Agreement:

The failure of a Party to fulfill any of its obligations hereunder shall not be considered to be a breach of or default under this agreement insofar as such inability arises from an event of Force Majeure, provided that the Party affected by such an event has taken all reasonable precautions, due and reasonable alternative measures, all with the objective of carrying out the terms and conditions of this agreement.

- a) A Party affected by an event of Force Majeure shall take all reasonable measures to remove such Party's inability to fulfill its obligations hereunder with a minimum of delay.
- b) A Party affected by an event of Force Majeure shall notify the other Party of such event as soon as possible, and in any event not later than fourteen (14) days following the occurrence of such event, providing evidence of the nature and cause of such event, and shall similarly give notice of the restoration of normal conditions as soon as possible.
- c) The Parties shall take all reasonable measures to minimize the consequences of any event of Force Majeure.

2.7.3 Consultation:

Not later than thirty (30) days after the Consultant, as the result of an event of Force Majeure, have become unable to perform a material portion of the Services, the Parties shall consult with each other with a view to agreeing on appropriate measures to be taken in the circumstances.

2.7.4 Extension of Time:

Any period within which a Party shall, pursuant to this Agreement, complete any action or task, shall be extended for a period equal to the time during which such party was unable to perform such action as a result of Force Majeure.

2.7.5 Termination:

During the period of their inability to perform the Services as a result of an event of Force Majeure. If the performance in whole or in the part or any obligation under this contract is prevented or delayed by any reason of force majeure for a period exceeding 90 days, either party may at its option terminate the contract without any financial repercussion on either side.

2.8 Suspension:

The GOAW, Neemuch by written notice of suspension to the Consultant, may suspend all payments to the Consultant hereunder, if the Consultant fail to perform any of their obligations under this Agreement, including the carrying out of the Services, provided that such notice of suspension (i) shall specify the nature of the failure and (ii) shall request the Consultant to remedy such failure within a period not exceeding fifteen (15) days after receipt of such notice of suspension by the Consultant. The GOAW, Neemuch, for any reasons beyond its reasonable control, may ask the consultant to suspend whole or part of the work/services for such time till the reasons are removed or settled. The extra time period of such duration shall be granted as time extension on the original terms and conditions.

3. OBLIGATIONS OF THE CONSULTANT

3.1 General

3.1.1 Standard of Performance:

The Consultant shall perform the services and carry out their obligations hereunder with all due diligence, efficiency and economy, in accordance with generally accepted professional techniques and practices, and shall observe sound management practices, and employ appropriate advanced technology and safe and effective equipment, machinery, materials and methods. The Consultant shall always act, in respect of any matter relating to this Agreement or to the Services, as faithful advisers to the GOAW, Neemuch, and shall at all times support and safeguard the GOAW, Neemuch's legitimate interests in any dealings with Sub-Consultant or Third Parties.

3.1.2 Law Governing Services:

The Consultant shall perform the Services in accordance with the Applicable Law and shall take all practicable steps to ensure that any Sub-Consultant, as well as any personnel of the Consultant and/or Sub-Consultant and agents, comply with the Applicable Law for the time being in force.

3.2 Conflict of Interests

3.2.1 Consultant not to benefit from Commissions discounts etc.:

The remuneration of the Consultant pursuant to Clause 5 of this Agreement hereof shall constitute the Consultant's sole remuneration in connection with this Agreement or the services and subject to Clause 3.2.2 of this Agreement hereof, the Consultant shall not accept for their own benefit any trade commission, discount or similar payment in connection with activities pursuant to this Agreement or to the Services or in the discharge of their obligations hereunder, and the Consultant shall use their best efforts to ensure that any of the Personnel and agents, or either of them, similarly shall not receive any such additional remuneration.

3.2.2 Procurement Rules of Funding Agencies:

If the Consultant, as part of the Services, have the responsibility of advising the GOAW, Neemuch on the procurement of goods, works or services, the Consultant shall comply with any applicable procurement guideline and shall at all times perform

such responsibility in the best interest of the GOAW, Neemuch. Any discounts or commissions obtained by the Consultant in the exercise of such procurement responsibility shall be for the account of the GOAW, Neemuch.

3.2.3 Consultant and Affiliates not to engage in certain activities:

The Consultant agree that, during the term of this agreement and after its termination, the Consultant and any entity affiliated with the Consultant, any entity affiliated with such Sub-Consultant, shall be disqualified from providing goods, works or services (other than the services and any continuation thereof) for any Project resulting to the Services.

3.2.4 Prohibition of Conflicting Activities:

The Consultant shall not engage and shall cause their personnel as well as Personnel of its affiliates, not to engage, either directly or indirectly in any business or professional activities which would conflict, with the activities assigned to them under this Agreement.

3.3 Confidentiality:

The Consultant, their sub-Consultant and the personnel of either of them shall not, either during the term or within two (2) years after the expiration of this Agreement, disclose any proprietary or confidential information relating to the project, the services, this agreement or the GOAW, Neemuch business or operations without the prior written consent of the GOAW, Neemuch.

3.4 Limitations of the Consultant's liability towards GOAW, Neemuch:

- (a) Except in case of gross negligence or willful misconduct on the part of the Consultant or on the part of any person or firm acting on behalf of the Consultant in carrying out of the services, the Consultant, with respect to the damage caused by the Consultant to the property of GOAW, Neemuch, shall not be liable to GOAW, Neemuch.
 - (i) For any indirect or consequential loss or damage, and
 - (ii) For any direct loss or damage that exceeds: (A) the total payments for services made and expected to be made to the Consultant hereunder; or (B) the proceeds Consultant may be entitled to receive from any insurance maintained by the Consultant to cover such a liability, whichever of (A) or (B) is higher.
- (b) The limitation of liability shall not affect the Consultant's liability, if any, for damage to third parties caused by the Consultant or person or firm acting on behalf of the Consultant in carrying out the services.

3.5 Documents Prepared by the Consultant to be the Property of the GOAW, Neemuch:

All plans, drawings, specifications, designs, reports, other documents and software prepared by the Consultant for GOAW, Neemuch under this agreement shall become and remain the property of GOAW, Neemuch. The Consultant shall, not later than termination or expiration of this Agreement, deliver all such documents etc. to the GOAW, Neemuch, together with a detailed inventory thereof. The Consultant may retain a copy of such documents and software.

3.6 Equipment and Materials furnished by the GOAW, Neemuch:

Equipment and materials made available to the Consultant by the GOAW, Neemuch or purchased by the Consultant with funds provided by the GOAW, Neemuch shall be the property of the GOAW, Neemuch and shall be marked accordingly. Upon termination or expiration of this agreement, the Consultant shall make available to the GOAW, Neemuch an inventory of such equipments and material and shall dispose of such equipments and materials in accordance with the directions of the CMC of GOAW, Neemuch. The Consultant, unless otherwise instructed by GOAW, Neemuch in writing, shall insure the equipment and materials them at the expense of GOAW, Neemuch in an amount equal to their replacement value.

4. CONSULTANT'S PERSONNEL AND SUBCONSULTANT

4.1 General:

The Consultant shall employ and provide such qualified and experienced Personnel and sub Consultant as are required to carry out the Services.

4.2 Description of Personnel:

- (a) The titles, agreed job descriptions, minimum qualifications and approximate period of engagement in carrying out of the Services of each of the Consultant's Key Personnel are described in Section 5, TOR.
- (b) If additional work is required beyond the scope of the Services specified in TOR, the estimated periods of engagement of Key Personnel set forth in TOR, may be increased by an Agreement in writing between the GOAW, Neemuch.

4.3 Removals and / or Replacement of Personnel:

- a) Except as the GOAW, Neemuch may otherwise agree, no changes shall be made in the Key Personnel. If for any reason beyond the reasonable control of the Consultant, it becomes necessary to replace any of the Personnel, the Consultant, shall forthwith provide as a replacement a person of equivalent or better qualifications acceptable to GOAW, Neemuch, such replaced person shall be inducted only after approval by the GOAW, Neemuch;
- b) If the GOAW, Neemuch (i) finds that any of the Personnel has committed serious misconduct or has been charged with having committed a criminal action, or (ii) has reasonable cause to be dissatisfied with the performance of any of the personnel, then the Consultant shall, at the GOAW, Neemuch's written request specifying the grounds thereof, forthwith provide as a replacement a person with qualifications and experience acceptable to the GOAW, Neemuch.
- c) Substitution of key personnel can be allowed in compelling or unavoidable situations only and the substitute shall be of equivalent or higher credentials. Such substitute may ordinary be limited to not more than 30% of total key personnel, subject to equally, or better, qualified and experienced personnel being provided to the satisfaction of procuring entity. Replacement of first 10% of key personnel will be subject to reduction of remuneration. The remuneration is to be reduced, say, by 5% of the remuneration which would have been paid to the original personnel, from the date of the replacement till completion of contract.

In case of next 10% replacement, the reduction in remuneration may be equal to 10% and for the third 10% replacement such reduction may be equal to 15%. In case such percentages are not relevant, or for some other practical considerations, for the particular contract, the procuring entity may formulate a suitable mechanism following the above logic, which should be specified in the tender documents.

4.4 Team Leader:

The Consultant shall ensure that at all times during the Consultant performance of the Services, under this agreement, a Team leader in the Project, acceptable to the GOAW, Neemuch, shall take charge of the performance of such services.

5. PAYMENTS TO THE CONSULTANT:

The payment will be made on submission of Invoice in triplicate addressed to General Manager in the following manner.

5.1 Breakup of phases & percentage of lump sum amount payable

stage	Description of work	Payment in percentage	Amount payable in Rs.
Phase-1	Monitoring of shutdown work as mentioned in TOR	10	
Phase-2	FDA audit & Certification of Plant for cGMP, Schedule "M" on or before 31-03-2024	25	
Phase-3	Documentation, Preparation of specifications, Validation as mentioned in TOR.	30	
Phase-4	Training, batch trials & continuous six months support as mentioned in TOR.	35	

No advance/mobilization advance payment on any account shall be made.

5.2 Currency of Payment:

All payments under this Agreement shall be made by PFMS.

6. INTEGRITY PACT (IP):

The pre-bid integrity pact is binds both buyers and sellers to ethical conduct and transparency in all activities from pre selection of bidders, bidding and contracting, implementation, completion and operation related to the contract. This removes insecurity of bidders, that while they themselves may abjure bribery. It depends on the nature of procurements/contracts above a threshold value. The nature of procurement and threshold of value is to be decided by the GOAW. As guidance, the threshold should be such as to cover bulk (80-90%) of its procurement expenditure.

All pages of the integrity pact are to be returned by the bidder (Along with the technical bid) duly signed by the same signatory who signed the bid. Any bid not accompanied by integrity pact duly signed by the bidder shall be considered to be a non-responsive bid and shall be rejected straightway.

7. FAIRNESS AND GOOD FAITH

7.1. Good Faith: The Parties undertake to act in good faith with respect to each other's rights under this Agreement and to adopt all reasonable measures to ensure the realization of the objectives of this Agreement.

7.2. Operation of the Agreement:

The Parties recognize that it is impractical in this Agreement to provide for every contingency which may arise during the life of the Agreement, and the Parties hereby agree that it is their intention that this Agreement shall operate fairly between them, and without detriment to the interest of either of them and that if during the term of this Agreement either Party believes that this Agreement is operating unfairly, the Parties will use their best efforts to agree on such action as may be necessary to remove the cause or causes of such unfairness, but on failure to agree on any action pursuant to this Clause shall give rise to a dispute subject to arbitration in accordance with GC Clause 7 hereof.

8. SETTLEMENT OF DISPUTES

8.1. Amicable Settlement:

The Parties shall use their best efforts to settle amicably all disputes arising out of or in connection with this agreement or the interpretation thereof.

8.2 Dispute Settlement:

Any dispute between the GOAW, Neemuch and the Consultant as to matters arising pursuant to this agreement, which cannot be settled amicably within thirty (30) days after receipt, by one Party of the other Party's request for such amicable settlement may be submitted by either Party for settlement in accordance with the provisions specified in Clause 7.2 hereof.

8.3 If any dispute or difference of any kind whatsoever shall arise in connection with or out of this Contract and which is not amicably settled between Consultant and the GOAW, Neemuch as per provisions of Clause 7.2 of the agreement the same shall be referred for settlement to the Adjudicator in the person of Chief Controller of Factories, GOAF, New Delhi, within 14 days of arising of such disputes. The Adjudicator shall give a decision in writing within 28 days of receipt of a notification of dispute. Performance under the Contract shall continue notwithstanding the reference to the Adjudicator.

8.4 A Party not satisfied with the decision of the Adjudicator shall be free to refer the case for arbitration under the provisions of The Arbitration and Reconciliation Act 1996 within 30 days. If neither Party prefers the dispute to Arbitration within the above 30 days, the Adjudicator's decision will be final and binding.

8.5 Except where the decision has become final, binding and conclusive in terms of sub Clause 7.2, the disputes or differences shall be referred for Adjudication through arbitration by a sole Arbitrator appointed by the Ministry of Finance, Department of Revenue.

8.6 It is the term of this contract that the Party invoking arbitration shall give a list of disputes with amounts claimed in respect of each such dispute along with notice for the appointment of Arbitrator and giving reference to the rejection by the Adjudicator.

8.7 The cost and expenses of arbitration proceedings shall be paid as determined by the Arbitrator.

9. JURISDICTION

The Agreement has been entered into at Neemuch, (MP.) and its validity, construction, interpretation & legal effects shall be to the exclusive jurisdiction of the courts of Neemuch, (MP). No other jurisdiction shall be applicable.

10. STANDARD OF ETHICS

GOAW, Neemuch may reject a proposal for award of contract, if it determines that the consultant recommended for award has engaged in corrupt or fraudulent activities in competing for the contract in question. GOAW, Neemuch may declare a consultant ineligible either indefinitely or for any stated period of time, to be awarded a Government contract if it at any time determines that the consultant has engaged in corrupt or fraudulent practices in competing for, or in executing the contract.

11. LIQUIDATED DAMAGES: In case of delay in consultancy and/or completion of work as per work order, you will be liable for liquidated damage @ 2% of value of the work order per month subject to maximum 5% of the contract value.

12. MISCELLANEOUS:

In any arbitration proceeding hereunder:

- (a) Proceedings shall, unless otherwise agreed by the Parties, be held in Neemuch (M.P.), where the dispute arises
- (b) English language shall be the official language for all purposes; and
- (c) The decision of the arbitrator shall be final and shall be enforceable in any court of competent jurisdiction, and the Parties hereby waive any objections to or claims of immunity in respect of such enforcement.

Annexure-IV

The details some of the machinery, which are proposed to be repaired/ replaced / upgraded in upcoming shutdown work are as under.

1. Centrifuge and it's piping system (GMP model) :- Installation of centrifuge for codeine phosphate.
2. S.S. tray dryers and it's ducting system (GMP model) :- Replacement of 02 nos. of 25 tray dryers, GMP model, with new 02 nos. of 50 tray dryers, GMP model capacity at NCT section. The 25 tray dryers shall be shifted and utilized at S.C. section & SRM section, to dry codeine & S.R. Morphine.
3. S.S. Ribbon Blender, (GMP Model) :- New equipment to be placed and utilized at NCT and VAP sections to blend Nascopine, Thebine and Pholcodine/Morphine sulphate.
4. S.S. 316 welding for the extractors :- The S.S. 316 extractor and their multiple weld joints at inner side of the vessels were weakened. Hence all the extractors i.e. 35 Nos. (SRM, NCT, and SC sections) and their multiple weld joints are to be re – welded with S.S. 316 welding.
5. Cooling tower (New) :- Removal of the existing old corroded/depleted timber cooling tower (1975) & Design, supply, installation, testing & commissioning of new induced draft, double cross flow type cooling tower pultruded FRP structure. Cap of the water pump 40 H.P. filed erected with necessary pipe & fittings.
6. Chilling unit (New) :- Present chilled water unit is not sufficient to cool opium broth solution to bring down 14 C , large chilled plant of capacity of 30 to 35 TR is required for present and future requirement.
7. Unit for manufacturing of synthetic codeine:- This is a new system and it is a extra facility to meet the production targets, and this system will be used at S.C. section to process synthetic codeine from semi refined Morphine. And this system is essential to install as the charging of opium batches will increase in near future, and in turn excess production of semi refined Morphine (SRM) and to process this excess SRM in to synthetic Codeine and converting into final drug of Codeine Phosphate.
8. Installation of Evaporator in NCT Section:- This is a new system, similar to existing Evaporator at NCT section, as the opium batches are increase in near future, in turn there will be increase in volumes of process liquids, which are required to be processed to recover the solvents.
9. Crystallizer: Production of codeine phosphate is increased; due to this one more chiller is required.

10. Alcohol Distillation unit: Existing distillation unit is not functioning since long time, Removal of old system and installation of new distillation unit is required.

Some other equipment, lines and etc replacement/ repair/installation are carried out in upcoming shutdown work to be monitored by Consultant.

11. Air handling unit(AHU) and related civil works :

Air handling system installation as per cGMP/USFDA/EUFDA norms including civil related works for Alkaloid finished products (04 numbers) i.e. Codeine Phosphate, Nascopine, Thebaine, Morphine Sulphate / Phalcodeine in recirculation type AHU for unclassified area. All specification for AHU and related civil works specifications are available with GOAW, Neemuch for further reference. Consultant to be monitored and validated along with shutdown contractor for AHU work, like pre filter, CHW type cooling coil, blower, bleed filter Sections, Drain piping, duct moulded heaters, Electrical and instrumentation work clean room flush metal doors and etc along with civil construction work.