

भारत सरकार
वित्त मंत्रालय
राजस्व विभाग
कार्यालय महाप्रबन्धक,
शासकीय अफीम एवं क्षारोद कारखाना
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.)

टेलिफोन Telephone : 07423-220199

ई-मेल

Email

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F.No. PM/GMP/CERT/2017-18

Date : 20.12.2017

INVITING EXPRESSION OF INTEREST (EOI).

Implementation of cGMP Description:

"Expression of Interest" is invited from renowned consultants within India for providing consultancy to undertake design, supervision and implementation of cGMP as per schedule "M" of Drugs & Cosmetics Act, at Govt. Opium and Alkaloid Works (GOAW), Neemuch, M.P. and Govt. Opium & Alkaloid Works, Gipazipur, U.P. having the required expertise and experience. The details regarding the scope of work etc. details in Annexure - I and are placed alongside with this notice in the website www.goaf.gov.in and also in CPP portal (www.eprocure.gov.in) Interested and eligible consultants (Corporation/Company/Firm) may submit their "EOI" with all relevant details and supporting documents as mentioned in the Annexure - I on or before 19-01-2018 to the General Manager, Govt. Opium & Alkaloid Works, Neemuch-458 441 (M.P.). E-Mail: gmopiumnmh@dataone.in. For any queries Shri. V.G. Darbha (Production Manager) may be contacted on Tel. No. 07423-220604, M-9479884179

o/c

General Manager
Govt. Opium and Alkaloid Works
Neemuch (M.P.)

**INVITATION OF EXPRESSION OF INTEREST (EOI) FOR
ENGAGEMENT OF CONSULTANT FOR IMPLICATION OF CGMP
EXPRESSION OF INTEREST (EOI)**

I) Invitation of EOI :

(I) The General Manager, GOAW, Neemuch (M.P.) invites renowned and experienced cGMP consultants for providing consultancy for the implementation of cGMP standards as prescribed under the Drugs and Cosmetics Act, at their existing manufacturing facility GOAW,Neemuch-458441(M.P.) and Govt. Opium & Alkaloid Works, Ghazipur, U.P.

(ii) GOAW, Neemuch is engaged in production of various Alkaloids namely Codeine Phosphate, Noscopine, Thebaine, Pholcodine and Papavarine. The manufacturing facility was setup in the year 1976 with a production capacity of approximately 18.00MT of Alkaloids. Its average turnover per year, for the last three years, is approximately Rs. 100 crores.

(iii) Govt. Opium & Alkaloid Works, Ghazipur, UP is engaged in production of various alkaloids namely Codeine phosphate, Noscopine, Thebaine etc., IMO Powder and IMO Cake.

(iv) Consultant means any corporation/company/firm but does not include any individual and provides professional services for implementation of cGMP as per the prescribed standards under the drugs and cosmetics Act.

(V) Works means Govt. opium and Alkaloid Works (GOAW), Neemuch and Govt. Opium & Alkaloid Works, Ghazipur, U.P.

II) Objectives and scope of work:

a Project Planning & Management for implementation of cGMP standards in Alkaloid Plant, which includes design for civil, Electrical, Mechanical, Heating, Ventilation and Air conditioning Utilities, Effluent Management, Environment Safety supervision, planning of work etc., and regulatory provisions applicable to the Alkaloid plant in coordination with Consultancy Monitoring Committee of the GOAW, Neemuch and Govt. Opium & Alkaloid Works, Ghazipur,(U.P)

b. Framing of guidelines and Standard Operating Procedures (SOP) and creation of Documentation as per prescribed cGMP norms and implementation thereof.

- c. Provide training to technical staff of GOAW, Neemuch and GOAW, Ghazipur 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.

III) Place of Execution:

The place of execution/work will be GOAW, Neemuch, Madhya Pradesh. (Neemuch is located on Nasirabad Mhow high way, 56 km from chittorgarh, 133 km from Udaipur) and Govt. Opium & Alkaloid Works, Ghazipur (U.P) (Ghazipur is located about 150 km from Varanasi, U.P.)

IV) Instruction to Consultant:

a. Nature of job:

The consultant is expected to provide professional services concerning cGMP norms as per the prevalent standards. The nature of the job for the consultant is to assist/guide the GOAW in identifying the areas of cGMP implementation at GOAW, Neemuch and Govt. Opium & Alkaloid Works, Ghazipur, (U.P) and includes all items of work covered in para (II) of EOI,

b. Submission Requirements:

The proposal to be submitted should contain details of experience of the consultant, number of assignments, financial turnover, etc. as detailed in pre qualification criteria in para (V) of EOI.

c. Last date of submission:

Eligible consultants are requested to submit their offer/proposals on or before 19.01.2018 at the following address.

**General Manager,
Govt. Opium & Alkaloid Works,
Neemuch-458441 (Madhya Pradesh)
Phone No. 07423-220199**

V) Pre qualification criteria:

- a. The consultant should have undertaken cGMP projects pertaining to pharmaceutical for at least three years indicating number of assignments handled by them successfully similar to the areas mentioned in the scope of work of EOI para (II)
- b. They have to submit Statement of Financial turnover for last three years supported with Annual Financial reports.
- c. The key personnel of the consultant must possess minimum level of professional qualification required for implementation of cGMP standards (i.e. BE, B.Tech, M.Sc, M. Pharma or equivalent).

d. The professionals (Key personnels) must have minimum three years of experience in the field of implementation of cGMP as per Schedule-M of Drugs & Cosmetics Act or similar to the scope of work mentioned in EOI.

e. A write – up on the understanding of the assignment.

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

- VI) A brief write up on cGMP related work which was carried out previously for GOAW, Neemuch, (M.P) and remaining work to be done by Consultant are enclosed in Annexure-II.
- VII) Format for evaluation sheet for selection of consultant on criteria specified as per EOI is enclosed in Annexure-III.
- VIII) Only short listed consultants will be issued Request For Proposal document (RFP) with an invitation to submit Technical and Financial Bid.

General Manager
Govt. Opium & Alkaloid Works,
Neemuch-458441(.M.P.)

1) The following area related to cGMP work already carried out in respect of GOAW, Neemuch (M.P)

GAP ANALYSIS:

The plant is very old 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 'V' of the Drugs & Cosmetic Acts & Rules. Accordingly Gap Analysis part of GOAW, Neemuch have been completed that covered all the sections and sub sections mentioned in the Schedule 'M'. (Complete detailed report available with GOAW. Neemuch for your further reference.)

GMP Gap Analysis has been carried out for assessment of existing infrastructure improvements in the following areas.

- a. Man Power: The persons approved in the manufacturing license have retired and hence approval of new staff is to be taken immediately from Drug Controller. M.P. QA Unit to be established. Individuals working at present are familiar with GMP and training to be imparted.
- b. Building: A lot of modification is required in the building to include separate entry of individuals, proper Toilet system, dining system, change room, laundry facility, hand and feet wash etc.
- a Production Equipment: Most of the key equipments are good, some of equipments need replacement. Level indicators, temperature regulators also need replacement.
- d. QC Equipment: New equipments to be provided, fuming hood and Air Handling system need to be installed.
- e. Utilities: RO water system and Air Handling System to be installed.
- f. Documentation: Almost complete document system needs to be developed.
- g. Other area required: Waste disposable system, housekeeping system, Self Inspection system etc. to be established.

A lot of changes in respect of Building, Documentation, Hygiene, Sanitation, Quality Control Lab and Air Handling System are to be under taken in Gap Analysis.

Project cost estimation for implementation of above mentioned areas of cGMP and project implementation schedule parts also available with GOAW, Neemuch, M.P.

2) The Consultant would be required to undertake remaining GMP work in the below mentioned area at GOAW, Neemuch, M.P.

<u>(Preparatory)</u>	
01.	The consultant would be required to provide detailed information on up gradation required on various civil, mechanical, utilities, HVAC and electrical works in the production building and other requirements necessary for compliance to GMP norms. Some major activities to be carried out by the consultant are detailed below:
01A	<u>Civil work:</u> Preparation of Preliminary Plant layout & detailed Plant drawing as per actual requirement for GMP implication with complete civil details of addition and alteration work.
01B	<u>Mechanical:</u> Complete detailed design specifications and capacities of the machines as per gap analysis preparing quotations and submit source of reputed standards, drafting, short listing, preparation of tender documents for the procurement of same.
01C	<u>Utilities:</u> Prepare drawings and specifications for utilities, which are suitable for plant. Quotation for procurement of utilities like purified water system, WFI system, central vacuum system, dust extraction system, compressed air system, gas system, CIP system and SIP system.
01D	<u>Electrical:</u> Provide cable trays and power point drawings, light fixtures and smoke detector drawings, LAN & telephone detailed layout, earthing drawings, AHU Panels drawings and single line diagram of different area, Bill Of Quantity (BOQ)
01E	<u>HVAC (AHU) work:</u> Provide HVAC ducting drawings, AHU specification, chiller specification pressure gradient drawing, BOQ.

02.	<u>(Implementation)</u> The consultant would be required to exercise supervision over modification and up gradation to be carried out in different areas to ensure their proper execution in line with GMP norms.
02A	<u>Monitoring and Supervision of Civil, Electrical, Installation of machineries and utilities, AHU work Etc. as per details prepared in the above mentioned Preparatory.</u>
02B	Batch trial & Validation
02B ₁	3 Batch trials for each product.
02B ₂	Validation & Quality
02C	<u>Documentation</u>
02C ₁	The consultant is required to provide complete GMP documentation for each product and also provide detailed guidelines for obtaining certification from international agencies in US, UK, Europe etc. Complete documentation including BMR/SOP/SMF etc
03	<u>Certification</u> The consultant would be required to obtain compliance certificate for GOAW manufacturing facility for cGMP from the specified statutory bodies in the State.
03A	FDA audit & Certification of Plant for Schedule "M". Providing continuous support for three months after certification.

ANNEXURE-III

EVALUATION SHEET BASED ON CRITERIA SPECIFIED AS PER E01.

No.	Name of Consultant	Exp. in oGiv1P Projects.	Financial Turnover	Key persons Qualification	Key persons Experience	Understanding Assignment	Remarks of Members of c e c _ _
01							
02							
03							
04							
05							
06							
07							