



**TENDER DOCUMENT
FOR PROJECT MANAGEMENT SERVICES**

Tender
Document No.
GIA-14
Version -02

RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED

Road No. 12, V.K. I Area, Jaipur- 302013 (Rajasthan) India


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**TENDER
DOCUMENT FOR PROJECT
MANAGEMENT SERVICES**

**Tender No.GIA-014
Version-02
Date - 06-08-2013**

Tender cost Rs.500/-

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RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED
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TENDER FOR PROJECT MANAGEMENT SERVICES

Sealed tenders are invited for “PROJECT MANAGEMENT SERVICES”. Interested parties may obtain tender documents with scope of work and commercial terms and conditions from Manager (Materials) on any working day up to 24/08/2013 on payment of Rs. 500/- (Rs. Five Hundred only) in cash/ Demand draft in favor of “Rajasthan Drugs & Pharmaceuticals Ltd.” payable at Jaipur. Tender duly completed with requisite documents and earnest money of 10,000 /- (Ten Thousand only) as Demand draft in favor of “Rajasthan Drugs & Pharmaceuticals Ltd.” payable at Jaipur, must reach the undersigned up to 3 PM on 28.08.2013. The technical bid shall be opened at 4.00 PM on the same day in presence of representatives of the bidders if available. The date of opening of financial bid of the technically qualified bidders will be informed later on. The company reserves the rights to accept or reject any offer without assigning any reason. For further details, please visit our website: www.rdpl-india.in.

Factory Manager

Date – 06-08-2013

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Project Management Services (WHO-GMP/GLP Consultant)

RDPL requires a pharmaceutical PMS for their on-going project work conforming to WHO-cGMP/GLP guidelines. The scope of work & Terms and conditions are as under-

Eligibility Criteria :-

Pharmaceutical project management (PMS) shall have the following eligibility Criteria:-

A.PMS agency should have at least one person who shall be a graduate/ Post Graduate in pharmacy / post graduate in chemistry with 20 years of experience as a minimum in pharma field. He must have exposure of WHO-cGMP/GLP, MHRA,USFDA, ICH, ISO guidelines with good communication in Hindi & English. He should have proven expertise in the implementation & certification of WHO-cGMP/GLP projects. He shall work as a Project consultant for RDPL.

B.PMS agency should have experience of completing minimum five pharmaceuticals formulation projects up to certification as per WHO-cGMP/GLP standards in last five years.

C. He should submit the documentary evidence in support of above along with the technical bid.

SCOPE OF WORK :

I. Project Management:

- a. The PMS has to carry out conceptual study and gap analysis in the site of current WHO-cGMP/GLP guidelines.
- b. PMS has to give suggestions so that the project compiles with WHO-cGMP/GLP norms.

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c. PMS has to review & finalize the detailed engineering including P& I diagrams, GA drawings, capacity calculations etc. as required for the project work in coordination with architect , suppliers & other project agencies.

d.The PMS has to prepare and review the tenders. He has to provide necessary knowledge support & assistance for the procurement and installation of the equipment.

e.PMS has to review & finalize the DQ document and carry out the risk analysis as per WHO-cGMP/GLP & ICH guidelines.

f. PMS has to carry out the qualification, validation and calibration activities along with RDPL team.

g. The main thrust shall be given to complete the project in time by meticulous follow up taking up the documentation work simultaneously.

h. PMS will assist in constituting high level taskforce committee to take the stock of the progress made by the project team for the achievement of WHO cGMP certification & review on monthly basis.

i. Proposing minor changes if any in the layout suggested by the previous PMS with minimum cost to company etc.

j. PMS will be responsible for technical evaluation of the tenders, coordination of vendors & contractors making comparison of quotations received and present to management for decision with his expert opinions. He will be accountable for final execution of work with quality standards for WHO compliance of our pharmaceutical project.

k. PMS will prepare a project progress schedule with key milestones & he will prepare bar chart/PERT chart to monitor the project schedule.

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II. DOCUMENTATION:

The PMS has to carry out all types the documentation as per WHO-cGMP/GLP guidelines which includes –

- a. Standard Operating Procedures.
- b. Batch Manufacturing Records.
- c. Master Formula Records.
- d. Site Master File
- e. Stability study schedules, protocols & reports
- f. And any other document which is required to achieve WHO cGMP certification

III. VALIDATION / QUALIFICATION:

PMS has to prepare all type of document required for validation & qualification which includes plans, protocols, reports etc.

The agency shall also ensure the execution, review & approval of validation & qualification activities as per WHO cGMP/GLP requirements such as -

- a. Validation Master Plan.
- b. Qualification of equipment, Instruments & Utilities which includes
 - i. Design Qualification, risk analysis, Factory acceptance test (FAT), Site Acceptance Test (SAT).
 - ii. Installation Qualification.
 - iii. Operational Qualification.
 - iv. Performance Qualification.

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c. Analytical method validation

d. Process Validation.

e. Cleaning Validation

f. Software Validation.

g. Other validation related activities such as change control management, deviation control etc.

IV. GLP Implementation :- PMS has to do the gap analysis & propose the necessary inputs to achieve WHO-cGMP/GLP certification as per WHO guidelines.

V. QMS :- PMS has to define & assist in implementation of the QMS as per ICH, WHO-cGMP/GLP & ISO norms

VI. TRAINING :

The PMS has to define the job description, responsibility & authorities, review management and organisation structure and identify training needs in line of same. PMS has to prepare the training schedules, training procedures, training evaluation sheets etc. PMS will also assist in identifying the external agency if required for specialized training if needed, he will prepare the training program for the whole calendar year for the following :-

a. Class room training from Managers to Supervisors WHO - cGMP/GLP module.

b. Training of work man by officers and supervisors.

c. Training of senior managers and officers.

VII. Terms & Conditions:-

1. RDPL technical team may visit the plants where agency has provided such type of services to ascertain their capability. PMS shall arrange the visit of RDPL technical team for the same. RDPL may demand additional documentary evidence in support of the agency's claim.

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2. The PMS agency shall visit RDPL minimum five days in a month for the above scope of work as per the requirement of the job to achieve WHO cGMP/GLP.

3. **The time period of PMS shall be one year.** The time period may be extended with mutual consent of both the parties at the discretion of the management.

4. The agreement for the above work shall be executed on a Rs. 100/- Non judicial stamp paper for which the stamp duty shall be borne by the agency.

5. PMS has to make his own arrangement for boarding ,lodging , travelling & other requirements as per their convenience.

6. The PMS shall assist in filing application for WHO cGMP/GLP certification.

7. No sub-letting of services shall be permitted by the RDPL. Under any circumstances .The PMS shall not sublet the services however for any specialized work he may take services of experts at their own cost. PMS has to depute persons for the timely execution of work from their agency as & when required for the specific task.

8. Except with the prior written consent by the RDPL, the PMS and their representative shall not any time communicate to any person or entity any confidential information disclosed to them for the purpose of the services. The PMS shall not publicize any information pertaining to RDPL which is discussed with them during course of execution of work in the interest of project completion.

9. If the PMS fails to perform any of its obligations under this agreement and if RDPL is dissatisfied with the services of the PMS, RDPL may issue seven days written notice intimating the PMS of their failures or deficiencies and calling upon PMS to rectify within such time as may be specified in the notice and if the PMS fails to perform such obligation or make good such deficiencies as pointed out to the PMS in the notice, RDPL may terminate the services of PMS under this agreement.

10. RDPL may also terminate the PMS ' services hereunder if :

i) the firm is adjudged a bankrupt or

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ii)the firm make a general assignment for the benefit of their creditors or

iii)a receiver is appointed on account of their insolvency or

iv)They disregard law, ordinances, rules, regulations or orders of any public authority having jurisdiction on the works.

11. The termination shall be without prejudice to all rights, liabilities and remedies that have arisen or accrued till date of such termination or that may arise on account of termination and RDPL may get the project completed by whatever method they may deem expedient. In such case, the PMS shall not be entitled to receive any further payment, if due, until the loss damages or expense incurred by RDPL due to breach of this agreement by PMS have been settled by them.

12.In case the PMS abandons the work during the course of the project, the RDPL has the right to appoint an alternate PMS or make an arrangement for carrying out the work of PMS, at the risk and cost of the PMS.

13.In case of any dispute or difference arising between the parties then in such an even the same shall be referred to Managing Director (RDPL) who shall be the sole Arbitrator for this contract & whose decision shall be binding on both the parties.

14.Any dispute arising out of this contract shall have jurisdiction in Jaipur courts only & not outside Jaipur.

15. Any statutory deduction as per Govt. rules shall be made from the bills of PMS agency. However, service tax shall be paid extra as applicable.

16.The above terms & conditions are only indicative & not exhaustive. An agreement on suitable stamp paper specifying the various terms & conditions of the contract shall be entered into between both the parties governing the PMS activities.

17. The security held in deposit shall be forfeited for the following reasons-

(i) Agency fails to enter into agreement within 15 days of award of work.

(ii) Agency fails to achieve completion of project including certification of WHO cGMP/ GLP

(iii) In case agency does comply the terms & conditions of the contract & the security held in deposit shall be forfeited.

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18. Payment terms:-

The interested parties may quote their own terms of payment clearly defining & giving breakups payment terms. However the same shall be finalized at the time of negotiation with mutual consent. 10% payment at each payment stage shall be deducted from agency as a security which shall be payable after successful completion of project including WHO cGMP/GLP certification.

19. **Earnest Money:-** An amount of Rs. 10000/- in the form of demand draft in favour of Rajasthan Drugs & Pharmaceuticals Ltd. Payable at Jaipur is to be deposited with the technical bid. EMD of unsuccessful bidders shall be refunded after one month from the date of opening the bid. The EMD of successful bidders shall be converted in to security deposit & shall be returned without any interest after completion of work. The bids submitted without EMD are liable to be rejected. The bids are to be submitted in two bid system-

20. Technical Bid :- It should carry the information required for the eligibility criteria.

1. It should carry the demand draft of EMD.
2. The envelope should be marked as ‘ Tender for PMS Technical due on 28-08-2013

21. Financial Bid :-it should carry the quoted rates with payment terms. The envelope should be marked as ‘ Tender for PMS Financial bid'


Both the technical & financial bid should be sealed in an envelope marked as ‘ **TENDER DOCUMENT FOR PROJECT MANAGEMENT SERVICES** due on 28.8.2013 .

22. Opening of the bid:- The bids can be submitted up to 3.00 PM on dated 28.8.2013 & Technical bid shall be opened. shall be openedat 4.00 PM dated 28.8.2013 . The selected bidders shall be imported the date of opening of the financial bid.

23.The deduction on account of PF, ESI, TDS of Income Tax, Services Tax and any others statutory liability as applicable shall be borne by the agency.

24.SETTLEMENT OF DISPUTE (ARBITRATION)

All disputes and differences of any kind whatever arising out of or in connection with the

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contract or the carrying out of the works, whether during the progress of the works or after their completion and whether before or after the determination or breach of the contract, shall be referred to INTERNATIONAL CENTRE FOR ALTERNATIVE DISPUTE RESOLUTION having its office at plot no.6 ,vasant kunj institutional area , phase –ii ,New Delhi-110070 and its decision/ award shall be binding on both the parties.

In case either party fails to accept the award of the arbitrator the other party may refer the matter to the court of law having jurisdiction at Jaipur only.