RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED
Road No. 12, V.K. I Area, Jaipur- 302013 (Rajasthan) India

REQUIRED PHARMACEUTICAL CONSULTANT

Applications are invited for "PHARMACEUTICAL CONSULTANT". The scope of work and terms and conditions are as follow. Interested candidate should apply through an application to the under signed and the application should reach at our office up to 09/12/2013 at 5.00 PM.

Factory Manager

Date – 25-11-2013

PHARMACEUTICAL CONSULTANT(WHO-GMP/GLP Consultant) required by RDPL

RDPL requires a Pharmaceutical consultant for their on-going project work to be compliant of WHO-cGMP/GLP standard / certification. The scope of work &Terms and conditions are as under-

Eligibility Criteria :-

Pharmaceutical consultant services (Pharmaceutical consultant) shall have the following eligibility criteria:-

1. Pharmaceutical consultant agency should be a Post Graduate in pharmacy / post graduate in chemistry with 10 years of experience in pharma field. The candidate must have exposure of WHO-cGMP/GLP, MHRA, guidelines with good communication in Hindi & English. The candidate should experience in the implementation & certification of WHO-cGMP/GLP projects. The candidate shall work as a Pharmaceutical consultant in RDPL for one year.

2. Performance to be given to a candidate who has residence in Jaipur.

SCOPE OF WORK:

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

II. PHARMACEUTICLAS CONSULTANT has to carry out the qualification, validation and calibration activities along with RDPL work force.

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

I. DOCUMENTATION:

The PHARMACEUTICAL CONSULTANT 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

II. VALIDATION / QUALIFICATION:

PHARMACEUTICAL CONSULTANT 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.

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.

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

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

V. TRAINING :

The PHARMACEUTICAL CONSULTANT has to define the job description, responsibility & authorities, review management and organisation structure and identify training needs in line of same. PHARMACEUTICAL CONSULTANT has to prepare the training schedules, training procedures, training evaluation sheets etc. 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. The PHARMACEUTICAL CONSULTANT shall visit in RDPL minimum 150 hours in a month for the above scope of work as per the requirement of the job to achieve WHO cGMP/GLP.

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

3. 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 consultant.

4. PHARMACEUTICAL CONSULTANT has to make his own arrangement for boarding ,lodging , travelling & other requirements as per their convenience.

5. The PHARMACEUTICAL CONSULTANT shall assist in filing application for WHO cGMP/ GLP certification, must be present during WHO-cGMP audits .

6. The PHARMACEUTICAL CONSULTANT shall not sublet the services however for any

specialized work he may take services of experts at their own cost.

7. Except with the prior written consent by the RDPL, the PHARMACEUTICAL CONSULTANT 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 PHARMACEUTICAL CONSULTANT 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.

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

9. The salary and payment conditions will be negotiable.