KERALA STATE DRUGS AND PHARMACEUTICALS LTD
(A Government of Kerala Enterprise)
KALAVOOR, ALAPPUZHA – 688 522, KERALA STATE, INDIA
Ph : 0477-2258184
Telefax : 0477-2258162
Email-ksdpltd@gmail.com
Website : www.ksdp.co.in

Request for Expression of Interest
Pharma Formulation Plant Consultancy.

We require Pharmaceutical Formulation Plant Consultant for the Modernisation /Diversification/GMP (Revised Schedule M) implementation Programme in our existing Formulation Facility.

Terms of Reference and other Details can be obtained from the company by E-mail/Fax and from Website.

The Consultancy Firm should have minimum 15 years experience in similar work and should have executed two individual Pharma Formulation Projects of 50 Crore or more.

The interested Firms may submit their E.O.I in two envelopes (Technical and Commercial) giving their company profile and experience including details of similar projects undertaken, to the undersigned on or before 22.09.2008.

28.08.2008 Sd/-
Alappuzha Managing Director

Pharma Formulation Plant Consultancy

Terms of Reference

The business plan is to modernize Kerala State Drugs and Pharmaceuticals Ltd (KSDP) by implementing Good Manufacturing Practices (GMP) also termed as Schedule M Standards under Drugs & Cosmetics Act and diversifying its operation by establishing a Separate Beta Lactum Plant. Implementation of Schedule M Standards will help to increase the production standards and performance by ensuring consistant and good quality medicines. KSDP plans for major investment for modernization to meet the industry standards. It is also essential to establish facilities for Quality Assurance & Control including equipments as per GMP Standards. Detailed plans are to be provided for implementing Modernisation to achieve GMP standards.

The scope of work would include to:

A. Prepare a Detailed Project report to modernize and redesign the existing manufacturing facility at KSDP to comply as per GMP (Revised Schedule M) requirement.

- The service would include Preparation of Detailed layouts for restructuring and redesigning the existing Production facilities to establish separate Plants for Beta Lactum Products, non-Beta Lactum Products, Veterinary Products, Quality Control, Quality Assurance and Store Departments.

- In Beta Lactum Products, Tablets – 1 unit, Capsules – 1 Unit, Dry Syrup – 1 Unit are proposed to be set up.

- In Non Beta Lactum Products, Tablet Section – 2 Units, Capsule Section – 1 Unit, Oral Liquid Section – 1 Unit, Large Volume Parenteral – 1 Unit, Small Volume Parenteral – 1 Unit, Dry Powder – 1 Unit are proposed to be set up.

- In Veterinary Plant Tablets, Capsules and Liquids are proposed to be manufactured using the existing machineries after relocating them.

- Plant layout and Equipment layout with detailed drawings with Civil/Electrical/HVAC work estimates, according to site conditions, for these departments to be prepared as per GMP requirement.

- The service would also include fixing specifications for machineries and utilities required for these departments, PERT, CPM and work Flow Chart of Scheduled activities.

B. Supervise Erection and Commissioning as per the Detailed Project report.

C. Also service is required for the following:

(i) Preparation of Site Master File, Validation system, Documentation, SOP, QA Systems, Master Formula Cards etc.

(ii) Preparation of IQ (Design and Installation qualification) for Rooms, Buildings, HVAC, Light Electrification, utilities etc.

(iii) Give guidance to Quality Control Department in Testing of Raw materials/Finished Goods for latest GLP standards.

(iv) Advise the Production team on new cost effective methods for manufacture of formulations.

(v) Help KSDP to implement Good Ware House Practice.

(vi) Help in coordinating inspections by CDC/Drugs controller and also to assist in obtaining Drug Licence.

In short, the service should cover all aspects relating to implementation, Trial run and successful completion of the proposed scheme as envisaged in the detailed Project Report.

- Commercial : Charges for works detailed in A, B, C Parts may separately be given.

- Schedule:

Part – A. Submission of Detailed Project Report: Oct. 30, 2008.
Part – B & C: Completion of Project : Oct. 30, 2009.