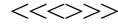


Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulation & Coordination



REQUEST FOR EXPRESSION OF INTEREST (EOI)
[For Hiring Individual Consultant]

Drug Regulatory Authority of Pakistan (DRAP), established under DRAP Act, 2012 to provide for effective coordination and enforcement of The Drugs Act 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods, invites Expression Of Interest (EOI) from the consultants, who are on Active Taxpayers List of the Federal Board of Revenue for provision of consultancy to bring improvement in the regulatory framework of Drug Regulatory Authority of Pakistan (DRAP), Islamabad and align it with the international best practices. Method of selection will be Least Cost.

2. Expression of Interest documents, containing scope of work, instructions to bidders and qualification criteria can be obtained from the office of undersigned located at DRAP Headquarters, First Floor, T.F. Complex, 7-Mauve Area, G-9/4, Islamabad during office hours on payment of Rs.5000/- through pay order in favour of Drug Regulatory Authority of Pakistan, Islamabad as non-refundable tender document fee for each set. Scope of work can be downloaded from DRAP website www.dra.gov.pk.

3. The proposals prepared in accordance with the instructions in the EOI documents should reach the office of undersigned by **Oct 28, 2019** at **11:30 AM**. The proposals will be opened on the same day at **12:00 PM**. This advertisement is also available at DRAP & PPRA websites www.dra.gov.pk & www.ppra.org.pk.

(ASMAT ULLAH)
Assistant Director (Admn-II)
Ph. 051-9107307

SCOPE OF WORK FOR CONSULTANT

i. REGULATORY HARMONIZATION

The consultant will review existing rules and regulations and prepare recommendations for harmonization of rules and regulations with international best practices including/requiring amendments in existing rules governing therapeutic good's enlistment, licensing, registration, inspection, market surveillance and pharmacovigilance.

ii. STRENGTHENING OF QUALITY ASSURANCE AND LICENSING

The consultant will be required to review the existing Licensing, Quality Assurance and Laboratory Testing (QA<) system with special focus on inspection, enforcement & compliance. Consultant shall prepare a work plan with timeline to improve the system in line with the International Standards. This will enhance the access to quality therapeutic goods and will create a positive impact on export of pharmaceuticals in Pakistan.

iii. DEVELOPMENT OF POLICY GUIDELINES & PROCEDURES

The consultant will assist in the development of comprehensive guidelines on various subjects particularly for Clinical Trials, Bio-Availability & Active Pharmaceutical Ingredients (APIs).

iv. DRAP MEMBERSHIP OF PHARMACEUTICAL INSPECTION COOPERATION SCHEME

DRAP has applied for PIC/S Pre-accession on 18th September, 2017 and application was completed on 12th February, 2018, which is a landmark achievement. DRAP has paid annual membership fee for PIC/S. For pre accession of PIC/s, targeted timeline is December, 2019 subject to audit of PIC/s Experts. The consultant will prepare a strategic pathway to meet all the requirements of PIC/S membership. This activity may require analysis of current organizational structure, re-structuring of inspectorate, streamlining of the inspection activities with PIC/S guidelines, preparation of implementation plan, monitoring and evaluation plan, risk assessment by identification of hurdles and impediments to be addressed.

v. FACILITATION OF EXPORT

The consultant will develop a comprehensive framework outlining key strategies for DRAP as well as for industry to enhance exports of therapeutic goods including capacity building of regulator and therapeutic goods industry.

vi. INTERNATIONAL COOPERATION

Consultant shall assist DRAP in preparing a roadmap for signing Memorandum of Understanding (MoU) with stringent regulatory authorities and bodies in order to achieve International Cooperation, particularly in the area of GMP Compliance, Market Authorization of therapeutic goods, and sharing of regulatory information.

vii. COST RECOVERY & USER FEE

Consultant will be required to prepare a framework to strengthen the cost recovery & user fee programs of DRAP in a systematic manner based on budget and performance standards.

viii. NRA LEVEL III ATTAINMENT

DRAP is currently working to attain maturity level III in WHO NRA Global Benchmarking tool, which is considered as a baseline for stringent regulatory authorities. DRAP has successfully submitted revised WHO Global Benchmarking Self-Assessment Tool. During this self-assessment, strengths and areas for improvement were identified. A number of guidelines, SOPs and databases were pointed out during the initial assessment to build upon strengths, address the identified gaps and to attain WHO level III. In this regard, 288 Institutional Development plans have been identified. In this context, WHO has intimated to conduct an audit of DRAP in September, 2019. Consultant will be required for completion of identified IDPs including but not limited to development of guidelines, SOPs and databases, etc.

ix. IMPLEMENTATION OF QMS

It is aim of Authority to implement internationally recognized standards, facilitate advancement and up gradation to meet international standards. In this prospect, Quality Management System (QMS) is under process of establishment and implementation. It is also an integral part of level III compliance in WHO Global benchmarking of National Regulatory Authorities. The QMS Cell / Section has been

established and implementation is under process, which covers all 13 Divisions of DRAP along with field offices. Consultant will be required to strengthen the QMS in Drug Regulatory Authority of Pakistan and provide a roadmap for continual improvement.

- x. Any other task as may be assigned by DRAP
