



National Medicines Regulatory Authority

Procurement of two Individual Consultant for technical activities of National Medicines Quality Assurance Laboratory (NMQAL) of the National Medicines Regulatory Authority (NMRA).

Contract Name : Obtaining Consultant Services for technical activities of NMQAL.

The National Medicines Regulatory Authority (NMRA), is an independent authority in the Ministry of Health which plays a leading role in protecting and improving public health by ensuring medicinal products available in the country meet applicable standards of safety, quality and efficacy. The Authority regulates medicines, medical devices, borderline products, clinical trials and cosmetics.

National Medicines Quality Assurance Laboratory (NMQAL) functions under the purview of the NMRA which provides the technical support needed to operate the quality assurance system on Medicines, Medical Devices, Borderline products and Cosmetics. The primary function of the NMQAL is to conduct laboratory tests necessary for determining compliance with product quality, safety and efficacy.

Due to limited number of technical staff at NMQAL, technical activities which require expert scientific skills are lagging behind. (Ex: In-house analytical method evaluation, method validation) For the time being to cover up above areas, NMRA is seeking for two (02) Technical officers in consultancy basis to carry out technical activities which urgently require at NMQAL.

Deliverables: The contracted individual is expected to submit evaluation report for In-house analytical methods (Chemical and Microbiological).

Interested individual consultants are requested to submit a Curriculum Vitae (CV) as per required format with required details.

The "Terms of Reference" and the "Format for the Curriculum Vitae" is attached herewith.

Interested parties may obtain further information from Director (NMQAL) via 0112-687741

The Curriculum Vitae (CV) with requested information must be delivered no later than 14:00 hrs on 08.05.2024 either hand delivered or by post to the address; Chief Executive Officer, National Medicines Regulatory Authority, State Engineering Cooperation Building, No.130, W.A.D. Ramanayake Mawatha, Colombo 02. Envelope containing the Curriculum Vitae (CV) to be marked "Obtaining Consultant Services for technical activities of NMQAL"

Chief Executive Officer
National Medicines Regulatory Authority

TERMS OF REFERENCE FOR THE RECRUITMENT OF TWO TECHNICAL OFFICERS

GENERAL INFORMATION

- Services/Work Description : Recruitment of Consultant for technical activities of NMQAL
- Project Title : Consultant Service
- Post Title : Technical Officer
- Duty Station : On site (National Medicines Quality Assurance Laboratory (NMQAL), National Medicines Regulatory Authority (NMRA)/
On line
- Duration : 03 months' period
(may be subject to change based on the decision of the NMRA)
- Expected Start Date : After Signing the Contract and inception meeting

1. **BACKGROUND** : Due to limited number of technical staff at NMQAL, technical activities which require expert scientific skills are lagging behind. E.g. In-house analytical method evaluation, method validation. For the time being to cover up above areas, NMRA is seeking for two Technical Officers in consultancy basis, to carry out technical activities which urgently require at NMQAL.
2. **SCOPE OF ASSIGNMENT**: Technical Officers in consultation with NMQAL will perform the evaluation of In-house analytical methods with validation reports in the registration dossiers.

3. DELIVERABLES

- The contracted individual is expected to submit evaluation report for In-house analytical methods (chemical and microbiological).
- Expected outcome – 8 evaluation reports per week per person (may be subject to change after recruitment)

4. INSTITUTIONAL ARRANGEMENT:

The hired consultant will directly be under the supervision of the CEO/ NMRA.

Evaluation Reports will be submitted to the Director/NMQAL in a timely manner.

5. EXPECTED DURATION OF ASSIGNMENT

3 months and extendable based on annual performance evaluation. The individual, therefore, is required to prepare and submit the entire plan in a way that allows the achievement of deliverables.

6. QUALIFICATION/EXPERIENCE

The successful officer shall meet the following minimum criteria:

A. Educational Qualifications of the Successful Contractor:

- Post-graduate degree in Scientific disciplines including chemical, microbiological, pharmaceutical sciences or related subjects.

B. EXPERIENCE:

- Minimum 10 years of experience in analytical laboratories involves in the areas given in the scope.
- In-depth and proven knowledge and experience to deliver the expected deliverables.
- Knowledge in international pharmaceutical standards (e.g., ICH), regulations and NMRA policies.

C. COMPETENCIES:

- Strong analytical skills with conceptual understanding.
- Strong, proven functional skills in analytical writing, and producing reports.
- Excellent demonstrated ability to be flexible and work under tight deadlines in an independent working environment.
- High level of communication and interpersonal skills.
- Good understanding of NMQAL common system and policies.
- Demonstrates commitment to the NMQAL/NMRA mission, vision and values.
- Consistently approaches work with energy and a positive, constructive attitude.

CURRICULUM VITAE (CV)

**Individual Consultant for technical activities of National Medicines Quality Assurance
Laboratory of the National Medicines Regulatory Authority (03 months period)**

01. Identity

Position /Title/Consultancy	Consultant Service
Name of the Consultant:	
Date of Birth:	
Address	
NIC Number	
Contact Number	
Email Address	

02. Education: *(Attach copies)*

S/N	Name of the University/Institution	Title of the Qualification	Duration of Study	
			From	To

03. Experience record relevant to the assignment: *(Attach copies)*

S/N	Name of the Organization	Nature of the Job	Title/position	Duration	
				From	To

04. Membership in Professional Associations and Publications:

- i. _____
- ii. _____
- iii. _____
- iv. _____

05. Expected consolidated fees for the consultant service :

Cost Component	Monthly Rate	Number of Months	Total for three months (LKR)
Consultant service fee		03	

Certification:

I, the undersigned, certify that to the best of my knowledge and belief, attached CV correctly describes myself, my qualifications, and my experience, and I am available to undertake the assignment in case of an award. I understand that any misstatement or misrepresentation described herein may lead to my disqualification or dismissal by the NMRA.

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Name of Consultant

.....
Signature

Date: