

## **REQUEST FOR EXPRESSIONS OF INTEREST (REOI) FOR INDIVIDUAL CONSULTANTS**

### **Consultancy Services to Support Operationalization of the Network of African Reliance Laboratories (NARL)**

**PROCUREMENT NUMBER: 52/AUDA/HCID/ID/ICS/2024**

**Method: Individual Consultants Selection (ICS) - Individuals Only**

#### **1. INTRODUCTION**

African National Quality Control Laboratories (NQCLs) have over the last decade made significant advances in the quality control (QC) of small molecule drugs. However there still remains a significant capacity gap in bio-analytical testing of large molecule drugs (biologicals) including vaccines comparable with international best practices. As the continent steps up efforts for local manufacturing of vaccines with the announcement of new vaccine manufacturing initiatives by 17 African countries, their national regulatory authorities (NRAs) and associated NCLs would need support to build capacity for vaccine regulatory oversight.

Lot release (LR) is a regulatory function specific to biological products, such as vaccines, with the purpose of ensuring a product's quality in comparison with defined specifications through a system of regulatory release. A component of LR may include independent quality control (QC) testing of the product. QC testing can also be a requirement for product registration, investigations of adverse events, vigilance (checking and confirming the quality of products placed on the market), and for detecting substandard and falsified medical products.

To advance regulatory harmonisation and operationalisation of the African Medicines Agency (AMA), there is a need to build African regulatory systems in general, and laboratory capacity, specifically. The development and operationalization of a Network of African Reliance Laboratories (NARL) one of the identified priorities for the African Medicines Regulatory Harmonisation (AMRH) in support of AMA operationalisation.

#### **2. SCOPE/MAIN RESPONSIBILITIES OF THE ASSIGNMENT**

The Consultant shall work with the AUDA-NEPAD AMRH Secretariat to deliver on the following tasks:

- a. Develop and administer an Expression of Interest (EOI) among African NQCLs to facilitate the membership within the various categories of the ANCL-RN (full members, associate members and observers).
- b. Define the Central Coordination Unit (CCU) of the NARL in alignment with the AMRH governance structure within the AUDA-NEPAD and AMRH Secretariat including recommendation on competencies, job description, reporting channel and job description of CCU staff.
- c. Facilitate the launch of NARL during AMRH governance meetings.
- d. Guide NARL in development and domestication of harmonized guidelines, regulatory frameworks, standards and tools.
- e. Support the CCU to facilitate the first annual meeting of the NARL to constitute the Assembly of Member, the Steering Committee and initial working groups.
- f. Establish outreach programs of NARL, monitor and report progress and impact.
- g. Establish peer review mechanisms for processes and conduct mock audit programs for the NARL.
- h. Develop a comprehensive roadmap to address capacity gaps in facilities, equipment's and supplies, personnel, trainings and emergence preparedness

### **3. DELIVERABLES**

The deliverables of the consultant shall include:

- a. Central Coordination Unit (CCU) designed, governance and reporting system defined
- b. Outreach programs for ANCL-RN established and bi-annual reporting mechanism instituted
- c. Roadmap for reliance laboratories developed in alignment with the continental regulatory reliance framework.
- d. Capabilities and competencies for participating laboratories mapped and comprehensive report disseminated to stakeholders.
- e. Harmonized guidelines, procedures, protocols and tools for the network finalised and approved by the AMRH governance.

4. AUDA-NEPAD now invites eligible individual consultants (“Consultants”) to indicate their interest in providing the Services. Interested Consultants should provide information demonstrating that they have the required qualifications and relevant experience to perform the Services.

### **5. QUALIFICATIONS, EXPERIENCE AND COMPETENCIES**

#### **Qualifications and Skills**

- Master’s degree in pharmacy, biopharmaceutics, biochemistry, biology, microbiology, regulatory sciences, pharmaceutical sciences or Health Economics or related fields from a recognised institution.

#### **Experience**

- At least 10 years’ experience working in leading regulatory and/or laboratory systems strengthening and medical products in Africa.
- Experience in the implementation of Laboratory Quality Management Systems, analytical test methods, laboratory readiness, and technology transfer activities such as qualification/validation, assay development and verification to support testing of vaccines and biological products.
- Experience and knowledge of regulatory requirements related to vaccines and biological products.
- Experience in conducting risk analysis, audits and inspections of testing facilities to determine compliance with ISO/IEC 17025 and WHO Good Practices for Pharmaceutical

### **6. SHORTLISTING CRITERIA**

For evaluation of the expressions of interest, the following criteria will be applied:

- a. Qualifications - Education and Relevant Training (30 points);
- b. Experience related to the Assignment (40 points);
- c. Similar previous experience related to the Assignment (20 points); and
- d. Knowledge and experience of the region & local conditions (10 points).

A Consultant will be selected in accordance with Individual Consultant Selection (ICS) method set out in the AU Procurement Manual. TORs are attached as annex 1

### **7. SUBMISSION REQUIREMENTS**

Interested candidates are requested to submit the following documents for AUDA-NEPAD consideration:

- I. Cover letter confirming compliance to eligibility;
- II. Signed declaration of undertaking (downloadable from AUDA-NEPAD website and attached as Annex 1 below);
- III. Curriculum Vitae (CV); and
- IV. Proof of stated qualifications in the form of the copies of the degrees obtained

### **8. REPORTING AND TIME SCHEDULES:**

- I. In undertaking this exercise, the consultant will be expected to frequently exchange and interact with the , Principal Programme Officer – Policy Specialist.

**9. Only Individual Consultants are eligible for this assignment if they fulfil the following eligibility criteria:**

- a) Have no conflict of interest in relationship to performance of this assignment;
- b) Are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the African Union Commission, World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank. Further, are not ineligible pursuant to a decision of the United Nations Security Council;
- c) Have not been convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations or Country for involvement in a criminal organisation, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons which themselves are subject to such convictions or sanctions;
- d) Are not being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganisation or being in any analogous situation;
- e) Are not involved in corruption: offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;
- f) They have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the AUDA-NEPAD financial interests;
- g) they have not been declared guilty of gross professional misconduct proven by any means which AUDA-NEPAD can justify;
- h) Comply with their national tax and social security laws

Interested consultants may obtain further information from the address listed below. All Expression of Interests should be sent electronically to email listed below.

10. Expressions of interest must be delivered to the address below by email on or before **August 22<sup>nd</sup> ,2024 14:30 hours (South African Time)**. All EOI's must be marked **"52/AUDA/HCID/ID/ICS/2024 – Consultancy to Support Operationalization of the Network of African Reliance Laboratories (NARL)** in the subject line of the email.

11. **Privacy Policy:** *AUDA-NEPAD Procurement office collects and uses your personal information for "Procurement Process" when you intend to compete and deliver any service or goods for the organization either individually or as a firm based on your consent. Your personal data is our highest security and kept for a period strictly necessary for the purpose set out. This privacy notice supplements the AUDA-NEPAD standard privacy notice and should be read in conjunction with the same available on AUDA-NEPAD website.*

**The Chairperson Internal Procurement Committee (IPC)**

AUDA-NEPAD

230, 15th Road, P. O. Box 218 Midrand,  
1685 Johannesburg, South Africa

Email: [procurement@nepad.org](mailto:procurement@nepad.org) & copy [ngonik@nepad.org](mailto:ngonik@nepad.org)

Attention of: Head of Procurement Division

annex 1

## DECLARATION OF UNDERTAKING

{Location, Date}

To: **The Chairperson Internal Procurement Committee (IPC)**

AUDA-NEPAD

230, 15th Road, P. O. Box 218 Midrand,

1685 Johannesburg, South Africa

Attention of: Head of Procurement Division

1. I, the undersigned, offer to provide the services for {insert Title and Procurement Number} in accordance with your Request for Expression of interest dated {insert Date}
2. I declare that I:
  - i) Have no conflict of interest in relationship to performance of this assignment;
  - j) Am not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the African Union, World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank. Further, are not ineligible pursuant to a decision of the United Nations Security Council;
  - k) Have not been convicted by a final judgement or a final administrative decision or subject to financial sanctions by the African Union, United Nations or Country for involvement in a criminal organisation, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons which themselves are subject to such convictions or sanctions;
  - l) Am not being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganisation or being in any analogous situation;
  - m) Have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the AUDA-NEPAD financial interests;
  - n) Have not been declared guilty of gross professional misconduct proven by any means which AUDA-NEPAD can justify;
  - o) Are not involved in corruption: offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;
  - p) Comply with their national tax and social security laws.
3. I, the undersigned, certify that to the best of my knowledge and belief, that my CV correctly describes myself, my qualifications, and my experience. I understand that any willful misstatement described herein may lead to my disqualification or dismissal, if engaged;
4. I hereby declare that at any point in time, at AUDA-NEPAD's request, I will provide certified copies of all documents to prove that I have the qualifications and the professional experience which are attached to this CV as photocopies;
5. By signing this statement, I also authorize the AUDA-NEPAD's to contact my previous or current employers indicated in my CV, to obtain directly reference about my professional conduct and achievements.

We remain,

Yours sincerely,

Signature:  
Name of Consultant:  
Address