Template for Short-term Opportunities

Stellis CVs of interested applicants must be sent to: Dr Gaby VERCAUTEREN at vercautereng@who.int

1. Division/Dept/Unit	2. Supervisor
MHP/RPQ/REG	Dr Ute Rosskopf
3. Contract dates	**4. Contract type**
Give accurate contract dates. 10 October to 10 December 2021	Consultant

5. Location

Please specify where the staff / non-staff will work:

On site: _____(please indicate office and duty station)

Off site: _____X_____(please indicate location/address).

Acceptable time difference if in off-site location: _____ +/- _____hours

Home based

6. Travel

No travel - Home based

7. Remuneration and budget *(travel costs excluded)* – to note that a retiree cannot be offered a contract at a level higher than the grade held upon retirement

For consultant contract: US$ 500 daily for 42 days (Pay Band C – Expert, P5)

For staff contract: indicate only grade

8. Purpose of Temporary appointment/Consultant contract

The Regulation and Prequalification Department is introducing a new IT solution to replace the previous systems used by the Prequalification (PQT) unit and the Laboratory Services and Networks (LNS) Team of the Regulation and Safety (REG) unit. The Laboratory Services and Networks (LNS) Team will be introducing a Laboratory Information Management System (LIMS) to adequately manage and document its work conducted for as part of the prequalification activities for vaccines. This work includes lot release testing of vaccines, monitoring of the quality of prequalified vaccines and carrying out audits of the contracted testing laboratories (customer audits).

The consultant will work with the Laboratory Networks and Services (LNS) Team – Vaccines (Vx), within the Regulation and Safety (REG) Unit focusing on the following:

IT solution under development for LNS-Vaccines

Assistance is required to support and evaluate the selection and implementation of an electronic IT solution, e.g. a customized laboratory information management system (LIMS):

- prepare for and participate in meetings with relevant teams in WHO, LIMS suppliers, IT developers and other relevant stakeholders;
- assist in the clarification of WHO processes (e.g. IMT, cyber security, procurement requirements).
- compilation of requested information and data for the new LIMS IT system;
- assist in detailed definition of requirements / specification of the new LIMS IT system according to LNS needs;
- Visualize workflows as requested for LIMS;
- identify LNS configuration and customization needs and assist in evaluation of documentation and system designs provided by the suppliers;
- assist in evaluation of documentation and system designs provided by developers; and
- support assessment of proposed solutions to vaccine quality control and monitoring including services to and of national control laboratories.

Objectives of the Programme:

Preparation phase

Prior to the Development Phase, there is a need to prepare data and documents for the procurement of the new LIMS solution. Significant effort is required at this stage to ensure the information is ready for the procurement department to issue the request for proposals and select the most appropriate supplier/developers. This phase is assumed to be finalized with the conclusion of the contract.

Development phase

This is the phase in which the developers build the system. This would run for approximately nine weeks and include three sets of two-week on-line meetings with the developers.

As well as refining WHO data and other requirements WHO applicants need to provide feedback as the solution is being developed. The development will be iterative, running in several cycles. During each the developers will present their proposed solution to different aspects of the system, and/or, provide revised solutions to aspects of the system we have already provided feedback on.

Functions of the new system for LNS-Vx need to be presented as a basis for further discussion and evaluation. If a decision cannot be made based on provided solutions and functionality, additional time might be requested.

- Migration of information will start to occur if system/design is seen as adequate for the LNS-Vx requested system.

Go live

Prior to switching to the new system, there will be efforts required to migrate remaining current information; check that the information has passed into the system correctly, and generally ensure everything is working as it should.

Deliverables (consultancy)

1. Preparation of a document describing the detailed requirements for an IT laboratory information management system (LIMS) adapted to the needs of the LNS-Vx service processes.

Assist with the communication of these requirements to the relevant WHO teams: HQ/BOS/IMT/BRM, WHO Cybersecurity, HQ/BOS procurement, and external stakeholders.

Assist with the review of the proposed IT solutions.

2. Contribute to the development of the LIMS IT solution by:

- clarifying IT and Business requirements that address the needs of the LNS-Vx services to the IT developers.
- providing feedback on the concepts and designs to handle records, notifications, contacts, documents etc.
- suggesting improvements to ensure that the solution is sufficiently tailored to the requirements of LNS-Vx.

3. To prepare datasets to facilitate migration of this information into the new system.

To prepare and organize documents for migration into the new system and determining if this migration has occurred successfully.

REQUIRED QUALIFICATIONS:

Education:

Essential:

An advanced university degree (Masters level or above) in Biology, Pharmacy, Chemistry, Biochemistry, Medicine, Microbiology or related sciences

Experience

Essential:

A minimum of 10 years' experience in the regulation of biological products and expert knowledge in production/control/quality assurance of vaccines and biologicals acquired by working with a National Regulatory Authority (NRA), vaccine manufacturer or other relevant institution such as Foundations and Associations.

Use of Language Skills

Skills / Technical skills and knowledge:

The consultant is expected to have scientific background and expertise, particularly in the area of infectious diseases and vaccines. Extensive knowledge of production and quality control of vaccines. Expert knowledge of the standard ISO 17025 (General requirements for the competence of testing and calibration laboratories), understanding of Good Manufacturing Practices and of quality management systems. The ability to work in a highly political international environment. Ability to manage a project. Experienced in requirements and establishment of a laboratory management system and knowledge of electronic information management applications such as databases and SharePoint.

Computer proficiency intermediate level or above, particularly Microsoft program.

It is therefore essential that the consultant exhibit a high level of both professional and technical expertise and experience to assure credibility in the routine interactions and interviews performed

Essential: . English

Others

Date :