Template for Short-term Opportunities

Stellis CVs of interested applicants must be sent to: Local Production and Assistance (LPA) Unit, localproduction@who.int

1. Division/Dept/Unit	2. Supervisor
MHP/RPQ/LPA	Dr Jicui DONG
3. Contract dates	**4. Contract type**
From 20 April to 19 October 2022	Consultant

5. Location

On site for insurance purposes only – travel to manufacturing sites to conduct assessments, locations to be agreed as per the LPA 2022 workplan

6. Travel

Travel to manufacturing sites to conduct assessments, locations to be agreed as per the LPA 2022 workplan

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

8500 US$/month – Band level B

8. Purpose of Temporary appointment/Consultant contract

Objectives of the Programme:

The purpose of this consultancy is to assist and support the LPA Unit with programme activities in strengthening local production and technology transfer for improving access to quality-assured, safe and effective health products.

Descriptions of Deliverables:

1. Provide Prequalification (PQ)-related specialized technical assistance, with a report, for up to 6 manufacturers of vaccines and other biological/pharmaceutical/health products with inspections of the manufacturing facility and its quality management and quality assurance systems for compliance with current WHO good manufacturing practices standards

2. Provide PQ-related specialized technical assistance, with a report, for up to 6 manufacturers of vaccines and other biological/pharmaceutical/health products on the development and/or implementation of the manufacturer's corrective and preventive action plans

3. Provide PQ-related specialized technical assistance, with a report, for up to 6 manufacturers of vaccines and other biological/pharmaceutical/health products with on-site/virtual training and/or technical assistance on current GMP and/or the corrective and preventive action plans (CAPAs)

4. Prepare the relevant reports with the provision of PQ-related specialized technical assistance to up to 6 manufacturers of vaccines and other biological/pharmaceutical/health products

5. Conduct on-site assessments of the facilities, with a report, for up to 3 manufacturers of vaccines and other biological/pharmaceutical/health products

6. Provide technical input on a strategy for hands-on capacity building to strengthen local production and technology transfer of quality-assured vaccines and other health products

7. Provide technical input on the technical products of the LPA Unit, such as the situational analysis tool

REQUIRED QUALIFICATIONS:

Education:

Essential: Advanced university degree in pharmacy, sciences, life sciences or other health or socio-economic related fields.

Desirable: Advanced university degree related to development and/or production of vaccines and/or biological products, such as immunology, biochemistry, cellular biology or biotechnology.

Experience:

Essential: A minimum of seven years of relevant professional experience, including professional experience, some years of which are gained in an international context, in the production, quality assurance of vaccines and/or biological products and in conducting good manufacturing practice (GMP) audits under current WHO/international GMP standards.

Desirable: Relevant professional experience in the medical product manufacturing industry including experience in conducting GMP audits; in a national regulatory authority as a GMP inspector of vaccine/biological product manufacturers; in facility design for the vaccine/biological product and/or pharmaceutical manufacturing industry; with the WHO Prequalification and/or Emergency Use Listing procedures; in organizing and/or providing capacity building/training for quality production of medical products in low- and middle-income countries; in technology transfers; and/or with an international organization

Use of Language Skills:

Essential: Excellent knowledge of spoken and written English.
Desirable: Working knowledge of another WHO official language

Others

Skills/Knowledge
Essential:

- Sound knowledge of manufacturing, current Good Manufacturing Practices and/or quality management systems and regulation for vaccines and biological products;
- Knowledge of WHO and other internationally-recognized quality assurance standards, WHO emergency listing and/or prequalification procedures and/or health product regulation for vaccines and biological products;
- Ability to review, revise or develop technical documents, policies and activities in the area of local production and technology transfer of medical products;
- Ability to design, plan and implement activities to achieve the goal(s);
- Excellent communication and interpersonal skills, strong planning and organizational skills and ability to use a range of IT tools (Word, Excel, presentation software, databases and web navigators;
- Demonstrated ability to interact with all stakeholders with tact and diplomacy, upholding the reputation of the Organization at all times.

Desirable:

- Knowledge of the manufacturing processes, chemistry, manufacturing and control (CMC) and/or product dossier requirements of vaccines and/or biological products in accordance with current WHO/internationally-recognized standards;
- Knowledge of the manufacturing processes, CMC, GMP and/or product dossier requirements of mdicines in accordance with current WHO and/or internationally-recognized standards

Date : 22 March 2022