

### In-Country Quality Control Consultant Opportunity - Cambodia

The **U.S. Pharmacopeial Convention (USP)** is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

USP is an independent nonprofit organization with nearly 200 years of experience developing quality standards for medicines. Through its global public health programs, USP strengthens medicines quality assurance systems, increases the supply of quality-assured medicines, and develops capacity to detect and remove poor-quality medicines from the market. By sharing scientific expertise and providing technical support and leadership, USP helps local regulators improve and sustain local health systems and enables manufacturers to supply quality-assured essential medicines for years to come. Through these efforts, USP is able to help detect and identify poor quality health products in disease areas such as HIV/AIDS, tuberculosis, malaria and neglected tropical diseases, as well as helping safeguard the maternal, newborn, and child health sectors.

The Regulatory Laboratory Capacity Strengthening program, funded by the Australian Department of Foreign Affairs and Trade's (DFAT) is aimed at strengthening the capabilities of the national quality control laboratories (NQCL) in Cambodia and Laos. This program will complement the Indo-Pacific Regulatory Strengthening Program (RSP), implemented by the Therapeutic Goods Administration (TGA). USP is anticipating a two-year contract to strengthen the capacity of lab staff of Cambodia and Laos NQCLs to reliably perform their function of quality control testing of medical products. USP will build on its experience and proven approaches to implement sustainable, systems-based approaches to support the governments of Cambodia and Laos to establish Quality Assurance/Quality Control management systems.

To successfully implement this project, USP is seeking a Cambodia-based, in-country Quality Control Consultant to manage day-to-day in-country activities in Cambodia for the duration of this project. The in-country Quality Control Consultant will have the overall responsibility of implementing laboratory quality management systems (QMS) in the laboratory and to assure that the laboratory conducts its technical activities according to international standards of ISO 17025 or the World Health Organization-Pre-Qualification (WHO-PQ) . The consultant will also be responsible for managing material, financial and technical resources of USP and that of the project in each country. The Quality Control Consultant will report to the Project Director, with technical functional reporting to the Director of Laboratory Program Unit.

# **Scope of Work:**

- Provide in-country oversight of the day-to-day project implementation by working with the lab and stakeholders to build laboratory quality management system.
- Working with the laboratory, lead the development of standard operating procedures (SOPs), quality manual, quality policy and good documentation practices per the requirement of ISO 17025 and WHO-PQ.
- Identify and work with in-country implementing partners and donors, with interest in medicine quality control, as well as the MoH to develop or adopt national laboratory strategic plans.
- Working with USP international and regional consultants, facilitate short-term technical assistance training to laboratory staff in good laboratory practices, laboratory safety, analytical methods and instrumentation.
- Provide oversight for continuous equipment maintenance and validation and support external consultants and vendors to conduct equipment calibration and qualification.

- Provide in-country project management leadership through planning, executing and monitoring
  of USP's financial, materials and technical resources, with support from the Project Manager.
- Attend all meetings and workshops organized under the project.
- Provide periodic updates to the project director and manager on laboratory activities and assignments.
- Assist in drafting and reviewing project reports for submission to DFAT.
- Facilitate all logistics arrangements for USP project staff, regional and international consultants when in-country.
- Coordinate with USP, MoH, DFAT, TGA and other relevant stakeholders the procurement, shipment, clearing and transportation of laboratory equipment and consumables.
- Other assignments requested by the project director/manager.

#### **Deliverables:**

- Monthly activity-based report to USP project manager.
- Minutes and sign-in sheet of meetings attended on behalf of the project.
- Trip reports of within country and out of country technical support travels.

## **Minimum Requirements**

### **Education**

 Bachelor's degree in chemistry, biochemistry, pharmacy, pharmaceutical/life science or related field.

### Experience:

- At least 5 years professional experience working in a Quality Control laboratory either within a pharmaceutical manufacturing company or a medicines regulatory authority.
- At least 2 years' experience in project management support/coordination.

#### Knowledge, Skills and Abilities:

- Ability to work independently and to effectively liaise with relevant parties, including government and non-government stakeholders.
- Must be proficient in English and possess excellent verbal, written and presentation skills.
- Must have basic project management skills.
- Computer proficiency in Word, Excel, PowerPoint, and Internet.
- Firm knowledge of the operations of drug regulatory authorities and national quality control laboratories.
- Understand the basics of monitoring and evaluation of program activities.
- High level of integrity and commitment to quality.
- Must possess ability to handle multiple priorities in a fast-paced environment.
- Ability to write lucid technical and management reports in English, preferred.

#### **Period of Performance**

The anticipated period of performance for this consultancy will commence on September 2020 for a 2-year duration.

Please send CV, 3-References, and Hourly Rate to Pascal Echeverri, Senior Procurement Specialist, at GPH\_Procurement@USP.org, salwan.hager@USP.org and info@nhqc.org.kh by the closing date of October 9, 2020. When submitting your application, write "Cambodia - Quality Control Consultant" in the email Subject Line.