

Senior Operations Consultant Opportunity

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.

The **Promoting the Quality of Medicines (PQM) program** is a program funded by the United States Agency for International Development (USAID) and implemented by USP. Since 1992, USP has worked in partnership with USAID to support developing countries in addressing critical issues related to medicines quality. The PQM program provides technical assistance to build capacity of medicines regulatory authorities and quality assurance systems in countries with emergent health systems and it supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health. There is increasing recognition of the burden of poor-quality medicines and their threat to public health, especially in low- and middle-income countries. Falsified and substandard medicines can cause treatment failure and adverse reactions, can increase morbidity and mortality, and may contribute to antimicrobial resistance. These medicines represent not only a waste of scarce resources but also a substantial risk to public health. Further, they risk undermining decades of health investments, including those made by USAID.

In 2016, PQM started program activities in Bangladesh, and is seeking a Senior Operations Consultant to support start-up and ongoing management of field-based operations in support of program implementation.

Overall country office operations as related to this consultancy includes field-based Financial Management, Procurement and Inventory Management, Logistics, Human Resources Management, and Information Technology in accordance with USP, the United States Agency for International Development (USAID) and Government of Bangladesh policies, rules and regulations. S/he shall serve as a primary point of contact with the USP PQM Rockville and Global Public Health Operations' team based in Rockville, Maryland, USA to ensure optimal day-to-day program operations.

Scope of Work:

- Support office start up activities ensuring a work-conducive environment for all working on PQM activities
- Ensure all PQM's operational activities are in compliance with USAID and USP rules and regulations to include USP's Code of Ethics
- Lead the planning and development of detailed annual work plan budget and monitor/track activity level expenses for the program
- Ensure the adoption and implementation of USP financial management policies and procedures in compliance with USAID and local regulations
- Support monitoring and tracking of procurement related activities in terms of timeliness and compliance in line with program needs
- Manage inventory (including government property) and office supplies in line with relevant regulations
- Oversee logistics function in support of meeting programmatic needs in a timely manner



- Serve as the point of contact to ensure IT meets the needs of the PQM program in a timely manner
- Lead, coordinate, and liaise with USP Rockville in ensuring local entity legal registration requirements are met and maintained (domicile, tax, business licenses, etc.)
- Advise USP senior management on any changes in regulations relevant to legal operations of the field office
- Perform other duties as assigned

Minimum Requirements

Education

- Bachelor's degree in Management/Business Administration or equivalent

Experience:

- At least 7-10 years of experience in progressively-responsible operations management roles on donor funded program in Bangladesh.

Knowledge, Skills and Abilities:

- Ability to work independently and to effectively liaise with relevant parties, including government and non-government stakeholders
- Excellent analytical skills; mature judgment combined with a proactive, energetic approach to problem solving
- Fluency and proficiency in written and oral English as well as one local language required
- Excellent organizational, communication, and interpersonal skills
- Computer proficiency in Word, Excel, PowerPoint, and Internet
- Prior experience using Quick Books or similar finance related software an advantage
- Ability to handle confidential information

Interested candidates should submit cover letter, CV, and USAID Form 1420 (available at <http://www.usaid.gov/sites/default/files/AID1420-17.doc>) to PQMBangladesh@USP.org clearly stating consultancy for which the applicant is applying for in the subject line of their application e-mail.

Quality Assurance/Quality Control Consultant Opportunity

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.

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In 2016, **PQM started program activities in Bangladesh, and is seeking a Quality Assurance (QA)-Quality Control (QC) Consultant to support implementation of activities.** As part of the USP PQM Bangladesh country team, the QA/QC consultant will provide technical oversight to both the National Control and Drug Testing Laboratories.

Scope of Work

- Provides technical assistance to the National Control and Drug Testing Laboratories to build sustainable QA/QC systems through capacity building and process improvements.
- Conducts quality assurance in-process checks in laboratory areas as directed by appropriate standard operating procedures and ISO standards, including ISO 9001 and ISO 17025.
- Works with validation and metrology to ensure the calibration, validation and preventive maintenance of equipment is performed.
- Performs annual quality management system/lab management system review at sites to identify gaps and improvement opportunities to ensure quality.
- Helps to determine development needs and assists in SOP development, optimization and training.
- Develops and implement environmental, health and safety systems and practices to ensure laboratories with the relevant legislations and/or other regulatory requirements.
- Assist laboratories in developing hazardous waste disposal procedures to be compliant with local regulations.
- Other quality systems activities as assigned.



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Trusted Standards
Improved Health

Minimum Requirements:

- A bachelor's degree or above (Master degree preferred) with at least 7 years of responsible QA/QC experience. Environmental, health and safety management preferred.

Knowledge, Skills & Abilities:

- Excellent problem solving technical writing and auditing skills are required.
- Candidate must understand GMP/GLP, and ISO regulations and the integration of the regulations into working systems in the laboratory and site.
- Must possess excellent written and verbal communications skills
- Fluent in Bengali and English , proficiency in written and oral English required
- Ability to travel to domestically to ensure project implementation.

Interested candidates should send CVs to Souly Phanouvong, Senior Manager, Asia Programs, PQM, at SXP@usp.org.

Technical Consultant Opportunity

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In 2016, PQM started program activities in Bangladesh, and is seeking a Technical Consultant to support implementation of activities.

The Technical Consultant will provide high-level inputs into work plan development, implementation, and reporting with relevant Bangladesh Directorate General of Drug Administration (DGDA) counterparts. The Technical Consultant will also maintain effective communications with program country and international partners as well as with PQM HQ staff.

Scope of Work:

- Responsible for technical and programmatic activities to develop and implement PQM's activities per the approved work plans to strengthen the medicine regulatory and QA/QC systems in Bangladesh.
- In country technical lead and resource to the USAID Bangladesh mission, Ministry of Health & Welfare and DGDA for all PQM activities.
- Manages technical assistance activities in support to the National Control Laboratory (NCL) and Drug Testing Laboratory.
- Prepares PQM quarterly I reports.
- Leads PQM activities associated with improving the capacity of local pharmaceutical manufacturers.
- Attend relevant in-country meetings with key stakeholders.

Minimum Requirements

Education and Experience:



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- Bachelor degree in the areas of public health, medicine, pharmacy, life or physical sciences
- Minimum 5 years of experience managing public health programs.
- Experience working with Bangladesh government (MOH and DGDA) and international donor agencies (USAID, Global Fund, etc.) required.

Knowledge, Skills and Abilities:

- Knowledge of public health and pharmaceutical management in low and middle income countries
- Knowledge of USAID programs, projects and grant administration
- Must possess ability to handle multiple priorities in a fast-paced environment.
- Must possess excellent written and verbal communications skills
- Fluent in Bengali and English, proficiency in written and oral English required
- Ability to travel to domestically to ensure project implementation.

Interested candidates should send CVs to Souly Phanouvong, Senior Manager, Asia Programs, PQM, at SXP@usp.org.

United States Pharmacopeia Job Description

Job Title: Laboratory Quality Management Services Specialist - Bangladesh	Reports to: Technical Program Manager - Bangladesh
Department: GHIP	Prepared by: Francoise Parr
FLSA Status: TBC	Salary grade: TBC
Reviewed by: Souly Phanouvong	Date Reviewed: November 1, 2016

Summary of the Position:

This is a hands-on, non-supervisory position which is primary responsible for providing technical assistance in such areas as laboratory equipment and instrument's evaluations and training, selecting approved International Laboratory Accreditation Cooperation (ILAC) accreditation bodies, conducting ISO/IEC 17025:2005 Section 4 and Section 5 Training, WHO- prequalification (WHO PQ) preparation and follow-up evaluations and generating documents for standardization as needed. The position supports the Global Health Impact Program department under the Promoting the Quality of Medicines (PQM) program. In addition, the incumbent designs, develops and implements new tools and techniques used in the overall Quality Management Systems (QMS) with the technical assistance support of PQM.

Roles and Responsibilities:

- Provide technical assistance for ISO/IEC 17025:2005 accreditation, proficiency testing (PT) evaluation and WHO PQ by assessing, auditing, preparing and reviewing documents, standard operating procedures and providing necessary training for onsite staff.
- Conduct facility audits and documentation review to ensure environmental, equipment and staffing capabilities, which will be applied to corrective and preventive actions (CAPA). Make recommendations to field laboratories.
- Participate in all QMS training, focusing on investigations, CAPA, PT, and Internal Auditing in order to evaluate and trend the laboratory's progress toward ISO 17025 accreditation or WHO PQ
- Track and trend data to support quality metric reports ensuring laboratory compliance and follow-up through continual improvement.
- Perform other related duties as required or assigned.

Minimum Requirements:

Education

Bachelors' degree or above in Public Health, Chemistry, Pharmaceutics, Biotechnology or other related field required; emphasis information-related aspects of laboratory assessments, laboratory technical training, quality management systems development or equivalent experience strongly preferred.

Experience

Minimum of three years QA experience and experience auditing QC labs, or a minimum of five years of experience working in a QC laboratory.

Knowledge, Skills and Abilities:

- Knowledge of analytical chemistry and QA/QC processes and procedures in the pharmaceutical industry required.
- Advanced understanding of ISO 17025:2005, ISO 17043:2010, ISO 9001:2008, and general understanding of cGMPs.
- Microbiological and virology background and familiarity with QA/QC of pharmaceuticals a plus.
- Exposure to the concept of "Measurement Uncertainty" within relevant laboratory areas.
- Well developed meeting facilitation skills .
- Demonstrated skill in audit planning and lead auditing techniques.
- Demonstrated strong public speaking and written communications skills.
- Solid skills in MS Word, MS Projects, Excel, and PowerPoint.
- Ability to explain complex information in simplistic terms, to a diverse audience.
- Ability to travel at least 25% of the time to local locations.
- Affluent in writing and communication in additional languages (i.e. English, and Bengali) and is required

Supervisory Responsibilities:

None

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United States Pharmacopeia (USP) Job Description

Job Title: Chief of Party – Bangladesh	Reports to: PQM Senior Regional Manager (Asia)
Department: GPH / PQM	Prepared by: Souly Phanouvong
FLSA Status:	Salary grade: TBD
Reviewed by:	Date Reviewed:

Summary of the Position:

The Promoting the Quality of Medicines (PQM) is a program funded by the United States Agency for International Development (USAID) and implemented by the United States Pharmacopeial Convention (USP). PQM provides technical assistance to build capacity of medicines regulatory authorities and quality assurance systems in countries with emergent health systems and it supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

The Chief of Party – Bangladesh is a key management position on the PQM program responsible for providing overall in-country leadership, management, programmatic vision, strategy and compliant implementation of this USAID-funded program in Bangladesh. S/he shall serve as the primary liaison with USAID, relevant government agencies, and key stakeholders to ensure achievement of program deliverables, and to ensure that PQM activities complement on-going initiatives. The Chief of Party is expected to manage a team of staff in achieving program results while maintaining operational excellence. S/he will also be responsible for overall program monitoring, evaluation and reporting, financial management, and compliance.

Roles and Responsibilities:

- Represent USP/PQM program and maintain all verbal and written communications with USAID in Bangladesh. Serve as the primary liaison between the USP/PQM program and partners including the USAID Mission, Ministry of Health and Family Welfare, the Global Fund, MSH SIAPS program, and other partners.
- Provide high quality technical and strategic leadership and oversight for overall management of the PQM program in Bangladesh. This includes but is not limited to leading program design and developing work plans, leading overall implementation of project activities, and setting high quality performance targets to ensure adherence to technical standards and global best practices as well as compliance with all USAID and USP administrative, and operational policies and procedures.
- Develop and maintain strong working relationships with key internal and external stakeholders, to include regular communication and liaison with the USAID Mission, the government of Bangladesh, and other nongovernmental organizations.
- Lead planning and convening/coordination of a PQM Advisory Group, who will serve in an advisory capacity on issues such as overall programmatic and technical approach tailored to in-country

context, expanding PQM's scope of work beyond maternal and child health (MCH)/Family Planning (FP) to other disease areas, etc. .

- Ensure timely, highly-quality submission of all program deliverables, including required work plans, quarterly and annual performance reports, and financial reports to USAID, and other key documents or reports as required by USAID as and when needed.
- Represent PQM and increase the program's visibility among key stakeholders through networking and participation at relevant meetings and forums.
- Work with regional and country stakeholders to improve pharmaceutical quality systems including the capacity for quality assurance and quality control with the aim of promoting sustainability of program activities. Ensure overall compliance of USP policies and procedures and USAID rules and regulations, particularly in the area of programmatic and financial reporting and financial and grants management, as well as that of the country.
- Supervise a team of technical, program management and operations staff and ensure strong communication and coordination with PQM management and other relevant USP Rockville-based staff.

Minimum Requirements

Education and Experience:

Education:

- Master's degree in a relevant field such as public health, or international development

Experience:

- Minimum of eight (8) to ten (10) years of progressively responsible management experience.
- Effective record of building relationships with governmental organizations as well as private and community organizations is required.
- Professional level of oral and written fluency in English required.
- Familiarity with USAID regulations and administrative procedures in the implementation of donor assisted projects required – preference will be given to applicants with USAID-funded program management experience

Knowledge, Skills and Abilities:

- Demonstrated experience and previous successful management roles in health or pharmaceutical management development assistance programs.
- Demonstrated experience in managing complex programs related to good governance, such as programs focusing on public administration, institutional capacity development, rule of law, transparency and accountability, and anticorruption.
- Demonstrated proficiency in the field of people and project management, as well as strategic planning.
- Demonstrated leadership skills related to complex program management, including multiple program components, relevant budget and personnel management, program planning, monitoring and evaluation, and achieving success in complex environments.
- Demonstrated ability to lead in-country implementation of the contract, and manage program coordination, including host country government relations, client satisfaction, and integration with other projects.

- A high level of interpersonal and diplomatic skills to enable maintaining ongoing contacts with high ranking public sector officials. Ability to work effectively with government officials, leaders of civic and community-based organizations, and at building lines of communication and cooperation among them.
- High level technical skills and a deep understanding of the political and social context in Bangladesh, and prior experience in similar positions.
- Working knowledge of and experience with United States Government -funded program management, policies, regulations, and procedures.
- Familiarity with and experience working in Bangladesh, and ability to speak/understand Bengali is a plus
- High level of computer literacy

Supervisory Responsibilities:

Oversee the day-to-day activities of approximately 10 staff in Bangladesh.

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