REQUEST FOR INFORMATION (RFI)
No. RFI-AID-GH-18-MQASSP

Issuance Date: June 6, 2018
Responses Due Date: June 20, 2018, 5 PM EDT
Subject: Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Dear Partners,

The quality of medicines and other health technologies (hereafter referred to as "medicines") is increasingly recognized as an essential condition for health program success. Without good quality, safe, and efficacious medicines, all other investments in health can be negated. However, low- and middle-income countries (LMICs) face considerable challenges, including weak medicines regulatory systems, human resource constraints, lack of appropriate financing, and inefficiencies in allocation and use of resources.

The U.S. Agency for International Development (USAID) is conducting market research on the capability of firms to provide services in the area of medicines quality assurance systems strengthening in LMICs, including support for local manufacturing. To participate in this RFI, please forward a Capability Statement detailing your organization's breadth of technical experience and geographic scope working in the following areas, including in LMICs:

1. Support for the development and implementation of medicines quality assurance policies, legislation, regulations, guidelines, and standard operating procedures (SOPs), including policies that advance investments in local manufacturing as appropriate
2. Support for the quality assurance components of medicines regulatory system strengthening, including management systems and specific regulatory functions (e.g., marketing authorization, post marketing surveillance, inspection, etc.)
3. Support for capacity building and expansion of the medicines regulatory and quality assurance workforce through curriculum reform and collaborations with educational institutions, international and local professional associations, WHO, and others
4. Support for medicines quality control laboratory capacity development, including International Organization for Standardization (ISO) accreditations (various), instrumentation and preventive maintenance, and laboratory networks
5. Developing Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) capacity for the conduct of bioequivalence studies, dossier submissions, post-approval

studies for generic products that are bioequivalent and therapeutically interchangeable, and increased number of qualified contract research organizations (CROs)

6. Support to manufacturers for Good Manufacturing Practices (GMP) and product dossier assistance for priority essential medicines that meet recognized international quality standards and achieve WHO prequalification, Stringent Regulatory Authority (SRA), or Expert Review Panel (ERP) approval status
7. Support for harmonization initiatives to strengthen regional medicines regulatory capacity and networks toward increased use of work-sharing platforms (e.g., for joint dossier reviews, GMP inspections, and post-marketing surveillance of medicine quality)
8. Development of innovative risk-based tools and approaches to address medicines quality issues, including supporting prioritization of donor and country investments and improved allocation of human and financial resources for regulatory system strengthening
9. Capacity and experience with the development/review/assessment of drug quality detection technologies and their application in LMICs
10. Development of monographs for essential medicines without public standards, particularly for medicines on the WHO Access, Watch and Reserve Lists of antibiotics
11. Experience supporting screening for, reporting on, and combating falsified and substandard medicines (locally, regionally, and/or globally)
12. Collaborations in the medicines quality assurance area with international donors, institutions, and initiatives -- such as the World Health Organization (WHO), the World Bank (WB), the Global Fund (GF), the Global Drug Facility (GDF), the Gates Foundation, the New Partnership for Africa's Development (NEPAD) African Medicines Regulatory Harmonization initiative (AMRH), etc
13. Experience supporting the adoption of data standards and integrated regulatory information management to improve transparency, information sharing, and regulatory processes (e.g., marketing authorization and post-marketing surveillance)
14. Contributions to advancing the medicines quality assurance agenda through publications, advocacy, etc.

Please be succinct and precise in your responses (footnotes and/or citations with weblinks to specific documentation or websites are encouraged). Capability Statements should **not exceed 28 pages** total with no more than two pages per any of the above areas of work. Respondents should detail only the areas in which they have organizational experience.

Please note that responding to this RFI will not give any advantage to any organization or individual in any subsequently issued Notice of Funding Opportunity/Request for Proposals, as responses are strictly for information gathering purposes. Therefore responding to this RFI will not preclude any organization from later being able to submit an application/proposal. Issuance

of this RFI does not constitute a Notice of Funding Opportunity/Request for Proposal, which is issued through a separate process. The RFI does not represent any award commitment on the part of the Government, nor does it obligate the Government to pay for costs incurred in the preparation and submission of any comments. Information received as part of this RFI shall become the property of USAID, therefore proprietary information that cannot be shared should not be sent.

This RFI can be downloaded from http://www.grants.gov and http://fbo.gov. Responses should be submitted to USAID via email to IHSIP@usaid.gov with a subject line "RFI-AID-GH-18-MQASSP" no later than the date and time indicated on the first page of this announcement. Please use exclusively the IHSIP@usaid.gov email address.

Thank you for your interest in our program. We look forward to receiving your response.

Sincerely,

Boryana Boncheva
Contracting and Agreement Officer