REQUEST FOR PROPOSAL

FOR

SUPPLIER QUALITY INSPECTIONS

Issuance date: 09th April 2024
Deadline date: 17th April 2024

RFP No: 042024

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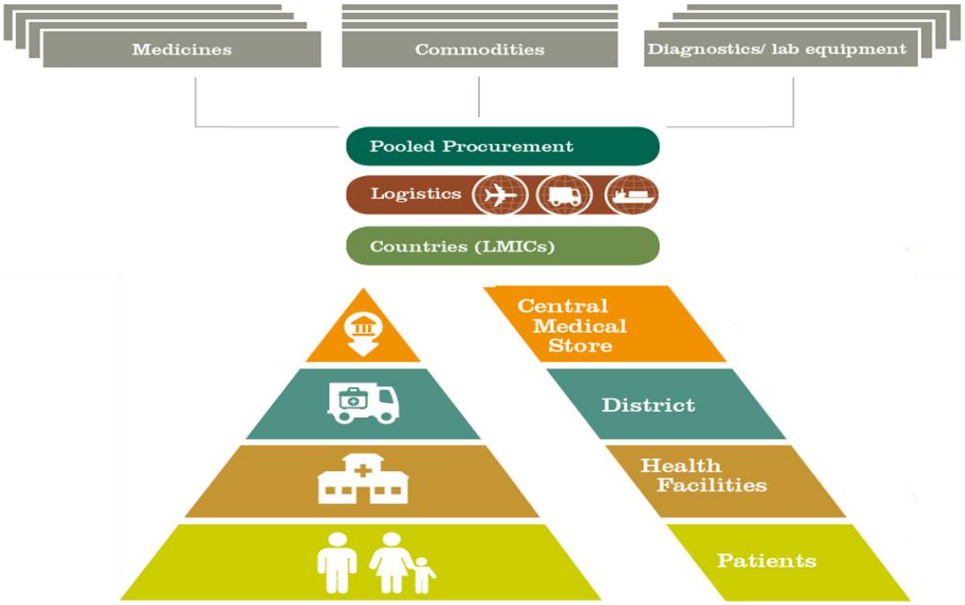
1.0 BACKGROUND OF i+ SOLUTIONS

i+solutions is an independent, international, not-for-profit organization specializing in pharmaceutical supply chain management (SCM) in low and middle income countries. It is i+ solutions' mission to build supply chains that are strong, reliable and ultimately self-sufficient, and support national health systems by using our technical expertise and knowledge. We strive for a world where no medical needs are being unmet.



As a procurement agent, we have a track record of buying high quality, generic medicines at the best possible price. As a supply chain specialist, we support low and middle income countries. Our consultants evaluate loopholes in national health systems and then develop intervention plans, which comprise training programs for healthcare providers, in-house supervision and other capacity-building projects.

i+ solutions is characterized by a multicultural workforce with over 90 employees from 40 countries, representing great diversity in cultural background, country experience, technical and language skills. With extensive experience from within the industry, i+ solutions' current staff include pharmacists, public health professionals, training experts, procurement specialists, capacity building advisors and logistics specialists.

i+ solutions has its head office in the Netherlands and has a representative office in DRC and Burundi. i+ solutions is ISO 9001-2015 certified. This certification covers i+solutions procurement and supply delivery services as well as technical support on project design, implementation and capacity building for low and middle income countries.

Visit our website for more information http://www.iplussolutions.org/

2.0 ABOUT THIS RFP

i+solutions wishes to subcontract with an independent auditing organization that can verify the compliance of our suppliers with the appropriate reference standard (i.e., WHO GMP, GSDP, MQAS, or GLP) as part of the i+solutions prequalification and requalification procedure, as well as ongoing supplier monitoring. The subcontracted organization shall be responsible for providing suitably qualified, trained and experienced inspectors or team of inspectors relevant to the type of audit to be performed. Key responsibilities for the subcontracted organization shall include the following:

1. Coordination of logistics for inspections to be performed;
2. Verification of audit scope, including the inclusion of performance monitoring data provided by i+solutions;
3. Appointing inspectors with appropriate qualifications and experience for the type of supplier audit;
4. Conducting inspections;
5. Preparation of inspection reports;
6. Follow-up of CAPA after inspections;
7. Finalizing inspection reports;
8. Informing i+solutions of the outcome of the inspection.

3.0 OUTPUTS AND DELIVERABLES

The following outputs and deliverables will be expected from the selected organization:

- Audit reports will be issued to supplier within 30 days after completion of the audit
- The organization will follow-up and close out (if applicable) the CAPA initiated by the supplier
- The organization will share recommendations to i+solutions about supplier compliance with corresponding reference standard

4.0 MINIMAL QUALIFICATIONS FOR MQAS AUDITORS

- Minimum: Bachelor's Degree in Process/Industrial Engineering, Pharmaceutical Manufacturing, Pharmacy or Pharmacology, Microbiology, Chemistry, Biochemistry or related science.
- Minimum of 5 years of experience performing MQAS audits and related inspections in pharmaceutical manufacturing (GMP), quality management systems, good storage and distribution practices (GSDP), and quality control testing.
- Demonstrated experience and knowledge of quality assurance systems for procurement of pharmaceuticals and health other commodities, including the requirements of the MQAS guidance document WHO Technical Report Series No. 986, 2014
- Demonstrated experience and knowledge of market authorization regulations and mechanisms for prequalification of health commodities in compliance with MQAS guidance document WHO Technical Report Series No. 986, 2014
- Demonstrated experience and knowledge of quality assurance systems for the storage and distribution of pharmaceuticals and health other commodities, including the requirements of the WHO GSDP guidance document Annex 7, WHO Technical Report Series, no. 1025.
- Knowledge of the international pharmaceutical and medical supply market, with specific reference to the commodities required for HIV/AIDS, Malaria and Tuberculosis prevention, treatment and care.
- Strong interpersonal skills and an ability to work across disciplines and in diverse locations internationally.
- Strong analytical, problem-solving, and communication skills
- Fluency in English.
- Executive-level computing skills in standard software systems, such as Microsoft Word, Excel, PowerPoint, and Project.
- Ability to travel, as needed.

5.0 MINIMAL QUALIFICATIONS FOR GSDP AUDITORS

- Minimum: Bachelor's Degree in Process/Industrial Engineering, Supply Chain or Logistics Management, Pharmaceutical Manufacturing, Pharmacy or Pharmacology, Microbiology, Chemistry, Biochemistry or related science.
- Minimum of 5 years of experience performing GSDP audits and/or related inspections in pharmaceutical manufacturing (GMP), quality management systems, or MQAS.
- Demonstrated experience and knowledge of quality assurance systems for the storage and distribution of pharmaceuticals and health other commodities, including the requirements of the WHO GSDP guidance document Annex 7, WHO Technical Report Series, no. 1025.
- Knowledge of the EMA and EU Directives, MHRA and UK regulations, and WHO GSDP guidelines for the appropriate storage and distribution of health commodities (Note: previous regulatory authority experience preferred).
- Knowledge of the international pharmaceutical and medical supply market, with specific reference to the commodities required for HIV/AIDS, Malaria and Tuberculosis prevention, treatment and care.
- Strong interpersonal skills and an ability to work across disciplines and in diverse locations internationally.
- Strong analytical, problem-solving, and communication skills
- Fluency in English.
- Executive-level computing skills in standard software systems, such as Microsoft Word, Excel, PowerPoint, and Project.
- Ability to travel, as needed.

6.0 MINIMAL QUALFICATIONS FOR GMP AUDITORS

- Minimum: Bachelor's Degree in Process/Industrial Engineering, Pharmaceutical Manufacturing, Pharmacy or Pharmacology, Microbiology, Chemistry, Biochemistry or related science.
- Minimum of 5 years of experience performing inspections of pharmaceutical manufacturers for compliance with GMP, plus experience with auditing quality management systems, quality control testing, and good storage and distribution practices.
- Demonstrated experience and knowledge of quality assurance systems for the manufacture pharmaceuticals and health other commodities, including the requirements of the WHO GMP for Pharmaceutical Products: Main Principles Annex 2, WHO Technical Report Series 986, 2014, and related guidance documents.
- Knowledge of the EMA and EU Directives, MHRA and FDA regulations, and WHO best practices guidelines for the manufacture, storage and distribution of health commodities (Note: previous regulatory authority experience preferred).
- Knowledge of the international pharmaceutical and medical supply market, with specific reference to the commodities required for HIV/AIDS, Malaria and Tuberculosis prevention, treatment and care.
- Strong interpersonal skills and an ability to work across disciplines and in diverse locations internationally.
- Strong analytical, problem-solving, and communication skills
- Fluency in English.
- Executive-level computing skills in standard software systems, such as Microsoft Word, Excel, PowerPoint, and Project.
- Ability to travel, as needed.

7.0 MINIMAL QUALIFICATIONS FOR GLP AUDITORS

1. Minimum: Bachelor's Degree in Microbiology, Chemistry, Biochemistry or related science.
2. Minimum of 5 years of experience working in and/or performing inspections of quality control testing laboratories for compliance with ISO 17025:2017 (Note: previous regulatory authority experience preferred).
3. Demonstrated experience and knowledge of the quality control testing methods and specifications used to analyze pharmaceuticals for compliance with the corresponding compendia (USP, BP, etc.)
4. Demonstrated experience and knowledge of the guidance document WHO good practices for pharmaceutical quality control laboratories, WHO Technical Report Series, No. 957, 2010
5. Knowledge of the international pharmaceutical and medical supply market, with specific reference to the commodities required for HIV/AIDS, Malaria and Tuberculosis prevention, treatment and care.
6. Strong interpersonal skills and an ability to work across disciplines and in diverse locations internationally.
7. Strong analytical, problem-solving, and communication skills
8. Fluency in English.
9. Executive-level computing skills in standard software systems, such as Microsoft Word, Excel, PowerPoint, and Project.
10. Ability to travel, as needed.

8.0 BIDDER REQUIREMENTS

Interested subcontractors should submit the following information to i+solutions for evaluation:

a.) Letter of interest
b.) Summary statement of organizational experience
c.) Procedures for hiring and onboarding new auditors
d.) CVs of proposed inspectors relevant to this RFP (i.e., MQAS, GSDP, GMP and GLP)
e.) History of audits performed by each inspector/submitting organization
f.) Process describing for each steps and actions related to the audit, including but not limited to audit planning, audit preparations, conducting audits, audit closure, etc.
g.) Example checklist and audit report template used by inspectors for the relevant inspection ((i.e., MQAS, GSDP, GMP and GLP)
h.) Example of a full audit report for the relevant inspection ((i.e., MQAS, GSDP, GMP and GLP) for an audit conducted over the past 3 years.
i.) Cost in USD by completing the below table:

Item Number	Description	Cost in USD
1	On-Site Inspection Day (cost/day)	
2	Travel Day (cost/day)	
3	Inspection Report Writing (cost/per report)	
4	Review of Vendor Corrective Action Plans (cost/plan)	
5	Additional Costs (if applicable, please describe)	

i+solutions shall review all documentation received before awards are made. A formal agreement for the performance of work and terms of reference shall be in place before commencement of work by contracted inspectors, provided that there is no conflict of interests and that all confidentiality undertakings are agreed upon and maintained.

Should any bidder's stated capabilities demonstrated during the course of this RFP to provide the requirements be found to be misrepresented later during contract execution, i+ solutions, at its sole discretion, will have the right to terminate any resulting agreement with immediate effect.

9.0 SUBMISSION OF OFFERS

Responses to this RFP shall be sent electronically via e-mail to: tender@iplussolutions.org, with cc to bvlietstra@iplussolutions.org.

Offers received after the closure date will **NOT** be considered. Any Proposal may be modified or withdrawn prior to the deadline. Any modification received after the deadline shall be deemed late and will **NOT** be considered.

Refer to the tender timetable below for timelines for each tender event.

Date	Time	Tender Event
09th April 2024	1000hrs CET	RFP release date
11th April 2024	1700hrs CET	Deadline for request for clarifications on the RFP
12th April 2024	1700hrs CET	i+ solutions' response to requests for clarifications of RFP
17th April 2024	1700hrs CET	Deadline for submission of bidder's proposals

Award Process

a) **Right to Accept or Reject any or All Offers**

i+ solutions reserves the right to accept or reject any offer, or cancel this entire RFP or part of the RFP and reject all offers at any time without thereby incurring any liability to the affected offeror. Information relating to the examination, clarification, evaluation of responses shall not be disclosed to responders, or any other persons not officially concerned with this process.

Any effort by the responder to influence i+ solutions or any of its employees in the evaluation, bid comparison, may result in the rejection of the offer.

b) **Clarification of Offers:**

During evaluation of the offers, i+ solutions may, at its discretion, ask for a clarification of the responses.

c) **Negotiations**

- Negotiations will be conducted fairly and with all offerors in the competitive range. An offer is in the competitive range unless it is technically inferior or out of line with regard to price that meaningful negotiations are precluded, or, that there is no possibility that it can be improved to the point where it becomes acceptable.
- Offerors that are not within the competitive range will be notified by i+ solutions.
- Offerors that fail to provide the requested information in this RFP and are not falling within the competitive range will be notified by i+ solutions

d) **Notification to Unsuccessful Offerors**

Upon issuance of an award, i+ solutions will promptly notify each unsuccessful offeror. If, after an award is made, offerors wish to ascertain the grounds on which their offer was not selected, they may address their request to tender@iplussolutions.org within two days after notification.

e) Contract type and Period of Performance

- The contract awarded will be a Long Term Supply Agreement with call off orders for an initial period of two years subject to renewal depending on performance. During this period i+solutions will periodically benchmark prices to ascertain value for money.