

USAID GHSC – PSM

Annex 7 – Additional Technical Information

SPECIAL CONTRACT TERMS AND CONDITIONS FOR QUALITY ASSURANCE TESTING AND INSPECTION

- A.** Unless otherwise specified in the Subcontract, the vendor will be responsible for the performance of all sampling and testing requirements specified herein. The vendor shall coordinate with GHSC-PSM's Quality Assurance (QA) contractor, SGS, who will implement sampling, QA testing and acceptance within the terms and conditions outlined below.
- B.** If/when deemed necessary and appropriate, Buyer may by written notice to Manufacturer require pre-delivery sampling, inspection and testing of the Goods including, without limitation, physical inspections of the production, warehousing and other facilities involved, the product packaging and labeling; inspection and review of manufacturing records, Certificates of Analysis, analytical reports and documentation; and product sampling and testing by an independent testing facility. In such cases, Vendor will cooperate fully with USAID | GHSC-PSM, the Sampling Agent and the testing facility and take such steps and supply such information as may be needed in order to ensure timely and effective quality assurance.

USAID | GHSC – PSM shall have the right to sample, inspect, and test the Goods at the time(s) and location(s) indicated in the Order Form. In addition, Buyer shall have the right to sample, inspect, and test pharmaceuticals, Long Lasting Insecticide treated Nets, diagnostics and other health commodities in course of their manufacture and packaging.

- C.** Vendor shall provide all reasonable facilities for such sampling, inspection and testing at no cost to USAID| GHSC– PSM. Buyer and USAID| GHSC– PSM may request that samples of each lot be shipped by the vendor to a designated laboratory for analysis.
- D.** USAID | GHSC – PSM Will use its best efforts to complete sampling, testing and inspection as promptly as possible after the Goods are made available.
- E.** USAID | GHSC – PSM may also direct post-delivery sampling, testing, and/or inspection of the Goods at any point in the chain of supply and distribution when it deems such action to be in the best interests of the Government. Manufacturer will fully cooperate with such measures as well. Prompt removal and replacement or correction (as applicable), for purposes of FAR 52.246-2 (g) and (h) shall be deemed, unless otherwise subsequently agreed by Buyer, to mean (10) business days after receiving notification of rejection of Goods or Services.
- F.** Vendor shall provide Buyer all information and documentation reasonably requested and shall render any other assistance reasonably requested, to enable USAID | GHSC- PSM or its collaborators to:
- 1- If the product is not registered in the destination country, the vendor should clarify its intent to register the product and/or provide any relevant information as it relates to the regulatory status in the destination country.
 - 2- Obtain from any regulatory authority authorization to import or waiver.
 - 3- Comply with any of its legal, regulatory and/or contractual obligations or any request by any regulatory authority; and

USAID GHSC – PSM

- 4- Determine whether the services have been performed in accordance with this Agreement.
- G.** Vendor shall notify USAID | GHSC – PSM when major variations to product dossiers are planned. Vendor shall coordinate and manage submission of major variations in collaboration with Buyer and provide information and documentation reasonably requested to maintain product local regulatory approval in country
- H.** If Sampling or Testing reveal that goods are not in compliance and goods are deemed out of specification (OOS), the vendor must perform an OOS investigation and if required, submit to GHSC-PSM a robust corrective and preventive action (CAPA) plan addressing root cause(s) of the noncompliance issues. Each non-compliance issue shall be reviewed individually and GHSC – PSM may work together with the vendor to resolve the matter. GHSC – PSM reserves the right to review and/or approve the investigation report and the corresponding CAPA plan. The related costs to remediate each non-conformance shall be the responsibility of the vendor, including but not limited to order cancelation, replacement of goods, additional sampling and testing, product recalls and other remedial actions.
- I.** Any systematic or isolated non-conformance or compliance gap that may directly or indirectly affect patient safety, product quality, purity, efficacy, integrity, or where there is a data integrity, validity of data and/or an ethical violation then that finding shall be considered a significant finding. In the event that Vendor or Buyer becomes aware of any issue that could meet the definition of “significant” and substantially affect data integrity, patient safety and/or product quality, USAID | GHSC – PSM shall be entitled to perform audits for cause with limited or no notification.
1. In the event that Vendor becomes aware of any incident that may directly or indirectly affect patient safety, product quality, purity, efficacy, integrity, or where there is a data integrity, validity of data and/or an ethical violation, the incident will be reported to the following GHSC-PSM emails: 1. point of contact for this RFQ; 2. bheiden@ghsc-psm.org. Vendor shall complete an investigation and issue a written report with the a corrective and preventive action (CAPA) plan addressing root cause(s), approved by the designated quality personnel of the Vendor, within twenty (20) business days after the Vendor has been informed or becomes aware of the incident. USAID | GHSC – PSM may work together with Vendor to resolve the matter. USAID | GHSC – PSM reserves the right to review and/or approve the investigation report and corresponding remedial actions.
- J.** Vendor and its subcontractors shall notify USAID | GHSC – PSM in the event of a Regulatory Authority inspection (e.g., Food and Drug Administration, European Medicines Agency, World Health Organization (WHO) or any local equivalent thereof) at the manufacturing sites for the products within seventy two (72 hours) of confirmation of the inspection dates. Vendor shall keep USAID | GHSC – PSM apprised of the outcome of any inspection. Buyer shall provide a copy of any written report or comments, whether written or oral, issued by the Regulatory Authority in connection with, or as a result of, the Regulatory Authority inspection within 5 days of Vendor receipt. In all circumstances where a warning letter, notice of concern, consent decree or other enforcement activity is issued by the Regulatory Authority and/or WHO, Vendor or its subcontractors will provide a copy within 48 hours of such letter to USAID | GHSC – PSM. USAID

USAID GHSC – PSM

| GHSC – PSM shall have the right to request to review any responses, whether written or oral, provided by the Vendor to the Regulatory Authority and/or WHO in response to inspection results if such responses concern the products.

All notifications regarding audit, inspection and quality related issues should be made to the following GHSC-PSM emails: 1. point of contact for this RFQ; 2. bheiden@ghsc-psm.org.

- K.** As per GMP requirements vendor is required to retain reference samples in its finished primary packing for at least one year after the expiry date. Additionally, the vendor's chemical and physical test data shall be on record for each batch shipped to GHSC-PSM and shall be available to GHSC-PSM upon request for a length of time equal to five (5) years from the time of acceptance.
- L.** Buyer may, at its sole discretion
- (1) require vendor to provide manufacturer's reference substances if testing is performed as per manufacturer's method.
 - (2) require Vendor to repair or replace any nonconforming Goods, or re-perform of any nonconforming Services, at no increase in the Contract Price, and with all additional costs, including those arising from the handling and disposition of the non-conforming Goods and the sampling, inspection and testing of replacement Goods, for the account of Vendor; and/or
 - (3) exercise any other rights and remedies available to it under the Contract, or under applicable law and regulation, including, but not limited to, termination of the Contract, call of performance security, and/or assessment of excess re-procurement and other resulting costs.

Buyer will use its best efforts to exercise the foregoing rights within a reasonable time after a nonconformity is discovered and, to the maximum extent practicable, before any substantial change occurs in the condition of the non-conforming Goods, unless such change is due to their nonconformity.

- M.** Without prejudice to the foregoing, FAR 52.246-2, INSPECTION OF SUPPLIES -- FIXED-PRICE (AUG 1996), and FAR52.246-16, RESPONSIBILITY FOR SUPPLIES (APR 1984), shall apply to the Contract. Pursuant to these provisions—

Only Goods that have successfully passed testing may be deemed to be ready for delivery in accordance with Article 12. Quality Assurance Testing, Inspection and Acceptance under the current GHSC-PSM GCTC.