KENYA MEDICAL SUPPLIES AUTHORITY

Commercial Street, Industrial Area
P.O. Box 47715, 00100 GPO,
Nairobi, Kenya

KENYA MEDICAL SUPPLIES AUTHORITY — YOUR PARTNER IN HEALTHCARE

Tel: +254 20 3922000, Fax:+254 203922400
GSM +254 719 033000, +254 733 606600
Email: info@kemsa.co.ke

All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/ GF ATM-TB/2023 **Date: 13th March, 2023**

CLARIFICATION 1:

Attn.: All Prospective Bidders

RE: TENDER NO.: GF ATM TB (RSSH) NFM- 2022/2023 OIT - 05 SUPPLY, INSTALLATION, COMMISSIONING AND TRAINING OF RAMAN SPECTROSCOPY

In accordance with ITT Clause 7.1 (Clarification of Tendering Document) of the Open International Tender (OIT) issued under the above reference, we hereby respond to queries raised by prospective bidders:

Queries

1. Incoterms are DAP – We confirm that this means KEMSA will handle ALL customs procedures and pay for clearing charges and applicable import taxes and duties.

Response:

Commodities being procured under GF ATM grant are free of local taxes and duties. The Purchaser will facilitate the tax exemptions upon receipt of the required documentation from the supplier. Please refer to the tender document, page 71,

2. Tender Data Sheet Clause ITT 16.3(b) states: "each Health product offered, documentary evidence demonstrating that such product has been manufactured in accordance with the latest publicly available monographs and that the finished product meets the standards as described in any of the following pharmacopoeia:

I. International Pharmacopoeia II. British Pharmacopoeia III. United States Pharmacopeia IV. European Pharmacopoeia V. Manufacturers Specifications VI. Any other Pharmacopoeia recognized by the PPB and documentary evidence demonstrating that such product meets one of the above standards must be provided"
The Raman instrument is not classified as a health product. It Is an investigative analytical equipment. It is not hence manufacturer to a pharmacopeia standard, But is mentioned in the Pharmacopeia as a applicable instrument for Raw material identification. Please confirm we should submit information showing our Raman instruments meets guidance set in Pharmacopeia.

Response:

All the above are not applicable. Please stick to the technical specifications and the evaluation criteria.

Query

3. SPECIFIC EVALUATION CRITERIA- B) TECHNICAL EVALUATION states we should provide: Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. Please confirm we can submit ISO certificate for Manufacturer and CE certificate for product as ISO certificated are not product specific but given to Company as whole.

Response:

Adhere to technical specifications. Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific.

Query

4. SPECIFIC EVALUATION CRITERIA- F) PAST PERFORMANCE. We are not clear if we are to submit any documentation for this section. Please advise what is required of us.

Response:

No documents required and the section is for your information. The tool is for purposes of measuring performance of contracted suppliers.

Query

5. FORM ELI 1.1 – Section 14 & 15 – I believe these apply to suppliers of pharmaceutical drugs/ medicines/ drug inputs etc. As mentioned this tender is for an investigative equipment and not subject to health authority registration. Please confirm we can put " NOT APPLICABLE " in these sections FORM ELI 1.1 – Section 16 to 28. We believe these are applicable to Manufacturers of Pharmaceutical drug/ raw materials/ drug inputs. As mentioned this tender is for an investigative equipment manufacturered by Equipment device manufacturers that are not subject to WHO/ health regulation. Raw material are electronic in nature. Please confirm we can put " NOT APPLICABLE " in these sections 6. TECHNICAL SPECIFICATIONS HEALTH PRODUCTS (pg 89-91) – sections Certificates/ . Standards of Quality Assurance for Supply/ General/ Labelling Instructions/ Bar coding The requirements listed here are again for health products which the Raman Analyser is not.

Response:

All the above is not applicable.

Query

For part 4 certificates – please confirm ISO of manufacturer is sufficient . For other sections, please advise what you would like us to submit for equipment, or if this section is Not applicable.

Response:

Adhere to technical specifications. Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific.

Question

There is a tender out for the Raman system and I am writing to enquire about the intended use so that I am able to quote the right configuration.

This system is basically for identifying of pharmaceutical raw materials.

I would like to know the types of pharma raw materials they need to identify as well as the packaging of these raw materials.

Response:

The equipment will be used mainly for identification and quantification of finished pharmaceutical products (FPPs)

Yours faithfully,

fr. **Dr. Justus Kinoti (Ph.D)**
Ag. DIRECTOR, PROCUREMENT
FOR: CHIEF EXECUTIVE OFFICER