BOTSWANA VACCINE INSTITUTE

EXPRESSION OF INTEREST (EOI)

1. EXPRESSION OF INTEREST FOR THE SUPPLY & INSTALLATION OF ULTRA-LOW FREEZERS

1.1. Background

Botswana Vaccine Institute Limited (BVI) is a public company incorporated with limited liability according to the laws of Botswana on the 5th December 1979. BVI is a company wholly owned by the Botswana Government, mandated to manufacture livestock vaccines with specific focus on vaccines with economically devastating effects such as foot and mouth disease (FMD). The Company is controlled by a Board of Directors which is appointed by the Minister of Agricultural Development and Food Security (MADFS).

1.2. Purpose

Botswana Vaccine Institute limited (BVI) is in the process procuring ultralow freezers (minus 80 degrees) for the purposes of storing pharmaceutical reagents and products at its site in Gaborone.

The BVI limited wishes to invite 100% citizen owned companies/ manufacturers/ authorised suppliers dealing with medical and pharmaceutical equipment to submit Expression of Interest (EOI) to **Supply and Install Ultra-Low Freezers** and must fulfil the stated pre-qualification requirements below.

1.3. High Level Specifications

1.3.1. Ultra-Low temperature freezers
1.3.2. Vertical Units
1.3.3. Capacity ≥ 740 Litres
1.3.4. Temperature range: Ambient to -80°C
1.3.5. At least 3 Inner doors

1.4. Prequalification Requirements

1.4.1. Evidence or proof of being a manufacturer and or authorized dealer of the Ultra-Low temperature
1.4.2. Commitment and capacity to provide the post installation service,maintenance and calibration support.
1.4.3. Verifiable evidence of similar jobs successfully executed in the past.
1.4.4. Reference letter from the bank demonstrating the financial capability of the vendor to supply this equipment.
1.4.5. Be registered with the Public Procurement and Asset Disposal Board (PPADB) in the following categories:
1.4.5.1. **CODE: 202, Medical Supplies and Related Equipment**
1.4.5.2. **Sub-code: 04 - Medical Devices, Consumables and Laboratory Reagents**

BVI will pre-qualify service providers based on assessment of the received EOI, using the information requested above. The short-listed service providers would then be invited to tender for the services by responding to the detailed invitation to tender (ITT).

1.5. Submission

Applicants are expected to submit by hand **one (1) original copy** and four (4) copies of Expression of Interest proposals in sealed envelopes clearly labelled **SUPPLY AND INSTALLATION OF ULTRA-LOW TEMPERATURES FREEZERS on 4th December 2021 at 10:00 Hours.**

2. EXPRESSION OF INTEREST FOR THE SUPPLY & INSTALLATION OF HIGH-SPEED CENTRIFUGE

2.1. Purpose

Botswana Vaccine Institute Limited (BVI) is in the process of procuring refrigerated tissue culture centrifuge at its site in Gaborone.

The BVI limited wishes to invite 100% citizen owned companies/ manufacturers/ authorised suppliers dealing with medical and pharmaceutical equipment to submit Expression of Interest (EOI) to **Supply and Install Refrigerated Tissue Culture Centrifuge** which fulfills the stated pre-qualification requirements below.

2.2. High Level Specifications

2.3.1. Refrigerated cell culture centrifuge
2.3.2. Cell culture floor or benchtop model
2.3.3. Swinging bucket -rotor, Buckets, 1000L round bottomed Nalgene Bottles

2.4. Prequalification Requirements

2.4.1. Evidence or proof of being a manufacturer and or authorized dealer of the refrigerated tissue culture centrifuge.
2.4.2. Commitment and capacity to provide the post installation service and calibration support.
2.4.3. Verifiable evidence of similar jobs successfully executed in the past.
2.4.4. Reference letter from the bank demonstrating the financial capability of the vendor to supply this equipment.
2.4.5. Be registered with the Public Procurement and Asset Disposal Board (PPADB) in the following categories:
2.4.5.1. **CODE: 202, Medical Supplies and Related Equipment**
2.4.5.2. **Sub-code: 04 - Medical Devices, Consumables and Laboratory Reagents**

BVI will pre-qualify service providers based on assessment of the received EOI, using the information requested above. The short-listed service providers would then be invited to tender for the services by responding to the detailed invitation to tender (ITT).

2.5. Submission

Applicants are expected to submit by hand **one (1) original copy** and four (4) copies of Expression of Interest proposals in sealed envelopes clearly labelled **SUPPLY AND INSTALLATION OF REFRIDGERATED TISSUE CULTURE on 4th December 2021 at 10:00 Hours.**

3. CONSULTANCY SERVICES FOR IMPLEMENTATION AND ACCREDITATION TO LABORATORY MANAGEMENT (ISO 17025:2017)

3.1. Purpose

BVI is implementing the requirements of Laboratory Management System (ISO/IEC 17025:2017) at its two testing laboratories, being Quality Control (QC) for testing intermediate and final product for compliance to quality standards and the Office International des Epizooties (OIE) laboratory for diagnostic/confirmatory tests against FMD outbreaks locally, regionally and beyond. The Institute seeks to enhance compliance to the above quality standard and therefore improve customer confidence to its products and services.

The BVI Limited therefore wishes to invite 100% citizen owned consultancy firms or individuals with expertise in Quality Management Systems to submit Expression of Interest (EOI) to provide Consultancy Services of assessing the level of its compliance to ISO/IEC 17025:2017 at the two laboratories and guide on the strategy of implementation and obtaining accreditation to the same standard. The consultancy must fulfil the stated **Pre-Qualification** requirements below;

3.2. Pre-Qualification Requirements

The incumbent shall meet the following requirements
3.2.1. Demonstrate competency and experience in the provision of consultancy services for the implementation of ISO/IEC 17025:2017 in a pharmaceutical industry and related sectors
3.2.2. Be in possession of a valid and appropriate Tax Clearance Certificate or an Exemption thereof
3.3.3. Have an appropriate license for providing the services
3.2.4. Be registered with the Public Procurement and Asset Disposal Board (PPADB) in the following categories:
3.2.4.1. **PPADB Code 317, Other Consulting Services**
3.2.4.2. **Sub Code 01, Management Consulting Services**

3.3. Terms of Reference

3.3.1. Assess the current level of implementation of the ISO/IEC 17025:2017 standard in the OIE/QC laboratories, review resource adequacy and guide on effective implementation strategy
3.3.2. Review the relevant documentation required for BVI laboratories to comply with the requirements of ISO/IEC 17025:2017 accreditation and advise as appropriate.
3.3.3. Conduct internal audits, guide and capacitate staff to do the same and to implement corrective and preventive actions in preparation for accreditation.
3.3.4. Conduct at least two (2) Management Review Meetings and have them documented.
3.3.5. Facilitate the application for ISO/IEC 17025:2017 accreditation.

3.4. Expected Deliverable

3.4.1. Technical report on the assessment of the level of implementation of the management system indicating the needed capacities to enable the laboratories to be eligible for ISO/IEC 17025:2017 accreditation process
3.4.2. Employees bench-trained and competent in implementing QMS in accordance with ISO/IEC 17025:2017
3.4.3. Document detailing the accreditation programme, communication plan and budget for implementation
3.4.4. Reviewed QMS Manual, standard operating procedures, log books and other related documentation
3.4.5. Complete records for internal audit including schedules, audit reports, CAPA and evidence of closure of non-conformances.
3.4.6. Complete records of management review meetings that are compliant to the ISO/IEC 17025:2017 accreditation process
3.4.7. Successful accreditation to ISO/IEC 17025:217 requirements.

BVI will pre-qualify service providers based on assessment of the received EOI, using the information requested above. The short-listed service providers would then be invited to tender for the services by responding to the detailed invitation to tender (ITT).

3.5. Submission

Applicants are expected to submit by hand **one (1) original copy** and four (4) copies of Expression of Interest proposals in sealed envelopes clearly labelled **PROVIDE CONSULTANCY SERVICES FOR IMPLEMENTATION AND ACCREDITATION TO LABORATORY MANAGEMENT (ISO/IEC 17025:2017) on 4th December 2021 at 14:00 Hours.**

4. CONSULTANCY SERVICES FOR THE IMPLEMENTATION AND CERTIFICATION TO GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS.

4.1. Purpose

BVI is implementing the requirements of European Union (EU) Guidelines to Good Manufacturing Practice (GMP) at its Manufacturing laboratories, testing Laboratories as well as supporting units. The Institute seeks to enhance compliance to the above quality standard and therefore improve customer confidence to its processes, products and services.

The BVI Limited therefore wishes to invite 100% citizen owned consultancy firms or individuals with expertise in guiding implementation of Quality Management Systems in pharmaceutical and related sectors to submit Expression of Interest (EOI) to provide Consultancy Services. The services shall include but not limited to assessing the level of its compliance to EU Guidelines to GMP requirements and guiding on the strategy of implementation until certification to the same standard. The consultant must fulfil the stated **Pre-Qualification** requirements below;

4.2. Pre-Qualification Requirements

The incumbent shall meet the following requirements
4.2.1. Demonstrate competency and experience in the provision of consultancy services for the implementation of EU Guidelines to GMP in a Pharmaceutical Industry and related sectors
4.2.2. Be in possession of a valid and appropriate tax clearance certificate or an exemption thereof
4.2.3. Have an appropriate license for providing the services
4.2.4. Be registered with the Public Procurement and Asset Disposal Board (PPADB) in the following categories:
4.4.1. **PPADB Code 317, Other Consulting Services**
4.4.2. **Sub Code 01, Management Consulting Services**

4.3. Terms of Reference

4.3.1. Assess the current level of implementation of EU Guidelines to GMP requirements at the production laboratories and supporting departments, review resource adequacy and guide on effective strategy to address identified gaps.
4.3.2. Review documentation required for BVI laboratories to comply with the requirements of certification to EU Guidelines to GMP requirements.
4.3.3. Train laboratory and relevant support staff on the implementation GMP and related documentations in compliance to certification.
4.3.4. Conduct self-assessment/internal audits and capacitate staff to do the same and to implement corrective and preventive actions in preparation for certification
4.3.5. Conduct at least two (2) Management Review Meetings and have them documented.
4.3.6. Apply for certification to EU Guidelines to GMP requirements

4.4. Expected Deliverables

4.4.1. Technical report on the assessment of the level of implementation of the EU Guidelines to GMP requirements indicating the needed capacities to enable the laboratories to be eligible for certification process.
4.4.2. Employees trained and competent in implementing EU Guidelines to GMP requirements
4.4.3. Document detailing the certification programme,communication plan and budget for implementation
4.4.4. GMP Manual, management system procedures, standard operating procedures, worksheets, log books and other related documentation
4.4.5. Complete records of self-assessments including schedules, audit reports, Corrective and Preventive Actions and evidence of closure of non-conformities.
4.4.5. Complete records of management review meetings that are compliant to the EU Guidelines GMP requirements
4.4.6. Completed application for certification, with application scope determined
4.4.7. Certificate of compliance ton EU Guidelines to GMP

BVI will pre-qualify service providers based on assessment of the received EOI, using the information requested above. The short-listed service providers would then be invited to tender for the services by responding to the detailed invitation to tender (ITT).

4.5. Submission

Applicants are expected to submit by hand **one (1) original copy** and four (4) copies of Expression of Interest proposals in sealed envelopes clearly labelled **CONSULTANCY SERVICES FOR THE IMPLEMENTATION AND CERTIFICATION TO GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS on 15th December 2021 at 10:00 Hours.**

5. CONSULTANCY SERVICES FOR DEVELOPMENT OF VACCINE REGISTRATION DOSSIERS

5.1. Purpose

Current market requirements for sale of livestock vaccines and medicines require that products must be registered in each territory within which the products are sold. BVI is desirous to develop registration dossiers for its various vaccine products to enable registration in the global market.

Botswana Vaccine Institute wishes to invite local as well as international experts in the pharmaceutical regulatory public affairs and regulatory environment field to support the development and registration of BVI vaccine products to submit Expression of Interest (EOI) to **Provide Consultancy Services for Development of Vaccine Registration Dossiers** and must fulfil the stated **Pre-Qualification** requirements below.

5.2. Consultant Experience

The incumbent shall meet the following requirements:
5.2.1. Shall have at least 8 years' professional experience working within a pharmaceutical regulatory public affairs and regulatory environment with specific experience in registration and market authorisation procedures for veterinary vaccines.
5.2.2. Shall have a very good understanding of industrial operations in vaccines research and development, production and clinical quality control.
5.2.3. An understanding of the regulatory environment within the African context will be an added advantage.

5.3. Terms of Reference

5.3.1. To develop Vaccine Registration Dossiers for the inactivated, purified FMD vaccines for Market Authorisations in Botswana, Tanzania and Uganda.
5.3.2. To review and refine the Vaccine Registration Dossier for the Thermotolerant freeze dried live vaccine against Pest des Petits Ruminants (PPR T-VAC) for Market Authorisation in Botswana and East Africa.
5.3.3. To development a framework for registration dossiers for other existing BVI products (Contagious Bovine Pleuropneumonia, Anthrax and Blackleg) and other new products to be developed in the future.

5.4. Expected Deliverables

5.4.1. A properly documented Method Statement with clearly defined timelines and outputs.
5.4.2. Approved Market Authorisations for Foot-and-Mouth Disease (Aftovax & Aftovaxpur) and Peste des Petit Ruminants (PPR T-VAC) BVI vaccines.
5.4.3. A documented framework for developing registration dossiers for other existing BVI products.

BVI will pre-qualify service providers based on assessment of the received EOI, using the information requested above. The short-listed service providers would then be invited to tender for the services by responding to the detailed invitation to tender (ITT).

5.5. Submission

Applicants are expected to submit by hand **one (1) original copy** and four (4) copies of Expression of Interest proposals in sealed envelopes clearly labelled **PROVIDE CONSULTANCY SERVICES FOR THE DEVELOPMENT OF VACCINE REGISTRATION DOSSIERS on 15th December 2021 at 10:00 Hours for international based Consultants, documents may be emailed to procurement@bvi.co.bw.**

Important Notice

This is not an invitation to tender. A full tendering process will be followed to invite potential suppliers prequalified and found to be capable of executing this project. Only successful applicants will be contacted for the tendering process Nothing in this advert shall be construed to be a commitment on the part of BVI. Clarifications pertaining to this call for Expression of Interest may be obtained from the Procurement and Supplies Department during working hours from 0730hours to 1600hours at procurement@bvi.co.bw; Tel: **+267 3912711**, Fax: **+267 3986798**