

EXPRESSIONS OF INTEREST (EOI)

Sri Lanka Institute of Biotechnology

Procurement of Consultation Service for ISO 37301-Compliance Management Systems

Development and Implementation at SLIBTEC Innovation Park

CONTRACT NO: SLIBTEC/PROC/255/Consultancy/ Procurement of Consultation Service for ISO 37301- Compliance Management Systems Development and Implementation at SLIBTEC Innovation Park

1. **The Sri Lanka Institute of Biotechnology (SLIBTEC) Park at Mahenwatte, Thalagala Road, Pitipana, Homagama**, is part of Sri Lanka's first Biotechnology Innovation Park, aiming to position the country as a regional biotechnology hub. SLIBTEC was incorporated in October 2020 as a government-owned entity, Secretary to the treasury as the sole shareholder.

This document outlines the specifications for the procurement of the services of a consultant to assist SLIBTEC Innovation Park in the development and implementation of ISO 37301-Compliance Management Systems (CMS). The consultant shall be responsible for gap analysis, system development and implementation of the process with relevant controls and monitoring the CMS including documentation, conduct training to facilitate knowledge transfer, conducting internal audits, complete the documentation and implementation of the CMS, providing certification audit support and post-certification support and all other support relevant to ISO 37301 development and implementation at SLIBTEC Innovation Park.

2. The designated firm/ personnel should mainly include but not limited to project leadership & management expertise, sound technical knowledge in ISO 37301 & compliance expertise, risk & governance expertise, legal & regulatory expertise, industry specific expertise, training & change management expertise, internal audit expertise. Any other additional experts may be included as requirements arises to achieve the objectives specified in the TOR.
3. The scope of the consultancy service comprises of; (All procedures shall comply with applicable government/ local government rules and regulations)

3.1 Gap analysis

- i. Conduct a comprehensive gap analysis to identify the strengths and deficiencies of SLIBTEC Innovation Park with ISO 37301 requirements before consultation commences.
- ii. Provide a detailed report outlining the findings of the gap analysis and recommendations for the implementation of ISO 37301 at the SLIBTEC Innovation Park.

3.2 Development and implementation of the process with relevant controls and monitoring the CMS including documentation

- i. Assist in developing process with relevant controls and monitoring, documenting, and implementing comprehensive CMS at SLIBTEC Innovation Park based on ISO 37301. Provide guidance on establishing relevant policies, procedures, and controls.
- ii. Provide guidance on establishing relevant policies, processes, procedures, controls and monitoring.

- iii. Identify compliance requirements applicable to the current and potential clients of SLIBTEC Innovation Park by reviewing the statutory and regulatory requirements and other obligations relevant to the biotechnology industry and local and exporting markets/countries.
- iv. Ensure that the CMS established is tailor made to the specific needs and context of the SLIBTEC Innovation Park.

3.3 Training- knowledge transfer

- i. Develop and deliver training programs for relevant personnel on ISO 37301 requirements, including awareness training, documentation and implementation training, and internal auditor training.
- ii. Provide training materials and documentation in hard copies and soft copies.

3.4 Internal audits

- i. Provide support in planning, conducting, and documenting internal audits of the CMS at SLIBTEC Innovation Park and its industrial sites. Independence of the internal auditor is paramount.
- ii. Assist in developing internal audit procedures, program and checklists for the SLIBTEC Innovation Park and its industrial sites.
- iii. Provide guidance on taking corrective actions and follow-up activities at SLIBTEC Innovation Park and its industrial sites.

3.5 Complete the documentation and implementation of the CMS

- i. Handover Compliance Management manual, policies, Standard Operating Procedures (SOPs), procedures, formats, and all other relevant documentation to the SLIBTEC. All the documentation should be submitted in hard copies, as well as soft copies to be incorporated with intranet of SLIBTEC.

3.6 Certification audit support

- i. Facilitate and coordinate preparations for the certification audit conducted by an accredited body.
- ii. Guiding for the application submission process
- iii. Provide guidance on documentation requirements and audit logistics.
- iv. Support SLIBTEC Innovation Park during the certification audit.

3.7 Post-certification support

- i. Offer post-certification support, including assistance with annual surveillance audits and recertification audits.

- ii. Provide ongoing guidance on maintaining, improving and updating the CMS.

3.8 Other services

- i. Consultants are requested to detail any additional services they are able to provide.
4. The intended consultancy period is until the completion of project scope mentioned in section 3.
 5. Interested firms/ personnel should provide following information with sufficient proof of documents indicating that the firm/ personnel is qualified to perform the consultancy service according to the given format in the web site www.slibtec.gov.lk/procurement/. The TOR of the consultancy and other information are uploaded in the website for references.
 - a) Company profiles, organization chart, annual reports etc. if available
 - b) Details of similar consultancy assignments successfully completed during last 5 years with client references with the size of consultancy contracts
 - c) Details of available professional staff with their CVs
 - d) Availability of other resources applicable for this assignment
 - e) Any other related information/ documents (i.e. previous experience/ training related to ISO 37301)
 6. Firms/ personnel may associate to enhance their qualifications. Please note that firms/personnel are allowed to participate in only one proposal as a sole consultant, joint venture partner or a sub-consultant.
 7. A firm will be selected using the Quality-Cost Based Selection (QCBS) method, following the procedures outlined in the Guidelines: Selection & Employment of Consultants (August 2007)
 8. Interested firms/ personnel may obtain further information from Sri Lanka Institute of Biotechnology Pvt Ltd, Address: Phase I Building, Mahenwatta, Thalagala Rd, Pitipana, Homagama Attention: Mr. Tharindu Madushankha (Procurement Manager) TP: +94 11 3431844 Monday to Friday, between 9.00 am - 4.30 pm. For more information, please visit www.slibtec.gov.lk
 9. Expression of Interest including all requested information must be delivered in duplicate to the address given below **not later than 2.30 pm on 12th November 2025**. Envelope containing the Expression of Interest should be marked “EOI – ISO 37301 Development and Implementation at SLIBTEC Innovation Park”

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