Terms of Reference (TOR)

Consultation Service for ISO 37301- Compliance Management Systems Development and Implementation at SLIBTEC Innovation Park

1. Background of the assignment

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, with the Secretary to the Treasury as the sole shareholder.

Project rationale

SLIBTEC Park aims to achieve ISO 37301 certification for its Compliance Management Systems (CMS), seeing it as a vital investment for future operations. We expect this system to bring several key benefits: reducing legal risks and reputational harm, improving operational efficiency, strengthening risk management, showcasing our ethical commitment, supporting tenant compliance, enhancing our overall reputation, and preventing financial losses due to non-compliance.

Source of financing

The project is fully financed by the Government of Sri Lanka.

2. Objective of the assignment

The objective of this TOR is to appoint an experienced consultant to develop and implement the ISO 37301-CMS. The consultant shall:

i. Conduct a gap analysis
ii. Development and implementation of the process with relevant controls and monitoring the CMS including documentation
iii. Conduct training to facilitate knowledge transfer
iv. Conduct internal audits
v. Complete the documentation and implementation of the CMS
vi. Support certification audit
vii. Providing post-certification support
viii. Providing all other support relevant to ISO 37301 implementation at SLIBTEC Innovation Park.

3. Scope of consultancy services

The consultant shall provide the following services:

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.

ii. Provide guidance on establishing relevant policies, procedures, and controls.

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 industrial sites. Independence of the internal auditor is paramount.

ii. Assist in developing internal audit checklists and procedures for the SLIBTEC Innovation Park and industrial sites.

iii. Provide guidance on taking corrective actions and follow-up activities at SLIBTEC Innovation Park and industrial sites.

3.5 Complete the documentation and implementation of the CMS

i. Handover CMS 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 and improving and updating the CMS.

3.8 Other services

i. Consultants are requested to detail any additional services they are able to provide.

4. Reports, deliverables, and schedule

4.1 Key documented information

i. CMS manual
ii. Standard Operating Procedures (SOPs)
iii. Procedures
iv. Guidelines and working instruction (WI)
v. Other formats
vi. All other relevant documentation

4.2 Delivery Schedule

Consultants must identify and discuss potential factors that could impact on the project timeline.

Stage	Description	Duration
I	Planning	1m
II	Gap analysis	1m
III	Draft documentation	1.5m
IV	First review of documentation including legal clarifications	2m
V	Amendments as per the review	2 w
VI	Second review of documentation including legal clarifications	1m
VII	Amendments as per the review	2w
VIII	Final review of documentation including legal clearance	1m
IX	Obtaining approval for documentation	2w
X	Implementation stage	1m
XI	Internal Audit	1w
XII	Correcting nonconformities of internal audit	1w
XIII	Applying for the ISO 37301- CMS including a pre-audit	1m
XIV	Certification audit	Depending on the certification body
XV	Correcting nonconformities if identified at certification audit	1w

(m) month/s; (w) week/s

4.3 Total period of performance: Until the implementation of the ISO 37301- CMS and obtaining the certificate

This contract will remain valid until all activities described in the 'scope of the services' (sections 3.1 to 3.8) are completed.

4.4 Pricing and payment

4.4.1 Cost breakdown

i. Consultants must provide a detailed cost breakdown for their services, including separate pricing for each of the following components:

   a. Gap analysis

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

   c. Training- knowledge transfer

   d. Internal audits

   e. Complete the documentation and implementation of the CMS

   f. Certification audit support

g. Post-certification support

h. Other services

4.4.2 Support provided by SLIBTEC

i. Personnel: SLIBTEC staff for coordination and documentation.
ii. Providing venue facilities for training.

4.4.3 Institutional arrangements

i. SLIBTEC ensures project success by overseeing execution and monitoring consultant performance
ii. Consultant responsibilities and reporting lines will be clearly defined.
iii. Regular progress meetings will ensure alignment with objectives.

5. Proposal submission requirements

5.1 Consultant experience and qualifications

5.1.1 Consultant qualifications

i. Consultants must possess relevant qualifications and certification in similar international standards implementation

Key professional staff	**Academic qualification**	**Experience in the proposed role**	**Experience in process improvement studies- no. of similar projects**
Project leadership & management expertise	PhD/ MSc in Biotechnology Management; MBA or equivalent in relevant field from a recognized institution	led to the establishment of multi-tenant research/ industrial facilities	12+ projects. Led the design and implementation of integrated management systems (i.e. ISO 9001, ISO 14001) in reputed companies or government entities
Technical knowledge in ISO implementation & compliance expertise	Lead auditor for any similar ISO standard	15 years' experience in ISO implementation	8+ Projects. Conducted gap analyses and led full scale implementations at reputed companies

Risk & governance expertise	MSc in risk management; CIA (Certified Internal Auditor) or equivalent in relevant field from a recognized institution	8 years focused on enterprise risk management (ERM), particularly within the science and technology sectors/ Expertise in integrating compliance risks into the overall organizational risk framework.	Conducted risk assessment workshops at least for SMEs.
Legal & regulatory expertise	Attorney-at-Law (Sri Lanka)	Specialist in Sri Lankan corporate law/ intellectual property (IP) law/ the regulatory landscape for biotech/ tech startups/research institutions	Past experience in ISO related legal framework in reputed companies or government entities
Industry specific expertise	PhD/ MSc in Molecular Biology; MSc in Technology Entrepreneurship or equivalent in relevant field from a Recognized Institution	Intimate knowledge of the operational, ethical/IP-related compliance challenges faced by biotech and deep-tech startups.	5+ Projects. Experience in lab safety and bioethics compliance protocols for research labs.
Training & change management expertise	Lead auditor/ lead implementor or equivalent in relevant field	Expert in developing engaging training programs for diverse audiences, from scientists to administrators/ Specializes in fostering a culture of compliance and	10+ Projects. Developed and delivered change management and training programs for ISO 9001 and ISO 27001 implementations across various industries, ensuring high adoption rates.

		ethical decision-making.	
Internal audit expertise	Lead auditor for any similar ISO standard	5 years of experience conducting internal audits for management systems/ Specific experience auditing in research and development environments.	20+ Audits. Performed internal audits for ISO 9001, ISO 14001, and ISO 45001 for manufacturing and service companies. Trained over 50 internal auditors.

ii. Detailed Curriculum Vitae (CVs) of the members of the firm/ consultant assigned to the project must be provided.

5.1.2 References

i. Consultants must provide documented references from previous clients, including reputed companies or government entities who have successfully implemented similar international standards with your firm's/your assistance (locally or internationally). *Each project consultancy fee should be over Rs. 0.3 million LKR.*

5.1.3 Confidentiality

i. All information provided by SLIBTEC Innovation Park will be treated as confidential.

ii. Consultants must agree to maintain the confidentiality of all information received during the project.