

REQUEST FOR QUOTATION (RFQ/P)

TERMS OF REFERENCE TO IMPLEMENT AND OFFER TRAINING ON ISO 13485:2003

1. Introduction

The basis of this terms of reference is to give effect to the implementation of Section 9A and 10(1) [a-d] of the National Small Business Amendment Act no. 29 of 2004 dealing with Seda's objectives and functions which enjoin Seda to:

- (a) *design and implement development support programmes;*
 - (b) *promote a service delivery network that increases the contribution of small enterprises to the South African economy, and promotes economic growth, job creation and equity; and*
 - (c) *generally, strengthen the capacity of-*
 - (i) *service providers to support small enterprises; and*
 - (ii) *small enterprises to compete successfully domestically and internationally;"*
- and
- (a) *implement the policy of national government for small enterprise development;*
 - (b) *design and implement a standard national delivery network that must uniformly apply throughout the Republic in respect of small enterprise development, integrating all government-funded small enterprise support agencies across all spheres of government;*
 - (c) *design and implement small enterprise development support programmes; and*
 - (d) *establish provincial structures to ensure the effective implementation of its functions as defined in section 10," respectively.*

2. Background

Seda Technology Programme a division of Seda is inviting proposals from experts in conformity assessment who have in depth knowledge of ISO: 13485:2003 standard (Medical devices - Quality Management Systems Requirement for Regulatory Purposes) and CE- Mark requirement.

These services are urgently needed at our client who is based in the Western Cape and the details are as follows:

Organization	Area	Type of business	Requirement
Life Assay Diagnostics (Pty) Ltd	Muizenburg, Cape Town	Manufacturer and distributor of medical diagnostic devices	ISO 13485:2003 and ISO 9001:2008

*This is an SMME currently employing 6 people.

3. Project objective

To document and implement the above management system in the business of the SMME who is the client of Stp. This documented management system should meet the requirement of the ISO 13485:2003 and the World Health Organization (WHO) and also be certifiable by an international certification body.

This in turn will enable the manufacturer to obtain the necessary CE-Mark. This will enable the client to dominate both the local and international markets

4 Scope of Work

- a) Conduct awareness training on the ISO 9001:2008 and ISO 13485:2003 to the employees of the SMME;
- b) Document the required manual;
- c) Document all applicable policies, procedures, forms and template;
- d) Train internal management system auditors;
- e) Review the documented management system;
- f) Assist the organization through the certification process;
- g) Assist the organization in closing all the findings raised by the certification body;
- h) Instil the culture of good housekeeping in the organization; and
- i) Submit to Seda on 25th of each month a detailed progress report on the project

5 Purpose of assignment

To appoint an Expert in the conformity assessment to implement and train people on ISO 13485: 2003 and ISO 9001:2008 that will enable the SMME to acquire the ISO 13485:2003 Certification and the CE Mark. This being the standard for **Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.**

6 Reporting requirements

The service provider will report to Stp on a monthly basis on the progress of the project.

7 Evaluation of proposal

- Experience
- Price
- Capacity to deliver
- Delivery
- Quality
- HDI

6 Organisation

6.1. Lines of communication

The service provider will work in close collaboration with following Seda staff in the order specified, to ensure effective and efficient implementation of the project.

Contact persons at Seda:

Name	Contact details	Email details
Jerry Skosana	012 441 1106	jskosana@seda.org.za
Malembe Mtsweni (Stp)	012 441 1178	mmtsweni@seda.org.za

8. Proposals

It is required that the service provider submit a written quotation/proposal to Seda of how best the service provider will meet and/or exceed Seda's needs and requirements. The bidder will include in the proposal the following elements:

- a. The full range of services they propose to Seda
- b. Budget breakdown for services proposed
- c. Company profile
- d. The Ownership and Management Structure of the company
- e. The experience of the company in providing their core services
- f. A record and/or list of previous and current clients, especially corporate clients.
- g. Curriculum Vitae (CVs) of the service provider

9. Quotation/Proposal Submission Date:

The deadline for the submission of the quotation/proposal is as follows:

- Date: **19 October, 2011**
 - Time: 16h00 pm
 - Address: **Seda: Small Enterprise Development Agency**
3rd Floor, Block G, the dti Building
Sunnyside
Pretoria,
0007
Telephone: (012) 441-1106
or
Email: jskosana@seda.org.za
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ANNEXURE

Terms and Conditions of this Request:

1. Quotation must be delivered to 2nd Floor Small Enterprise Development Agency, Block G, the dti Building, Sunnyside, and Pretoria or emailed to jskosana@sedaorg.za.
ATT: Jerry Skosana on or before the specified closing date and time.
2. Late quotations **will not** be accepted
3. Company **letterhead** or **stamp reflecting Companies name** and address must appear on all pages of quotation.
4. Correct Quotation/Reference Number must appear on all pages.
5. All pages of **quotation must be signed** by responsible person.
6. Where applicable, price(s) quoted is/are to be **Include Value Added Tax**.
7. **Quotation must reflect cost break down.**
8. **Unless otherwise stated**, quotations will be regarded as being valid to period of **30 days from closing date**.
9. All quotations **must** be accompanied by the following documents: **Valid Tax clearance certificate**

Note: Unsuccessful companies may be considered for registration in the Seda supplier database, provided that the above conditions have been met.

10. The successful Company will also be requested to indicate:
- Whether it is in service of Seda and/or the Department of Trade and Industry(DTI), or has been in the service of Seda and or DTI in the previous twelve months
 - If the provider is not a natural person, whether any of its directors, managers, principal shareholder is in the service of the state, or has been in the service of the state in the previous twelve months
 - Whether a spouse, child or parent of the provider or of a director, manager, shareholder or stakeholder referred to before is in the service of Seda and/or the DTI, or has been in the service of Seda and/or the DTI in the previous twelve months.
 - Complete Declaration of Interest Form - SBD 4
11. Seda has the right to withdraw any quotation at any time within the validity of the quotation.