

Request for Proposals (RFP)

For

The provision of ISO 9001, ISO 13485 consulting and internal auditing services to the CSIR

RFP No. 3450/06/05/2021

Date of Issue	Thursday, 22 April 2021	
Closing Date	Thursday, 06 May 2021 at 16:30	
Place	tender@csir.co.za	
Enquiries	Strategic Procurement Unit	E-mail: tender@csir.co.za
CSIR business hours	08h00 – 16h30	
Category	Professional	

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SECTION A – TECHNICAL INFORMATION

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific research and technology development organisations in Africa. In partnership with national and international research and technology institutions, CSIR undertakes directed and multidisciplinary research and technology innovation that contributes to the improvement of the quality of life of South Africans. The CSIR's main site is in Pretoria while it is represented in other provinces of South Africa through regional offices.

2 BACKGROUND

CSIR's company structure has been revised as of 1 April 2019 in which three divisional structures containing "clusters" were introduced. The Industrial Sensors Impact Area falls under the Manufacturing Cluster in Division 2. Industrial Sensors holds certification in ISO 9001 and ISO 13485, require consulting and internal auditing services to ensure compliance in order to retain this certification.

3 INVITATION FOR PROPOSAL

Proposals are hereby invited for the provision of consulting and internal auditing services against ISO 9001:2015 and ISO 13485:2016 to the CSIR.

4 PROPOSAL SPECIFICATION

All proposals are to be submitted in a format specified in this enquiry (if applicable). However, tenderers are welcome to submit additional / alternative proposals over and above the originally specified format.

The required consulting services will include:

- a) Twice yearly internal auditing of the existing, combined 9001 & 13485 quality management system (QMS) via a combination of physical and virtual audit approaches
- b) Guidance to answer queries relating to ongoing maintenance and development of the QMS as well as assistance with management reviews.
- c) Guidance on regulatory aspects / compliance of medical devices both locally and internationally (e.g. SAHPRA and CE Mark submissions), including guidance around aspects such as vigilance and post-market surveillance.

It is estimated that, in addition to the internal audit requirement of point (a) above, points (b) and (c) will require approximately 20-30 hours a month in ongoing consulting time and quotations should include costs for both the lower and higher of these numbers.

All proposals are to be submitted in a format specified in this RFP (if applicable). However, tenderers are welcome to submit additional / alternative proposals over and above the originally specified format.

Proposals from suitable service providers should cover Certification Audits to both ISO 9001 and ISO 13485:2016 (and any revised versions thereof) with acknowledgment of the following certification schedule:

- 2021 = Renewal Audit
- 2022 = Surveillance Audit
- 2023 = Surveillance Audit
- 2024 = Renewal Audit
- 2025 = Surveillance Audit

Proposals should include all costs and fees, including on-site internal auditing of the full scope of both ISO 9001 and ISO 13485 each year as well as consulting services both on and off site in support of improvements to the quality management system and project specific compliance to that system, taking into account inflation increases over the five year term.

Proposals should indicate the anticipated team members from the tenderer and brief, relevant qualification and experience information on each person.

5 FUNCTIONAL EVALUATION CRITERIA

5.1 The evaluation of the functional / technical detail of the proposal will be based on the following criteria:

#	Functional/Technical criteria	Weight%
1	Previous ISO 9001 and ISO 13485 consulting and auditing experience of the company in years and the number of company certifications successfully secured	20%
2	Examples (evidence & brief details) of previous ISO 9001 and ISO 13485 consulting and auditing cases successfully handled through to certification.	30%
3	Examples (evidence & brief details) of SAHPRA and CE Mark consulting cases handled successfully	20%

4	Staff experience in ISO 9001 and ISO 13485, detailed description of resources, capacity and expertise, including qualifications, experience and affiliations of personnel and examples of companies handled. (N.B. for staff who would handle this contract)	20%
5	A detailed Project Plan with timelines and milestones	10%
	Total	100%

5.2 Proposals with functionality / technical points of less than the pre-determined minimum overall percentage of 70% will be eliminated from further evaluation.

5.3 Refer to Annexure A for the scoring sheet that will be used to evaluate functionality.

6 ELIMINATION CRITERIA

Proposals will be eliminated under the following conditions:

- Submission after the deadline;
- Proposals submitted at incorrect email address
- Incomplete proposal submission
- No previous experience of ISO 9001 and ISO 13485 consulting and auditing
- No previous experience assisting companies with SAHPRA and international (e.g. CE, FDA) medical device applications / registrations

7 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE REGISTRATION

Before any negotiations will start with the winning bidder it will be required from the winning bidder to:

- be registered on National Treasury's Central Supplier Database (CSD). Registrations can be completed online at: www.csd.gov.za;
- provide the CSIR of their CSD registration number; and
- provide the CSIR with a certified copy of their B-BBEE certificate. If no certificate can be provided, no points will be scored during the evaluation process. (RSA suppliers only)

SECTION B – TERMS AND CONDITIONS

8 VENUE FOR PROPOSAL SUBMISSION

All proposals must be submitted at:

- tender@csir.co.za
- All bids must be clearly marked with the bidders name, and the contents of the email
- Emails may be sent in parts if it exceeds 30MB

9 TENDER PROGRAMME

The tender program, as currently envisaged, incorporates the following key dates:

- Issue of tender documents: 22 April 2021
- Last date for submission of queries: 28 April 2021
- Closing / submission Date: 05 May 2021
- Estimate appointment date of successful tenderer: May 2021

10 SUBMISSION OF PROPOSALS

10.1 All proposals are to be clearly marked with the RFP number and the name of the tenderer.

Proposals must consist of two parts:

PART 1: Technical Proposal: RFP No.:

PART 2: Pricing Proposal, B-BBEE and other Mandatory Documentation:

RFP No.:

10.2 Proposals submitted by companies must be signed by a person or persons duly authorised.

10.3 The CSIR will award the contract to qualified tenderer(s)' whose proposal is determined to be the most advantageous to the CSIR, taking into consideration the technical (functional) solution, price and B-BBEE.

11 DEADLINE FOR SUBMISSION

Proposals shall be submitted at the address mentioned above no later than the closing date of **Thursday, 06 May 2021** during CSIR's business hours. The CSIR business hours are between 08h00 and 16h30.

Where a proposal is not received by the CSIR by the due date and stipulated place, it will be regarded as a late tender. Late tenders will not be considered.

12 AWARDING OF TENDERS

12.1 Awarding of tenders will be published on the National Treasury e-tender portal or the CSIR's tender website. No regret letters will be sent out.

13 EVALUATION PROCESS

13.1 Evaluation of proposals

All proposals will be evaluated by an evaluation team for functionality, price and B-BBEE. Based on the results of the evaluation process and upon successful negotiations, the CSIR will approve the awarding of the contract to successful tenderers.

A two-phase evaluation process will be followed.

- The first phase includes evaluation of **elimination** and **functionality criteria**.
- The second phase includes the evaluation of **price** and **B-BBEE** status.

Pricing Proposals will only be considered after functionality phase has been adjudicated and accepted. Only proposals that achieved the specified minimum qualification scores for functionality will be evaluated further using the preference points system.

13.2 Preference points system

The 80/20 preference point system will be used where 80 points will be dedicated to price and 20 points to B-BBEE status.

14 PRICING PROPOSAL

14.1 Pricing proposal must be cross-referenced to the sections in the Technical Proposal. Any options offered must be clearly labelled. Separate pricing must be provided for each option offered to ensure that pricing comparisons are clear and unambiguous.

14.2 Price needs to be provided in South African Rand (excl. VAT), with details on price elements that are subject to escalation and exchange rate fluctuations clearly indicated.

14.3 Price should include additional cost elements such as freight, insurance until acceptance, duty where applicable.

14.4 Only firm prices* will be accepted during the tender validity period. Non-firm prices** (including prices subject to rates of exchange variations) will not be considered.

**Firm price is the price that is only subject to adjustments in accordance with the actual increase or decrease resulting from the change, imposition, or abolition of customs or excise duty and any other duty, levy, or tax which, in terms of a law or regulation is binding on the contractor and demonstrably has an influence on the price of any supplies, or the rendering costs of any service, for the execution of the contract;*

***Non-firm price is all prices other than "firm" prices.*

14.5 Payment will be according to the CSIR Payment Terms and Conditions.

15 VALIDITY PERIOD OF PROPOSAL

Each **proposal** shall be valid for a minimum period of three (3) months calculated from the closing date.

16 APPOINTMENT OF SERVICE PROVIDER

16.1 The contract will be awarded to the tenderer who scores the highest total number of points during the evaluation process, except where the law permits otherwise.

16.2 Appointment as a successful service provider shall be subject to the parties agreeing to mutually acceptable contractual terms and conditions. In the event of the parties failing to reach such agreement CSIR reserves the right to appoint an alternative supplier.

16.3 Awarding of contracts will be announced on the National Treasury website and no regret letters will be sent to unsuccessful bidders.

17 ENQUIRIES AND CONTACT WITH THE CSIR

Any enquiry regarding this RFP shall be submitted in writing to CSIR at tender@csir.co.za with **"RFP No 3450/06/05/2021 - The provision of consulting and internal auditing services against ISO 9001:2015 and ISO 13485:2016 to the CSIR"** as the subject.

Any other contact with CSIR personnel involved in this tender is not permitted during the RFP process other than as required through existing service arrangements or as requested by the CSIR as part of the RFP process.

18 MEDIUM OF COMMUNICATION

All documentation submitted in response to this RFP must be in English.

19 COST OF PROPOSAL

Tenderers are expected to fully acquaint themselves with the conditions, requirements and specifications of this RFP before submitting proposals. Each tenderer assumes all risks for resource commitment and expenses, direct or indirect, of proposal preparation and participation throughout the RFP process. The CSIR is not responsible directly or indirectly for any costs incurred by tenderers.

20 CORRECTNESS OF RESPONSES

20.1 The tenderer must confirm satisfaction regarding the correctness and validity of their proposal and that all prices and rates quoted cover all the work/items specified in the RFP. The prices and rates quoted must cover all obligations under any resulting contract.

20.2 The tenderer accepts that any mistakes regarding prices and calculations will be at their own risk.

21 VERIFICATION OF DOCUMENTS

21.1 Tenderers should check the numbers of the pages to satisfy themselves that none are missing or duplicated. No liability will be accepted by the CSIR in regard to anything arising from the fact that pages are missing or duplicated.

21.2 Pricing schedule and B-BBEE credentials should be submitted with the proposal, but as a separate document and no such information should be available in the technical proposal.

22 SUB-CONTRACTING

- 22.1 A tenderer will not be awarded points for B-BBEE status level if it is indicated in the tender documents that such a tenderer intends sub-contracting more than **25%** of the value of the contract to any other enterprise that does not qualify for at least the points that such a tenderer qualifies for, unless the intended sub-contractor is an exempted micro enterprise that has the capability and ability to execute the sub-contract.
- 22.2 A tenderer awarded a contract may not sub-contract more than **25%** of the value of the contract to any other enterprise that does not have an equal or higher B-BBEE status level than the person concerned, unless the contract is sub-contracted to an exempted micro enterprise that has the capability and ability to execute the sub-contract.

23 ENGAGEMENT OF CONSULTANTS

The consultants will only be remunerated at the rates:

- 23.1 Determined in the "Guideline for fees", issued by the South African Institute of Chartered Accountants (SAICA); or
- 23.2 Set out in the "Guide on Hourly Fee Rates for Consultants", by the Department of Public Service and Administration (DPSA); or
- 23.3 Prescribed by the body - regulating the profession of the consultant.

24 TRAVEL EXPENSES

- 24.1 All travel expenses for the CSIR's account, be it directly via the CSIR's travel agent or indirectly via re-imbursements, must be in line with the CSIR's travel policy. The following will apply:
- 24.1.1 Only economy class tickets will be used.
- 24.1.2 A maximum of R1400 per night for accommodation, dinner, breakfast and parking will be allowed.
- 24.1.3 No car rentals of more than a Group B will be accommodated.

25 ADDITIONAL TERMS AND CONDITIONS

- 25.1 A tenderer shall not assume that information and/or documents supplied to CSIR, at any time prior to this request, are still available to CSIR, and shall consequently not make any reference to such information document in its response to this request.
- 25.2 Copies of any affiliations, memberships and/or accreditations that support your submission must be included in the tender.
- 25.3 In case of proposal from a joint venture, the following must be submitted together with the proposal:
- Joint venture Agreement including split of work signed by both parties;
 - The original or certified copy of the B-BBEE certificate of the joint venture;
 - The Tax Clearance Certificate of each joint venture member;
 - Proof of ownership/shareholder certificates/copies; and
 - Company registration certificates.
- 25.4 An omission to disclose material information, a factual inaccuracy, and/or a misrepresentation of fact may result in the disqualification of a tender, or cancellation of any subsequent contract.
- 25.5 Failure to comply with any of the terms and conditions as set out in this document will invalidate the Proposal.

26 CSIR RESERVES THE RIGHT TO

- 26.1 Extend the closing date;
- 26.2 Verify any information contained in a proposal;
- 26.3 Request documentary proof regarding any tendering issue;
- 26.4 Give preference to locally manufactured goods;
- 26.5 Appoint one or more service providers, separately or jointly (whether or not they submitted a joint proposal);
- 26.6 Award this RFP as a whole or in part;
- 26.7 Cancel or withdraw this RFP as a whole or in part.

27 DISCLAIMER

This RFP is a request for proposals only and not an offer document. Answers to this RFP must not be construed as acceptance of an offer or imply the existence of a contract between the parties. By submission of its proposal, tenderers shall be deemed to have satisfied themselves with and to have accepted all Terms & Conditions of this RFP. The CSIR makes no representation, warranty, assurance, guarantee or endorsements to tenderer concerning the RFP, whether with regard to its accuracy, completeness or otherwise and the CSIR shall have no liability towards the tenderer or any other party in connection therewith.

DECLARATION BY TENDERER

Only tenderers who completed the declaration below will be considered for evaluation.

RFP No:

I hereby undertake to render services described in the attached tendering documents to CSIR in accordance with the requirements and task directives / proposal specifications stipulated in RFP No..... at the price/s quoted. My offer/s remains binding upon me and open for acceptance by the CSIR during the validity period indicated and calculated from the closing date of the proposal.

I confirm that I am satisfied with regards to the correctness and validity of my proposal; that the price(s) and rate(s) quoted cover all the services specified in the proposal documents; that the price(s) and rate(s) cover all my obligations and I accept that any mistakes regarding price(s) and rate(s) and calculations will be at my own risk.

I accept full responsibility for the proper execution and fulfilment of all obligations and conditions devolving on me under this proposal as the principal liable for the due fulfilment of this proposal.

I declare that I have no participation in any collusive practices with any tenderer or any other person regarding this or any other proposal.

I accept that the CSIR may take appropriate actions, deemed necessary, should there be a conflict of interest or if this declaration proves to be false.

I confirm that I am duly authorised to sign this proposal.

NAME (PRINT)
CAPACITY
SIGNATURE
NAME OF FIRM
DATE

WITNESSES	
1
2
DATE:	

28 ANNEXURE A

#	Functional/Technical criteria	Weight%	2	5	10
1	Previous ISO 9001 and ISO 13485 consulting and auditing experience of the company in years and the number of company certifications successfully secured	20%	Has 1 to 2 years' experience in ISO 9001 AND ISO 13485 consulting and auditing and can provide evidence of certifications successfully secured.	Has at least 3 years' experience in ISO 9001 AND ISO 13485 consulting and auditing and can provide evidence of certifications successfully secured.	Has at least 10 years' experience in ISO 9001 AND ISO 13485 consulting and auditing and can provide evidence of certifications successfully secured.
2	Examples (evidence & brief details) of previous ISO 9001 and ISO 13485 consulting and auditing cases successfully handled through to certification.	30%	The proposal offered presents less than 5 ISO 9001 AND ISO 13485 consulting and auditing cases successfully handled through to certification.	The proposal offered presents 5 or more consulting and auditing cases successfully handled through to certification.	The proposal offered presents 10 or more consulting and auditing cases successfully handled through to certification.
3	Examples (evidence & brief details) of SAHPRA and CE Mark consulting cases handled successfully	20%	The proposal offered presents less than 5 of SAHPRA and CE Mark consulting cases handled successfully.	The proposal offered presents 5 or more of SAHPRA and CE Mark consulting cases handled successfully.	The proposal offered presents 10 or more of SAHPRA and CE Mark consulting cases handled successfully.
4	Staff experience in ISO 9001 and ISO 13485, detailed description of resources, capacity and expertise, including qualifications, experience and affiliations of personnel and examples of companies handled.	20%	Inadequate capacity and experience to fulfill the requirements of the scope. Personnel assigned to the project have 1 to 2 years'	Adequate capacity and experience to fulfill the requirements of the scope. Personnel assigned to the project have 3 to 5 years'	Adequate capacity and experience to fulfill the requirements of the scope. Personnel assigned to the project have more than 6 years'.

			experience in this field qualified and/ or affiliated with recognized Bodies	experience in this field qualified and/ or affiliated with recognized Bodies	experience in this field, qualified and/ or affiliated with recognized Bodies
5	A detailed Project Plan with timelines and milestones	10%	The approach is poor / unlikely to satisfy project objectives or requirements. The service provider misunderstood certain aspects of the Scope of Work and does not deal with the critical aspects of the project. No clear project milestones and deliverables with a timeframe and budget	The approach is generic and not tailored to address the specific project objectives and requirements. The approach does not adequately deal with the critical characteristics of the project. The quality plan is too generic. The approach and does not satisfy the objective of ISO certification and time line requirements	The approach is specifically tailored to address the specific project objectives and requirements and is sufficiently flexible to accommodate changes that may occur during execution. The quality plan is specifically tailored to the critical characteristics of the Contract projects. The service provider provided a summary of project milestones and deliverables with a timeframe and summary budget
	Total	100%			