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RFQ Number	NTP-TM-LAB-RFQ-25-0063
Request for Quotation Date	2025/08/18
RFQ Closing Date	2025/08/22
RFQ Closing Time	12:00
Contact Person	Tshepiso Matshidiso
Quotation Validity	90 days
Submission Details	RFQ Response must be sent to: itumeleng.mathibe@ntp.co.za and Tshepiso.Matshidiso@ntp.co.za for Technically related
RFQ Description	Looking for Consultant that can assist the Sterile Radiopharmaceutical Finished Product Manufacturing facility with a GMP compliance audit.

Dear Service Provider

Kindly provide a quotation for goods and or services as outlined in section 2 of this document.

1. Introduction

Conducting its sophisticated operations amongst an array of state-of-the-art technology and by highly competent scientists, engineers, technologists and pharmacists, NTP Radioisotopes SOC Ltd is one of the world's leading suppliers of essential medical radioisotopes.

A subsidiary of the South African Nuclear Energy Corporation (Necsa), NTP produces a quarter of the world's medical radioisotopes which are used in about 40 million medical diagnostic images every year, making it the third largest producer and supplier globally. Use of nuclear medicines allows for gathering of medical information that may otherwise be unavailable, require surgery or necessitate more expensive and invasive diagnostic tests.

This proudly South African corporate company is situated at the sophisticated Necsa nuclear facility site, west of Pretoria and routinely serves customers spanning 60 countries worldwide with its range of nuclear radiation-based products and services. The company has maintained consistent revenue and market share growth and has over the past years created various business subsidiaries or increased holdings in these that strengthened its portfolio.

For more information on NTP Radioisotopes SOC Ltd visit: www.ntp.co.za

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2. Scope of Work

Description
Scope Definition • Purpose: Establish clear objectives for a Finished Product Manufacturer cGMP audit in line with the latest pharmaceutical standards • Benchmark Area: Sterile Finished product manufacturing facility to include Cyclotron, Radiochemistry and Dispatch areas • Peers/Standards: Identify benchmarks (e.g., industry leaders, regulations and cGMP) 2. Key Metrics and Benchmarks • Benchmarking to include Regulatory Compliance: Evaluate frequency of regulatory findings within all manufacturing facility areas and indicate a timeline to resolve compliance issues. 3. Data Collection • Internal data sources: Operational reports, compliance logs and • External data: Industry reports, peer data (where accessible), and published benchmarks. 4. Analysis and Comparison • Compare internal performance metrics against benchmarks. • Highlight areas of underperformance, parity, or excellence. 5. Gap Analysis • Identify gaps between current performance and benchmarks. • Diagnose root causes of underperformance (e.g., inefficiencies, lack of resources). 6. Recommendations and Action Plans • Propose actionable strategies for improvement. • Prioritize actions based on impact and feasibility. • Set timelines and measurable goals. 7. Reporting • Summarize findings in a clear and actionable format. • Include visual aids such as graphs, charts, and dashboards for better comprehension. 8. Continuous Monitoring • Establish KPIs for ongoing performance tracking. • Conduct periodic reviews to ensure sustained improvements.

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3. Pricing

- All price must be quoted in South African Rand, exclusive of VAT with details on price elements that are subjected to escalation and exchange rate fluctuations clearly indicated.
- Price must be fixed and firm
- Price should include additional cost elements such as freight, insurance until acceptance, duty where applicable, disbursements etc.
- Quotation must be completed in full, incomplete quote could result in a quote being disqualified.
- Payment will be according to Necsa's General Conditions of Purchase.

4. Evaluation

4.1. Phase 1- Functionality Evaluation / Technical Evaluation

Where functional or technical evaluation criterion is applicable, assessment will be performed in terms of the criterion listed below and the criterion may include Technical, Performance, Quality and Risk. If the Bidder's response to the Technical templates does not indicate that the Bidder can support an acceptable technical solution, the Bidder's response will be rejected and not evaluated further.

Together the Technical, Performance & Quality and Risk criteria make up the functionality criterion and a Bidder's Proposal will be evaluated for functionality out of a possible 100 points. Only RFQ responses achieving an evaluation score of greater than the set threshold points out of the possible 100 points and which score a number of points for functionality that is greater than or equal to the set threshold points of the number of points achieved by the highest scoring Bid for functionality will be selected to progress to the second stage

4.1.1 Eligibility Requirements

4.1.2 Pre-qualification Criteria

Non-compliance to the following pre-qualification criteria will result in automatic disqualification:

<u>Item</u>	<u>Requirement</u>	<u>Yes</u>	<u>No</u>
1	Detailed Curriculum vitae		
2	Copies of required qualification		

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FUNCTIONAL EVALUATION CRITERIA

Item	Requirement	Weight	Points	Criteria
1	A Pharmaceutical consultant with experience dealing with at least SAHPRA, WHO, TGA and EU inspectorates	<u>20</u>	<u>20</u>	100% compliance to scope of work
			<u>10</u>	Slightly compliant to scope of work
			<u>0</u>	Out of specification
2	At least 10 years consulting experience in South Africa.	<u>10</u>	<u>10</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
3	At least 5 years' experience in quality management systems, and experience in QMS remediation in a pharmaceutical environment	<u>10</u>	<u>10</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
4	Consulting experience where sterile manufacture and remediation has been undertaken with examples of companies serviced (at least 3 references)	<u>10</u>	<u>10</u>	100% compliance to scope of work
			<u>5</u>	Slightly compliant to scope of work
			<u>0</u>	Out of specification
5	Consulting experience with Pharmaceuticals with experience in auditing pharmaceutical facilities	<u>20</u>	<u>20</u>	100% compliance to scope of work
			<u>10</u>	Slightly compliant to scope of work
			<u>0</u>	Out of specification
6	Qualifications B Pharmacy or equivalent, Post Graduate degree in life sciences and a management degree	<u>5</u>	<u>5</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
7	Registration with the SAPC	<u>5</u>	<u>5</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
8	Audit Report must be provided within 30 days and undertake assistance with a remediation plan	<u>5</u>	<u>5</u>	100% compliance to scope of work
			<u>2</u>	Slightly compliant to scope of work
			<u>0</u>	Out of specification

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Item	Requirement	Weight	Points	Criteria
9	Provide support during Regulatory audits and with closure of findings	<u>5</u>	<u>5</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
10	Experience in quality management systems, and experience in QMS remediation with focus on radiopharmaceutical manufacturing operations in a pharmaceutical setting for sterile product manufacturing (Reference to previous companies serviced)	<u>10</u>	<u>10</u>	100% compliance to scope of work
			<u>0</u>	Out of specification
Total Allocated Score 100				
Minimum qualifying threshold 80				

4.2. Phase 2 - Evaluation In Terms Of Preferential Procurement Policy Framework Act, 2022 This bid will be evaluated and adjudicated according to the 80/20 point system, in terms of which a maximum of 80 points will be awarded for price and 20 points will be allocated based on the specific goals (B-BBE status level).

	POINTS
PRICE	80
SPECIFIC GOALS (B-BBEE status level)	20
Total points for Price and SPECIFIC GOALS	100

Preference goal
B-BBEE status level contributor

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B-BBEE Status Level of Contributor	Number of points (80/20 system)
1	20
2	18
3	14
4	12
5	8
6	6
7	4
8	2
Non-compliant contributor	0

5. Required Documentation

- ☐ Tax Clearance Certificate (Tax pin issued by SARS)
- ☐ Declaration of interest (SBD 4)
- ☐ BEE Certificate / Applicable Affidavit if classified as EME
- ☐ Letter of Good Standing (COID) only if Applicable due to the nature of work required
- ☐ Any other document or certification that might have been requested on this RFQ

6. Important

- 6.1. Quotation must be submitted on or before the RFQ closing date and time stated above.
- 6.2. Orders above R 30 000 will be evaluated according to the PPPFA 80/20-point system and a functionality scorecard where applicable and the ones above R 1 Million will be subjected to the tender process.
- 6.3. This RFQ is subjected to the Necsa's General Conditions of Purchase, Preferential Procurement Policy Framework Act 2000 and the Preferential Procurement Regulations, 2022, the General Conditions of Contract (GCC) and, if applicable, any other legislation or special conditions of contract

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- 6.4. Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor together with the bid, will be interpreted to mean that preference points for specific goals are not claimed.
- 6.5. The purchaser reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to specific goals, in any manner required by the purchaser.
- 6.6. For a Bidder to obtain clarity on any matter arising from or referred to in this document, please refer queries, in writing, to the contact details provided above. Under no circumstances may any other employee within NTP be approached for any information. Any such action might result in a disqualification of a response submitted in competition to this RFQ.
- 6.7. No goods and/or services should be delivered to NTP without an official NTP Purchase order.
- 6.8. NTP reserves the right to; cancel or reject any quote and not to award the RFQ to the lowest Bidder or award parts of the RFQ to different Bidders, or not to award the RFQ at all.
- 6.9. The supplier shall under no circumstances offer, promise or make any gift, payment, loan, reward, inducement, benefit or other advantage, which may be construed as being made to solicit any favour, to any NTP employee or its representatives. Such an act shall constitute a material breach of the Agreement and the NTP shall be entitled to terminate the Agreement forthwith, without prejudice to any of its rights
- 6.10. By responding to this request, it shall be construed that: the bidder, hereby acknowledge to be fully conversant with the details and conditions set out in the Necsa's General Conditions of Purchase, Preferential Procurement Policy Framework Act 2000 and the Preferential Procurement Regulations, 2022, the General Conditions of Contract (GCC), Technical Information and Specifications attached, and hereby agree to supply, render services or perform works in accordance therewith