RFQ Number	**NTP260325-1**
Request for Quotation Date	**2026/04/08**
RFQ Closing Date	**2026/04/13**
RFQ Closing Time	**16:00**
Compulsory Site Briefing	**N/A**
Contact Person	**Berlina Mabogwane / Tel: 012 305 5637**
Quotation Validity	**90 Days from the closing date**
Submission Details	**RFQ Response must be sent to:Berlina.mabogwane@ntp.co.za**
RFQ Description	**GMP Consultant**

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

2. Scope of Work

NTP Radioisotopes SOC Ltd would like to strengthen is self-inspection (internal audit) system through engagement with an experienced external GMP consultant.

The objective of this RFQ is to appoint a qualified external consultant to:
Assess and enhance the current self-inspection system
Conduct an independent GMP self-inspection
Identify gaps against:
PIC/S GMP (as applicable)
ICH Q7 (as applicable)
SAHPRA and international regulators expectations
Support sustainable implementation of an effective, risk-based internal audit program

The consultant will be required to perform the following activities:
1. Review of Existing Systems
Evaluate current self-inspection SOP(s), procedures, plans etc
Review Previous internal audit reports, SAHPRA audit observations, CAPAs and effectiveness checks, and assess alignment with:
PIC/S GMP requirements,
Quality Risk Management principles,
Industry best practices

2. Enhancement of Self-Inspection Program
Design or improve a risk-based self-inspection program, including:
Annual audit schedule
Auditor independence criteria
Audit frequency based on risk (critical systems, products, etc.)

Provide:
Audit checklists (tailored to facility type)
Audit report templates
Audit report tracking tools

3 Execution of Self-Inspection
Conduct a full mock GMP inspection of the site, covering (as applicable):
Quality Management System
Production (including raw material management, intermediate production and packaging)
Quality Control laboratory
Dispatch
Maintenance
Validation and qualification
Documentation and data integrity
Classify observations (e.g. Critical / Major / Minor)

4. Gap Analysis & Reporting
Provide a detailed GMP gap analysis report, including:
Clear reference to PIC/S / ICH / SAHPRA requirements

Root cause considerations
Practical, risk-based recommendations for addressing gaps
Highlight high-risk compliance gaps requiring immediate action

5. CAPA Support
Facilitate or support:
CAPA development workshops
Root cause analysis (e.g. 5 Why, Fishbone)
Review and approve proposed CAPAs for adequacy and compliance

6. Training
Provide training to internal auditors
Provide training to relevant staff on:
Effective self-inspection techniques
GMP audit readiness
Identification of data integrity risks

7. Follow-Up Assessment (Optional)
Conduct a follow-up audit to verify CAPA implementation and effectiveness

Consultant Requirements
The consultant must demonstrate:
Proven experience with:
SAHPRA inspections
PIC/S GMP (Part I and/or Part II)
ICH Q7 (if API site)
Minimum 10 years in GMP quality / regulatory roles
Experience conducting regulatory inspections

Strong knowledge of:
Data integrity
Quality Risk Management
Relevant qualifications (e.g. pharmacist, quality professional, GMP auditor)

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

4.2. 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

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

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