Republic of Kenya

Ministry of Health

National Quality Control Laboratory

A WHO Prequalified and an ISO/IEC 17025:2017 Accredited Testing Facility
Hospital Road, KNH Complex, P.O. Box 29726 – 00202, Nairobi, Kenya
Telephone: +254 – 020 – 3544525/30, +254 703 311563
Email: info@nqcl.go.ke Website: www.nqcl.go.ke

# REQUEST FOR EXPRESSION OF INTEREST (REOI)

## CONSULTING SERVICES-FIRMS SELECTION.

## ASSIGNMENT TITLE: CONSULTANCY SERVICES FOR UNDERTAKING A FEASIBILITY STUDY AND DEVELOPING A CONCEPT DESIGN FOR A STATE-OF-THE-ART NATIONAL QUALITY CONTROL LABORATORY.

**REFERENCE NO. (AS PER PROCUREMENT PLAN): NCQL/962/RFP/0003/2026-27**

**ELECTRONIC SUBMISSION : THROUGH e-GP.**

**ISSUE DATE: 4TH November 2026**

**CLOSING DATE: 19th November 2026**

**CLOSING TIME: 10.00 Hours East African Time (EAT).**

## TERMS OF REFERENCE

## REQUEST FOR PROPOSAL FOR CONSULTANCY SERVICES FOR THE CONSTRUCTION OF THE NATIONAL LABORATORY FOR TESTING HEALTH PRODUCTS AND TECHNOLOGIES

### 1. BACKGROUND

The Constitution of Kenya, through the chapter on Bill of Rights, puts a heavy responsibility on the Health Sector to ensure that the right to health is realized. In Article 43 (1) (a), it is provided that all Kenyans shall have the right to the highest attainable standards of health, which includes the right to healthcare services. It is through this provision that the goal of the Health Sector as outlined in the Social Pillar of Kenya's Vision 2030 is to provide equitable, affordable and quality healthcare to all citizens. Safe, effective and quality (HPTs) are important in the achievement of this goal, with NQCL playing a central role in assuring HPTs quality and safety through testing and related functions. The Laboratory thus plays a key role in Kenya's realization of Universal Health Care for all citizens.

Part VII of the Health Act 2017 provides for the regulation of HPTs partly through conducting laboratory testing of these products, a mandate that envisages a functional Quality Control Laboratory that is well equipped and fit for purpose. This mandate rests on the NQCL, being the official Quality Control Laboratory in Kenya currently testing on behalf of the PPB and the Government. In addition, the Kenya Health Sector Strategic Plan 2018 – 2023 focuses on Enhancing the Quality of HPTs as one of its key outputs (4.5.2) and spells out Quality Control Testing, Intensification of pharmacovigilance and conducting post marketing surveillance as key actions in realization of this output.

The re-establishment and expansion of the NQCL is also spelt out in the Health Products and Technologies Supply Chain Strategy 2025 – 2026. One of its Strategic Objectives (1.5) is to strengthen the Laboratory's quality assurance systems with a focus on expanding its research capability to offer full range of HPT tests. The project will thus be a key contributor to attainment of the Government's objectives in the Supply Chain Strategy.

The National Quality Control Laboratory (NQCL) is established under Section 35D of the Pharmacy and Poisons Act (Cap 244) as Kenya's statutory national reference laboratory for HPTs. Operating under the Health Act 2017, NQCL holds the exclusive legal mandate to evaluate, verify, and certify the quality, safety, efficacy, and chemical/biological compliance of all pharmaceutical formulations, biologicals, medical devices, blood products, and nutraceuticals distributed within Kenya or exported across the East African Community (EAC) region.

Quality HPTs, especially pharmaceutical and medical products, are critical for a healthy and productive citizenry. Although Kenya has made strides in HPT testing indicators, substandard and falsified (SF) HPTs remain a significant public health

issue and a hindrance to achieving the Country's quality agenda. The Country is experiencing a triple burden of SF HPTs with poor quality products being on the increase.

The NQCL is currently hosted by the University of Nairobi's School of Pharmacy on one floor of the Old King George Hospital building, an outdated premise that has limitations with respect to operational space, structural fitness for quality control related activities and, due to its age, ability to withstand renovations. NQCL therefore faces challenges including lack of adequate infrastructure, equipment and reagents, which limits its effectiveness, efficiency and scope of service delivery.

In order to deliver on its mandate, the NQCL requires a modern Laboratory campus that is sufficiently equipped and that has structural requirements that meet globally accepted standards of pharmaceutical quality control laboratories. Further, Kenya is in the process of pursuing attainment of WHO's rating of Maturity Level 3 (ML3) to enable the manufacture and commercialization of biologics and vaccines, a key strategic direction that requires developing and improving on its key institutions including the NQCL. The NQCL is therefore seeking consultancy services for the construction of a modern laboratory that is well equipped for efficient and effective testing of HPTs including medical devices with an aim to accelerate and scale up efforts towards the elimination of substandard HPTs in Kenya in line with Kenya's Vision 2030 and sustainable development goals (SDGs).

## 2. CONSULTANCY OBJECTIVES

### 2.1 Overall Objective

To engage a qualified multidisciplinary consulting firm to provide comprehensive consultancy services for the establishment of the National Laboratory for Testing Health Products and Technologies, encompassing feasibility assessment, architectural design, and preparation of bills of quantities.

### 2.2 Specific objectives

i). Participate in assessing technical, financial, legal, and operational viability; quantify demand and developing an investment case.
ii). Develop functional, compliant, and sustainable laboratory designs meeting WHO and ISO standards.
iii). Prepare detailed, priced BQs for all works, equipment, and services to facilitate procurement.

## 3. SCOPE OF WORK

The consulting firm shall provide services under the following three components:

### 3.1 Component 1: Feasibility Study

#### 3.1.1 Situational Analysis and Needs Assessment

The consulting firm shall provide support to:

- Conduct a comprehensive assessment of the current laboratory testing landscape, including public, private, and academic facilities.
- Assist in quantifying current and projected demand for regulatory testing of pharmaceuticals, vaccines, medical devices, and IVDs.
- Assist in Mapping existing regulatory requirements and identify gaps in national testing capacity.
- Participate in stakeholder consultations with Ministry of Health, regulatory authority, manufacturers, importers, and development partners.

### 3.1.2 Technical Feasibility Assessment

The consulting firm shall provide support to:

- Assist in defining the recommended scope of testing services (chemical, microbiological, biological, device performance).
- Assess infrastructure requirements including HVAC, cleanrooms, waste management, security, and utilities, in compliance with WHO guidance on laboratory infrastructure.
- Develop preliminary architectural brief and site assessment.
- Specify essential equipment for each testing unit, aligned with WHO equipment selection standards.
- Identify the needed Quality Management System (QMS) framework aligned with ISO/IEC 17025 and WHO Good Practices.

### 3.1.3 Financial Feasibility Assessment

The consulting firm shall provide support to:

- Estimate capital costs for construction/renovation, equipment procurement, installation, and validation.
- Project recurrent costs: personnel, reagents, consumables, maintenance, utilities, accreditation fees.
- Assist in identifying potential funding sources: government budget, development partners, fee-for-service revenue.
- Conduct cost-benefit analysis comparing local testing vs. reliance on foreign laboratories

### 3.1.4 Legal and Regulatory Framework Analysis

The consulting firm shall provide support to:

- Review existing laws and make recommendations to update legal provisions for designation of the laboratory as a National Control Laboratory.
- Map requirements for ISO/IEC 17025 accreditation and WHO prequalification to the statutory functions of the newly designed laboratory.
- Define the laboratory's relationship with the national regulatory authority.

### 3.1.5 Organizational and Human Resource Assessment

The consulting firm shall:

- Design optimal organizational structure for laboratory operations, quality management, and administration.
- Determine staffing requirements (technical, quality, administrative).
- Identify training needs for specialized testing, QMS, and biosafety.

### 3.1.6 Risk Assessment and Mitigation

The consulting shall:

- Identify potential technical, financial, regulatory, and operational risks.
- Assist in developing mitigation strategies and a risk register.

## 3.2 Component 2: Architectural Design

### 3.2.1 Design Principles and Standards

The consulting shall ensure all designs comply with:

- WHO Guidance on Laboratory Infrastructure: Minimum dimensions, ventilation, power, water supply, lighting, drainage, waste management, and security.
- ISO/IEC 17025:2017: Requirements for testing and calibration laboratories.
- WHO Good Practices for Pharmaceutical Quality Control Laboratories and Pharmaceutical Microbiology laboratories.
- National Building Codes and occupational health, safety, and environmental standards.
- Accessibility standards for persons with disabilities.

### 3.2.2 Design Phases

The consulting firm shall deliver design services in the following phases, following NQCL process-oriented approach to laboratory design:

**Phase A: Concept Development**

- Establish design goals, functional requirements, and basis of design.
- Conduct risk assessment and analyze design solutions.
- Develop initial cost estimates.
- Present concept design for stakeholder approval.

**Phase B: Schematic Design**

- Develop schematic floor plans, sections, and elevations.

- Define laboratory zoning and workflow (clean/dirty separation, sample flow).
- Specify structural, mechanical, electrical, and plumbing (MEP) systems.
- Develop preliminary equipment layouts.

**Phase C: Detailed Design**

- Prepare detailed architectural, structural, and MEP drawings.
- Develop construction details and specifications.
- Prepare interior design and furniture layouts.
- Coordinate with equipment suppliers for technical requirements.
- Incorporate green buildings and sustainability principles where applicable.

**Phase D: Construction Documentation**

- Prepare complete construction drawings.
- Develop technical specifications for all works.
- Prepare tender documents for construction procurement.

### 3.2.3 Key Design Requirements

| **Design Area** | **Requirements** |
|---|---|
| Laboratory Zones | Separate zones for sample reception, chemistry, microbiology, biology, equipment storage, and waste management. |
| HVAC Systems | Appropriate ventilation, air filtration, and temperature/humidity control for each laboratory type. |
| Cleanrooms | Compliant cleanroom design for sterile testing areas. |
| Biosafety | Biosafety cabinets, containment measures, and emergency protocols. |
| Waste Management | Dedicated waste streams with compliant disposal systems. |
| Utilities | Uninterruptible power supply, backup generators, purified water systems, and gas systems. |
| Security | Access control, CCTV, and secure sample storage areas. |
| Sustainability | Energy efficiency, water efficiency, and environmentally responsible materials. |

### 3.3 Component 3: Bills Of Quantities (BQs)

#### 3.3.1 Scope

The consulting firm shall prepare comprehensive, priced Bills of Quantities for all works required for the establishment of the NQCL, in accordance with standard methods of measurement and best practices in cost management.

#### 3.3.2 BoQ Structure

The BoQ shall be organized into the following sections:

| Section | Content |
|---|---|
| Preliminaries | Site establishment, insurance, temporary works, contractor's overheads. |
| Substructure | Foundation works, ground floor slab, excavation, backfill. |
| Superstructure | Structural frame, walls, floors, roofs, staircases. |
| External Works | Roads, parking, drainage, landscaping, boundary walls. |
| Architectural Finishes | Internal and external finishes, ceilings, partitions, doors, windows. |
| Laboratory Fittings | Fume hoods, biosafety cabinets, laboratory benches, sinks, emergency showers. |
| Mechanical Installations | HVAC, plumbing, drainage, laboratory gas systems, fire protection. |
| Electrical Installations | Power distribution, lighting, UPS, generators, data networks, security systems. |
| Equipment | Laboratory equipment, cold storage, sterilization equipment. |
| External Services | Water supply, sewerage, power connection, telecommunications. |

#### 3.3.3 BQ Format and Deliverables

The consulting firm shall:

- Prepare BQs clearly describing and specifying items based on approved designs.
- Include preambles for each work category stating measuring and pricing methodology.

- Provide collection pages and grand summary sheets.
- Ensure costs reflect current market realities.
- Provide support during the procurement process, including bid evaluation and analysis.

## 4. DELIVERABLES

### Component 1: Feasibility Study

On feasibility study component, the consulting firm will deliver a feasibility study report that includes the results of:

i). Situational Analysis and Needs Assessment Report
ii). Technical Feasibility Report with Equipment Specifications
iii). Financial Feasibility Report with Detailed Budget
iv). Legal and Regulatory Framework Report
v). Organizational Structure and Staffing Plan
vi). Risk Assessment and Mitigation Plan

### Component 2: Architectural Design

The Consulting firm will deliver a Concept Design Report, Schematic Design Package, Detailed Design Package, Construction Drawings and Specifications

### Component 3: Bill of Quantities

**Deliverables:** Detailed Priced Bills of Quantities, Preambles and Specifications, Tender Documentation Support

## 5. METHODOLOGY

The consulting firm shall employ a mixed-methods approach:

i). Document Review: National health policies, regulatory frameworks, procurement data, existing assessments.
ii). Stakeholder Consultations: examples of stakeholders are Ministry of Health, national regulatory authority, laboratory managers, manufacturers, development partners.
iii). Site Assessments: Visits to existing laboratories and potential sites.
iv). Quantitative Analysis: Demand forecasting, cost modeling, cost-benefit analysis.
v). Expert Consultation: Engagement with WHO, international laboratory experts.
vi). Iterative Design Review: Regular design review meetings with stakeholders to ensure alignment with functional requirements.
vii). Validation Workshops: Present draft findings and designs for stakeholder validation.

## 6. IMPLEMENTATION TIMELINE

The total duration of the consultancy shall be 12 months, with the following indicative schedule:

| Phase | Duration | Key Activities |
|---|---|---|
| Phase 1: Inception | Month 1 | Team mobilization; document review; stakeholder mapping; methodology refinement. |
| Phase 2: Feasibility Study | Months 1-3 | Data collection; needs assessment; technical, financial, legal analysis; drafting feasibility report. |
| Phase 3: Design Development | Months 4-8 | Concept, schematic, and detailed design; stakeholder design reviews; coordination with equipment suppliers. |
| Phase 4: BoQ Preparation | Months 7-10 | Measurement; pricing; BoQ drafting; validation; tender documentation. |
| Phase 5: Finalization | Month 11-12 | Final report consolidation; validation workshop; submission. |

## 7. CONSULTING FIRM PROFILE AND TEAM COMPOSITION

The consulting firm shall demonstrate proven experience in health facility design, laboratory planning, and supervision of physicochemical laboratories, microbiology laboratories, medical devices testing facilities, or other technically complex laboratory environments of a similar nature to those set out in this REOI. Experience in projects in developing countries, particularly in Africa will be considered an advantage.

The Consulting firm should have the necessary personnel required to carry out the services, including and not limited to architecture, laboratory engineering, mechanical and electrical engineering, Quality control Laboratory specialist, biosafety and biosecurity. They should have the financial and technical resources required to undertake the assignment.

The Consulting firm should ensure that adequate staffing resources are available to complete the work within the period of performance of the project and shall not engage in any assignment that may place them in the position of not being able to carry out the services described in this REOI

The team shall include:

| Position | Qualifications | Experience |
|---|---|---|
| Team Leader / Senior Architect | Bachelor of Architecture or engineering; professional registration or evidence of experience | 15+ years; laboratory/health facility design experience |
| Feasibility Study Expert | Masters in Public Health, Health Economics, Health Systems, or related field | 10+ years; health laboratory systems experience; Health Economics |
| Quantity Surveyor | Bachelors in Quantity Surveying; professional registration | 10+ years; laboratory infrastructure experience; |
| Mechanical Engineer | Bachelors in Mechanical Engineering; professional registration or evidence of experience | 10+ years; laboratory HVAC and cleanroom experience |
| Laboratory Specialist | Degree in Chemistry, biochemistry, Laboratory Science or related field | 10+ years; quality control laboratory operations |
| Financial Analyst | Degree in Finance, Economics, or related field | 7+ years; health sector costing and financial modeling |

Equivalent professional registration in the consultant's country of origin shall be accepted

## 8. REPORTING AND COORDINATION

- The consulting firm shall report to the Technical Working Group constituted by the National Quality Control Laboratory with in consultation with Ministry of Health
- Monthly progress reports shall be submitted, indicating progress against the workplan
- Design review meetings shall be held at each design phase with stakeholders.

## 9. BUDGET AND PAYMENT SCHEDULE

The budget shall be proposed by the consulting firm based on the scope of services. Indicative payment milestones are:

| **Milestone** | **Payment (%)** |
|---|---|
| Submission and approval of Inception Report | 10% |
| Submission and approval of Feasibility Study Report | 25% |
| Submission and approval of Schematic Design | 20% |
| Submission and approval of Detailed Design | 20% |
| Submission and approval of Final BQs | 15% |
| Submission and approval of Final Report | 10% |

## 10. GOVERNANCE AND MANAGEMENT

The consultancy shall be overseen by:

- Technical Working Group: National Quality Control Laboratory, Ministry of Health, State Department for Public Works and the National Environmental Management Agency (NEMA).
- Contract Management

Key players in management of the project will be the National Quality Control Laboratory,

Ministry of Health, State Department for Public Works and the National Environmental Management Agency (NEMA).

- The Technical Working Group shall meet monthly to review progress and provide guidance.

## 11. CONFIDENTIALITY

All information obtained during the consultancy shall be treated as confidential and shall not be disclosed without prior written approval from the NQCL.

## 12. RESPONSIBILITIES OF THE CLIENT

The Client will avail all relevant documents and any other material considered relevant to the Consulting firm. The client will also provide quality control during implementation.

## 13. EVALUATION CRITERIA

The evaluation of proposals shall be undertaken in accordance with the applicable Government of Kenya procurement requirements. The evaluation shall consider the Consulting firm's understanding of the assignment, technical approach and methodology, relevant institutional experience, qualifications and experience of key personnel, quality of the proposed work plan, and financial proposal. The evaluation shall be conducted in two stages: Technical Evaluation and Financial Evaluation.

Only firms that attain the minimum technical score shall proceed to financial evaluation.

### 13.1 Technical Evaluation – 70 Points

| No. | Evaluation Criterion | Maximum Points |
|---|---|---|
| 1 | Understanding and interpretation of the Terms of Reference | 10 |
| 2 | Proposed methodology and technical approach | 10 |
| 3 | Relevant experience of the consulting firm | 20 |
| 4 | Qualifications and experience of key personnel | 20 |

| | | |
|---|---|---|
| 5 | Work plan, staffing schedule and time allocation | 5 |
| 6 | Quality assurance, risk management and stakeholder engagement approach | 5 |
| Total Technical Score | | **70** |

### 13.2 Detailed Technical Evaluation

***A. Understanding and Interpretation of the Assignment – 10 Points***

The Consulting firm shall demonstrate a clear understanding of the objectives, scope, complexity and expected outputs of the assignment.

| **Sub-criterion** | **Points** |
|---|---|
| Understanding of the NQCL mandate, laboratory testing environment and project context | 3 |
| Understanding of the feasibility, design and BoQ requirements and their interdependencies | 3 |
| Identification of key challenges, assumptions, constraints and critical success factors | 3 |
| Understanding of stakeholder, regulatory and institutional requirements | 1 |
| **Total** | **10** |

***B. Methodology and Technical Approach – 10 Points***

The methodology shall demonstrate how the Consulting firm will undertake the assignment and integrate the three components.

| **Sub-criterion** | **Points** |
|---|---|
| Feasibility study methodology, including demand assessment, technical, financial, economic and operational analysis | 2 |

| | |
|---|---|
| Laboratory planning and functional design methodology, including workflow, zoning, biosafety and containment considerations | 2 |
| Architectural, structural, MEP and specialist laboratory design approach | 2 |
| Equipment planning, specification, technology assessment and integration with laboratory design | 1 |
| Cost estimation, BoQ preparation and cost-control methodology | 1 |
| Stakeholder consultation, validation and design review approach | 1 |
| Risk management, quality assurance and compliance approach | 1 |
| **Total** | **10** |

***C. Relevant Experience of the Consulting Firm – 20 Points***

The firm shall demonstrate experience in assignments of comparable scope, scale and complexity.

| **Sub-criterion** | **Points** |
|---|---|
| Experience in feasibility studies for major health, laboratory, pharmaceutical or related infrastructure projects | 4 |
| **Experience establishing WHO-prequalified or ISO 17025-accredited laboratories and Recognition of experience with medicines regulation and quality assurance systems.** | |
| Experience in planning and design of pharmaceutical, public health, research, diagnostic or quality-control laboratories, particularly in low- and middle-income countries eg in Africa | 4 |
| Experience in multidisciplinary architectural, engineering and quantity surveying services | 4 |
| Experience in preparation of detailed designs, technical specifications and priced BoQs for major public infrastructure projects | **4** |
| Experience working with Government institutions, development partners or international health organizations | 4 |
| **Total** | **20** |

The Consulting firm shall provide evidence of relevant assignments, including client name, assignment description, contract value, duration, scope of services and completion status.

***D. Qualifications and Experience of Key Personnel – 20 Points***

The evaluation shall consider both academic/professional qualifications and relevant experience directly related to the assignment.

| **Key Personnel** | **Maximum Points** |
|---|---|
| Team Leader / Senior Architect | 3 |
| Feasibility Study / Health Economics Expert | 3 |
| Laboratory Planning / Quality Control Laboratory Specialist | 3 |
| Quantity Surveyor / Cost Management Specialist | 2 |
| Mechanical Engineer / HVAC and Cleanroom Specialist | 2 |
| Electrical Engineer / Laboratory Utilities and Security Systems Specialist | 2 |

| Key Personnel | Maximum Points |
|---|---|
| Financial Analyst | 2 |
| **Team Personnel Total** | **17** |
| Adequacy and complementarity of the proposed multidisciplinary team | **3** |
| **Total** | **20** |

The Consulting firm shall submit detailed CVs for all proposed key personnel, clearly indicating the assignments relevant to this ToR.

***E. Work Plan, Staffing Schedule and Time Allocation – 5 Points***

| Sub-criterion | Points |
|---|---|
| Realistic and logical work plan aligned with the proposed 12-month implementation period | 2 |
| Adequacy of level of effort and deployment of key personnel | 1 |
| Clear sequencing and integration of feasibility, design and BoQ activities | 1 |
| Provision for stakeholder reviews, validation and approval processes | 1 |
| **Total** | **5** |

***F. Quality Assurance, Risk Management and Stakeholder Engagement – 5 Points***

| Sub-criterion | Points |
|---|---|
| Quality assurance and internal technical review arrangements | 1 |
| Identification and management of technical, financial, environmental, regulatory and implementation risks | 1 |
| Stakeholder engagement and consultation strategy | 1 |
| Knowledge transfer and capacity-building approach | 1 |
| Document control, reporting and coordination arrangements | 1 |

| Sub-criterion | Points |
|---|---|
| **Total** | **5** |

### 13.3 Minimum Technical Score

A minimum technical score of **50 out of 70 points (70%)** will be shortlisted and invited to submit technical and financial proposals in accordance with the applicable provisions of the Public Procurement and Asset Disposal Act, 2015, and the Public Procurement and Asset Disposal Regulations, 2020.