



KENYA BIOVAX INSTITUTE

Health Emergency Preparedness Response and Resilience (HEPRR) Project

Credit Number: 7405-KE

Project ID: P180127

TERMS OF REFERENCE

FOR

CONSULTING SERVICES FOR BIOMANUFACTURING ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT (ESIA) OF THE KENYA BIOVAX FILL AND FINISH FACILITY IN EMBAKASI, NAIROBI, KENYA

(FIRMS SELECTION)

PROCUREMENT/CONTRACT REF NO.: KE-KBI-529559-CS-CQS

JANUARY 2026

Client:

Kenya BioVax Institute

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1 Introduction

1.1 Project Background

The Government of Kenya, through the State Department of Medical Services, and with support from The World Bank, is implementing the Health Emergency Preparedness Response and Resilience Program (HEPRR) which aims to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Kenya. The Program, in part, seeks to reduce dependence on imports by supporting national and regional capacity for pharmaceutical and vaccine manufacturing. In this regard, the Program will specifically support Kenya, through the Kenya BioVax Institute (BioVax), to establish local vaccine manufacturing capacity through human resource development and operationalization of a vaccine fill-finish facility in Nairobi, as part of efforts to strengthen pandemic preparedness and self-reliance in health commodities supply.

BioVax is a state-owned enterprise established in 2021 with the mandate to manufacture, commercialise, and distribute human vaccines and other specialised health products and technologies. It serves as the Government of Kenya's implementing agency for vaccine manufacturing under the HEPRR Program, leading efforts to ensure compliance with WHO Good Manufacturing Practice (GMP) standards and to strengthen the vaccines and biologics manufacturing ecosystem in the country.

BioVax intends to undertake a comprehensive Biomanufacturing Environmental and Social Impact Assessment (ESIA) of the BioVax fill and finish facility in Embakasi, Nairobi, Kenya, identify and assess the potential environmental and social impacts of the proposed Fill and Finish Facility to develop appropriate mitigation measures for minimising any negative impacts and enhance positive ones.

1.2 Rationale

Kenya is strategically positioned to become a regional hub for pharmaceutical and vaccine manufacturing. Under the HEPRR Program, the Government of Kenya, through BioVax, is receiving support to establish a WHO Good Manufacturing Practices compliant fill-finish vaccine manufacturing facility in Nairobi.

To ensure that this investment is underpinned by a sound and compliant environmental and social foundation, there is a need to undertake an in-depth biomanufacturing Environmental and Social Impact Assessment (ESIA) in line with national legislation and applicable international standards that govern environmental protection, occupational health and safety, waste management, community impacts, and resource use for pharmaceutical and vaccine manufacturing operations. The assignment will also assess potential environmental and social risks associated with establishing and operating the facility, implement the required mitigation measures, and recommend measures to strengthen compliance, institutional effectiveness, and alignment with international good practices.

BioVax intends to engage a consulting firm to conduct an in-depth biomanufacturing ESIA for the proposed fill-finish manufacturing facility. Further, the assessment will identify environmental and social risks, gaps, and compliance requirements, and propose interventions aimed at strengthening environmental and social management, regulatory adherence, and conformity with the World Health Organisation's (WHO) Good Manufacturing Practice (GMP) standards and relevant national environmental and social safeguards legislation.

2 Objectives of the assignment

The primary objective of the consulting services is to undertake a comprehensive Environmental Social Impact study and ensure compliance with international environmental and social impact standards and regulations for biomanufacturing, national environmental and social legislation, as well as The World Bank Environmental and Social Standards (ESSs) in the context of vaccines and biologics manufacturing.

Further, the assignment will serve to identify gaps in national regulations and standards against international best practices on biomanufacturing environmental and social impacts and make recommendations on mitigation measures.

- i. Undertake a comprehensive Environmental and Social Impact Assessment (ESIA) for the biomanufacturing project in line with national laws and international

standards, including World Bank Environmental and Social Standards (ESSs), covering all project phases and associated subprojects.

- ii. Identify, analyse, and evaluate all environmental and social impacts — including health and safety risks during construction, operation, and maintenance — assessing their significance, cumulative nature, indirect and induced impacts, and overall environmental viability by weighing potential damages against anticipated benefits.
- iii. Conduct inclusive and meaningful stakeholder consultations with affected communities, government agencies, and all relevant parties to ensure broad input into the assessment and decision-making process.
- iv. Develop practical and cost-effective mitigation and enhancement measures, including a comprehensive Environmental and Social Management Plan (ESMP), to guide implementation and monitoring of environmental and social performance across the project lifecycle.
- v. Assess alignment with national regulatory frameworks and international best practices, identify existing gaps, recommend improvements, ensure full legal and regulatory compliance, and highlight opportunities to enhance positive environmental and social outcomes.

3 Scope of Consulting Services and Specific tasks

3.1 Scope of consulting services

The scope of the Consulting Services will include:

Conducting ESIA study for the proposed vaccine fill-finish facility, covering project description, mapping, and baseline environmental and socio-economic conditions.

It will assess potential impact direct, indirect, cumulative, and long-term across all phases, and propose mitigation measures within an Environmental and Social Management Plan (ESMP) aligned with Kenyan regulations, WHO, IFC, and World Bank standards. Key focus areas include biomedical and hazardous waste management, water use and wastewater treatment, air quality, noise, transport, security, occupational health and safety, and socio-economic effects. The assignment will also include stakeholder engagement, public disclosure, and

grievance mechanisms, with findings compiled in accordance with National Environment Management Authority guidelines.

3.2 Specific tasks

Task 1: Project Description & Mapping

- i. Describe the proposed project, its components, and the area of influence.
- ii. Prepare detailed maps showing the project site and areas potentially affected by direct, indirect, and cumulative impacts.

Task 2: Baseline Data Collection

- i. Conduct environmental baseline studies covering land use, meteorology, air quality, noise, geology, soils, disaster risks, water resources, flora and fauna, protected areas, pollution levels, and waste generation.
- ii. Conduct socio-economic baseline studies including population, social composition, urbanization, traffic levels, health and education levels, infrastructure, cultural heritage, and vulnerability assessments.

Task 3: Labor, Gender, and Safety Considerations

- i. Assess and integrate Labour Management Procedures (LMP) covering recruitment, working conditions, and workers' rights.
- ii. Identify and address risks related to Gender-Based Violence (GBV), Sexual Harassment, Exploitation and Abuse (SHEA), and propose prevention and response measures.
- iii. Develop a comprehensive Occupational Safety and Health (OSH) plan in line with Kenyan regulations and international standards.

Task 4: Impact Assessment

- i. Identify and analyse potential environmental and social impacts during all project phases.
- ii. Evaluate direct, indirect, cumulative, short-term, and long-term impacts, and assess environmental viability.

Task 5: Mitigation Measures & ESMP Development

- i. Propose specific technical, management, and monitoring measures to address negative impacts.
- ii. Develop an Environmental and Social Management Plan (ESMP) with sustainability actions (energy efficiency, renewable energy integration, carbon offsets, Key Performance Indicator monitoring).

Task 6: Stakeholder Engagement

- i. Identify relevant stakeholders and conduct consultations through meetings, workshops, and questionnaires.
- ii. Ensure public disclosure of information, document feedback, and establish a grievance redress mechanism.

Task 7: Address biomedical and hazardous waste management, water resource use and wastewater treatment, air emissions, noise and vibration control, transportation impacts, site security, occupational health and safety, socio-economic effects, and green pharmaceutical practices.

Task 8: Compile ESIA report and non-technical summary in line with National Environment Management Authority (NEMA) guidelines and World Bank Environmental and Social Standards (ESS).

Data analysis from the findings shall be compiled in accordance with EIA guidelines issued by NEMA for comprehensive Project Report and World Bank ESS standards.

4 Duration and Location of the Assignment

The duration of consulting services will be a period of four (4) calendar months from contract commencement date.

The Consulting services will generally be offered in Nairobi (Kenya) at the BioVax offices. The consulting services may however involve engagement with various

stakeholders in the pharmaceutical and vaccine manufacturing ecosystem. All such engagements shall be supported by BioVax.

5 Reporting Requirements and Timelines for submission of deliverables.

5.1 Reporting

- i. The Consultant will deliver reports to the Chief Executive Officer. All reports shall be submitted to the:
 Chief Executive Officer
 Kenya BioVax Institute
 KWFT Centre, Kiambere-Masaba Road Junction, Upperhill, Nairobi
 P.O. Box 40776-00100. Nairobi. KENYA
 Tel:+254775751636
 Email: info@biovax.go.ke cc: hepr@biovax.go.ke
- ii. Upon submission of every report, the consultant may be asked to make a presentation of the submitted report to the Client in a scheduled meeting. The acceptance of the report shall be provided by the client to the consultant by e-mail and/or recorded in the minutes of the meeting.

5.2 Timelines for Submission of Deliverables

The following deliverables are expected from the ESIA study:

Table 1: Reporting Requirements and Timelines for Submission of Deliverables

No	Deliverable/ Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
1.	Inception Report	Detailed Project Work Plan and methodology to carry out the assignment.	0.5	2 printed copies & an electronic copy

2.	Interim Report	Interim progress report as detailed in the key tasks of the assignment. Annexure of minutes and attendance lists of stakeholder/ agencies engagements	1.5	2 printed copies & an electronic copy
3.	Environmental and Social Management Plan (ESMP) & Environmental and Social Management Framework (ESMF).	Detailing the implementation of mitigation measures and monitoring activities. Labor Management Plan LMP, Grievances Redress Mechanism, Infection Control and Pharmaceutical Waste Management Plan (ICPWMP)	2.5	2 printed copies & an electronic copy
4.	Stakeholder Engagement Report	Stakeholder Engagement Plan (SEP)	3	2 printed copies & an electronic copy
5.	Draft Final Report	Draft of the final report	3.5	Electronic copy
6.	Final Report	Final Revised Report incorporating feedback from a validation workshop	4	2 printed copies & an electronic copy

6 Payment Schedule

The proposed payment schedules based on satisfactory performance of the contract which will be negotiated with the successful consultant will be as presented in Table 2 below.

Upon submission of every report, the consultant is expected to make a presentation of the submitted report to the Client in a scheduled meeting. The acceptance of the report shall be recorded in the minutes of the meeting.

Table 2: Payment Schedule

S/No	Deliverable/Reports	Timelines for submission of deliverables after contract commencement (months)	% of the contract amount
1.	Submission and Acceptance of Inception report	0.5	10%
2.	Submission and Acceptance of the interim report	1.5	20%
3.	Submission and Acceptance of the ESMP and ESMF	2.5	20%
4.	Submission and Acceptance of Stakeholders engagement reports	3	10%
5.	Submission and Acceptance of Draft Final Report	3.5	0%
6.	Submission and Acceptance of Final Report	4	40%

7 Minimum requirements for Consultant Qualification and Experience

The consulting firm shall have the following minimum qualifications and experience:

7.1 Core Business and years in business

The firm shall be registered/incorporated as a consulting firm with core business in environmental and social impact assessment services or related fields for a minimum of ten (10) years

7.2 Relevant Experience

The firm shall demonstrate as having successfully executed and completed at least two (2) assignments of a similar nature, complexity and in a similar operating environment in the last seven (7) years. Details of similar assignments- name and address of the client, scope, value, and period should be provided in the submitted proposal including enumeration of these past assignments.

7.3 Technical and managerial capability of the firm

The firm shall demonstrate as having the requisite technical capacity and managerial capacity to undertake the assignment in the submitted company profile(s).

8 Team Composition, Minimum Qualifications and Experience for Key Experts

The Consulting firm shall have well-qualified and experienced professionals as required and appropriate for completion of the exercise. They should possess necessary resources to undertake services of such nature including equipment and software required to execute the assignment.

The key professionals/experts shall personally carry out (with assistance of other non-key staff deemed appropriate) the services as described in this Terms of Reference.

The team should consist of multidisciplinary experts with the following minimum qualifications:

8.1 Environmental Specialist- Team Lead

- i. A minimum of a Master's degree in Environmental Science/ Engineering, Public Health, or related field from an institution/ university recognised in Kenya;
- ii. A minimum of 10 years' experience in socio-environmental impact management/social environmental impact assessment;

- iii. A minimum of six (years) specific experience working with multilateral finance institutions funded projects and/or government agencies in environmental and social impact assessment with a focus on the pharmaceutical and vaccine environment; and
- iv. Must be a validly registered and holding a current annual practicing license from a relevant professional body recognised in Kenya.

8.2 Biosafety and Biosecurity Expert

- i. Minimum of a Master's degree in Microbiology, Biotechnology, or a closely related field from a university/ institution recognised in Kenya;
- ii. A minimum of eight (8) years of general experience in laboratory systems, biosafety and biosecurity;
- iii. A minimum of four (4) years specific experience working with donor-funded projects and/or government agencies in conducting biosafety and biosecurity assessments, laboratory risk assessments, or compliance reviews within vaccine manufacturing, biomedical and pharmaceutical manufacturing settings; and
- iv. Must be validly registered and holding a current annual practicing license from a relevant professional body recognised in Kenya.

8.3 Social Safeguards expert

- i. Minimum of a Bachelor's degree in Social Sciences, Anthropology, Development Studies, Sociology, or a closely related field from a university/institution recognised in Kenya;
- ii. A minimum of five (5) years of general experience in social development, social research, or social risk management;
- iii. A minimum of four (4) years specific experience working with donor-funded projects and/or government agencies in stakeholder engagement, gender inclusion, community engagement, social impact assessment, land acquisition and resettlement, and labour standards in line with Environmental and Social Standards (ESS2 and ESS5);
- iv. Must be validly registered and holding a current annual practicing license from a relevant professional body recognised in Kenya.

8.4 Occupational Health & Safety (OHS) Expert

- i. Minimum of a Bachelor's degree in Occupational Health, Public Health Industrial Hygiene, Environmental Health and Safety, or a closely related field from a university/institution recognised in Kenya;
- ii. A minimum of five (5) years of general experience in occupational health and safety management, industrial hygiene, or related fields;
- iii. A minimum of four (4) years specific experience working with donor-funded projects and/or government agencies in developing and implementing OHS systems, conducting workplace risk assessments, and ensuring compliance within pharmaceutical, vaccine manufacturing, or industrial settings;
- iv. Possession of a recognised professional certification in Occupational Safety and Health, such as National Examination Board in Occupational Safety and Health (NEBOSH), the Institution of Occupational Safety and Health (IOSH), or an equivalent qualification, is required.
- v. Must be validly registered and holding a current annual practicing license from a relevant professional body recognised in Kenya.

9 Time inputs for key experts

The number of key experts and the estimated time input for each key expert for the assignment are presented in Table 3.

Table 3: Estimated Time Inputs for Key Experts

No	Key Experts	No	Time inputs in months
1.	Environmental Specialist	1	4
2.	Biosafety and Biosecurity Expert	1	4
3.	Social Safeguards Expert	1	4
4.	Occupational Health & Safety (OHS) Expert	1	4

10 Management and Accountability of the Assignment

The Kenya BioVax Institute is the Client for these services. The Client is represented by the Chief Executive Officer. The CEO will designate a senior manager who will work closely with the HEPRR focal officer to oversee the day-to-day running of the assignment.

11 Obligation of the Client

- i. The client will provide all relevant information that can assist in this assignment;
- ii. Organise meetings with relevant stakeholders as may be required by the consultant; and
- iii. Review and approve reports

12 Obligation of the Consultant

- i. The consulting firm will be answerable to the Chief Executive Officer and will work closely with BioVax staff in the execution and delivery of this consulting service;
- ii. The consultant will be required to make their own travel and accommodation arrangements during consultations with different stakeholders to ensure the assignment is carried on smoothly and seamlessly within the timeframe provided;
- iii. The consulting firm will consult and include inputs from the stakeholders and is responsible for organising and achieving the evaluation and delivering the final report.

13 Proprietary Rights of Client in Reports and Records

- i. All the reports, data, and information developed, collected, or obtained from the implementing agencies etc., Client, and other Institutions during this exercise shall belong to the Client. No use shall be made of them without prior written authorisation from the Client.
- ii. At the end of the Services, the Consultant shall relinquish all data, manuals, reports and information (including the database, codes, and related documentation) to the Client and shall make no use of them in any other assignment without prior written authority from the Client.