



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 PREPARATION OF PRELIMINARY ENGINEERING
DESIGNS, EMPLOYER REQUIREMENTS AND CONSTRUCTION SUPERVISION,
AND GOOD MANUFACTURING PRACTICE COMPLIANCE CERTIFICATION FOR
ESTABLISHMENT OF A HUMAN VACCINES AND BIOLOGICALS FILL-FINISH
MANUFACTURING FACILITY
(FIRMS SELECTION)**

PROCUREMENT/CONTRACT REF NO.: KE-KBI-537982-CS-QCBS

MARCH 2026

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1.0 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 engage a qualified Consulting Firm to provide comprehensive Project Management and Regulatory Compliance support for the operationalisation of the sterile fill–finish manufacturing facility for human vaccines and biologics in Embakasi, Nairobi, Kenya. This assignment seeks to ensure that the facility, utilities, equipment, manufacturing processes, laboratory systems, documentation framework, and workforce capabilities are developed and implemented to meet the full spectrum of regulatory, quality, operational, and technical requirements applicable to sterile biopharmaceutical manufacturing. The Consulting Firm will guide BioVax in achieving end-to-end operational readiness, including preparation of preliminary engineering designs, employers requirements and construction supervision, qualification and validation activities, establishment of a robust Pharmaceutical Quality System, execution of technology transfer, preparation of regulatory dossiers, and attainment of licensing by the Pharmacy and Poisons Board, as well as alignment with international standards and future WHO Prequalification expectations.

1.2 Rationale

Kenya is strategically positioned to serve as the regional hub for manufacturing of specialised Health Products and Technologies, including vaccines for children, adolescents, and maternal populations. This potential is underpinned by an enabling business environment, a growing skilled workforce, the capacity to conduct relevant clinical research and trials, and a strategic role in regional health security initiatives. Evidence reveals that developing local manufacturing capacity for priority infectious diseases could avert over 4.44 million deaths and 206.27 million disability-adjusted life years across the African region, highlighting the transformative public health and economic benefits of domestic vaccine production.

It is in this regard that Kenya BioVax, under the HEPRR programme, is implementing the vaccine manufacturing component with an objective of establishing WHO Good Manufacturing Practices-compliant production capacities for human vaccines to strengthen health commodity security for Universal Health Coverage and self-reliance for pandemic preparedness captured in the Subcomponent 1.3: Strengthening of Local Pharmaceutical and Vaccine Manufacturing Capacity.

However, global vaccine manufacturing is technologically complex and capital-intensive, requiring carefully structured partnerships for new entrants to succeed. To ensure that this investment progresses smoothly toward full operational readiness, regulatory compliance, and commercial viability, BioVax, therefore, intends to engage a Consulting Firm to assess the status of existing works, evaluate technical and regulatory gaps, project management for facility establishment and guide the seamless transition into full operationalisation. A key objective of this assignment is to support BioVax in achieving GMP certification by the Pharmacy and Poisons Board (PPB), which is a critical milestone for initiating commercial manufacturing and for future WHO Prequalification.

2 Objective of the Assignment

The primary objective of the consulting services is to develop comprehensive preliminary engineering designs, employer requirements, draft bidding documents and construction supervision, and supporting the Client in achieving full operationalisation and licensing of the sterile fill-finish manufacturing facility for human vaccines and biologicals in accordance with national regulatory requirements, including Good Manufacturing Practices (GMP) certification by the Pharmacy and Poisons Board (PPB), and alignment with applicable international standards.

Further, the assignment will identify technical, regulatory, quality, and operational gaps in the existing facility, systems, and documentation when benchmarked against international best practices for sterile biomanufacturing and propose measures to ensure seamless transition into full operationalisation.

2.1 Specific Objectives

- i. Biomanufacturing readiness assessment: Conduct a comprehensive biomanufacturing assessment of existing infrastructure, personnel, works, documentation, and systems and generate assessment reports;
- ii. Preliminary Engineering Design: Develop Preliminary Engineering Designs and define Employers Requirements and functional specifications for a future FIDIC® EPC/Turnkey Projects (Silver Book) contract;
- iii. Project Risk Structuring: Formulate a comprehensive Project Risk Matrix and Project Risk Management Framework (Technical, Financial, Environmental and Social) to guide the risk allocation between the Employer and the Contractor in the future EPC/Turnkey Projects contract;
- iv. Cost Estimation: Prepare a confidential, highly accurate Engineer's Cost Estimate for a GMP-compliant sterile fill-finish manufacturing facility for human vaccines and biologicals;

- v. Procurement Documentation: Prepare comprehensive Employer’s Requirements and draft bidding documents incorporating all technical, GMP, environmental and social safeguards findings; and providing technical support during procurement, bid evaluation, and contract negotiations;
- vi. Construction supervision services: Acting as the Employer’s Representative during implementation to safeguard compliance with the Employer’s Requirements, GMP standards, and environmental and social obligations; reviewing and advising on contractor submissions, detailed designs, validation and commissioning plans, and method statements; supporting site inspections, testing, commissioning, qualification, and handover processes; and preparing periodic implementation and risk monitoring reports to the Client and financiers.
- vii. Stakeholder Engagement Support: Support the Client in technical coordination and stakeholder engagement activities (public consultations, national and county government meetings) required for project appraisal; GMP Documentation: support in the development of complete GMP documentation including equipment and utility qualification, process validation and analytical method transfer and regulatory dossier submissions;
- viii. Technology transfer support: provide specialised services to support the Client in undertaking a successful technology transfer from an identified sending unit ensuring suitability for qualification, validation, national regulatory approval, and support long-term alignment with WHO Prequalification expectations;
- ix. Training and capacity building: Design, deliver, and institutionalise a structured, comprehensive GMP-related training programme covering sterile manufacturing principles; and
- x. Business Process Reengineering: Evaluate existing business processes and design an end-to-end institutional business process reengineering plan

3 Scope of Consulting Services and Specific Tasks

3.1 Scope of Consulting Services

The Consulting Services shall support BioVax in the procurement and supervision of an EPC/turnkey contractor, and in the operationalisation, regulatory licensing, and Good Manufacturing Practice (GMP) certification of the sterile fill–finish manufacturing facility for human vaccines and biological products, through the provision of project management support and independent GMP oversight.

The assignment shall be implemented in two phases:

Lumpsum deliverables that shall comprise of independent, milestone-based activities focused on preparing preliminary engineering designs, employer requirements, development of complete EPC/ Turnkey tender documentation, and provision of technical support for tender evaluations, contract negotiation and finalisation; business process reengineering; biomanufacturing readiness assessments; regulatory alignment support; oversight of qualification and validation activities; technology transfer support; Pharmaceutical Quality System implementation; regulatory dossier preparation and submission; and training and capacity building, to support facility licensing and GMP certification.

Time-based deliverables shall comprise providing oversight on the implementation of the EPC/Turnkey contract and technology transfer process while ensuring alignment to regulatory requirements.

Across both phases, the Consultant shall provide project management oversight, technical and regulatory oversight to ensure that installation and operationalisation of cleanrooms, aseptic production lines, equipment, and critical utilities, and technology transfer processes are executed in compliance with applicable Good Manufacturing Practices and national regulatory requirements. The scope also includes support for regulatory submissions required for Good Manufacturing Practice certification and preparation for future WHO prequalification.

3.2 Lumpsum Tasks

3.2.1 Task One: Preparation of Preliminary Designs, Employer Requirements and Construction Supervision

3.2.1.1 Inception Phase

The Consulting Firm will hold an inception meeting, which will serve as the formal starting point of the assignment and will establish a common understanding between BioVax and the Consultant regarding the objectives, scope, deliverables, and implementation approach of the consultancy. This engagement will ensure strategic alignment, clarify roles and expectations required to deliver a successful GMP compliant human vaccines and biologicals fill finish manufacturing facility. In undertaking this task, the Consulting Firm will be expected to:

- i. Familiarise with all background documentation and preparatory work conducted to date, including but not limited to reports, studies, audits, and shall be responsible for carrying out initial reviews; and
- ii. Develop an inception report that clearly outlines the methodology, detailed implementation plan, sequencing of tasks, timelines, deliverables and key milestones. This report will provide a shared roadmap for the assignment and form the basis for monitoring progress and ensuring the timely and successful completion of the consultancy.

3.2.1.2 Stakeholder Consultation Workshop Report

- i. Document workshop logistics, including the date, venue, agenda, programme, and full participant list from national government agencies, county government, local communities, and civil society organisations;
- ii. Summarise all Consultant presentations, capturing key messages, proposed approaches, and technical outlines shared during the workshop;
- iii. Record all stakeholder questions, comments, and concerns, including thematic issues raised across groups;
- iv. Provide the Consultant's responses, clarifications, and commitments made in reaction to stakeholder input; and
- v. Compile photographic evidence and produce recommendations on how stakeholder feedback will be integrated into the ongoing design work.

3.2.1.3 Preliminary Concept Design

- i. Review existing data on the fill-finish manufacturing facility project and social and economic activities in the project study area, identifying critical information gaps and mitigation measures;
- ii. Develop preliminary concept designs and present recommended structural and facility layout concepts aligned with project scope and regulatory expectations;
- iii. Outline key engineering assumptions guiding the design approach;
- iv. Provide preliminary cost estimates, including high-level CAPEX components;

- v. Identify major technical constraints or design risks requiring further investigation and
- vi. Propose next steps and confirm readiness to proceed to the detailed engineering and investigation stage.

3.2.1.4 Preliminary Engineering Design

The Consultant shall conduct a preliminary design survey for the optimum alignment and design standards, in accordance with national regulatory requirements. The consultant shall:

- i. Compile the Draft Engineering Design Report, integrating all architectural, civil, structural, mechanical, and electrical components;
- ii. Consolidate all supporting technical investigations, including materials, geotechnical, hydrological, drainage, and structural assessment reports;
- iii. Prepare the Employer's Requirements, Preliminary Technical Specifications, Bill of Quantities, Book of Drawings and confidential Engineer's Cost Estimates, that will form the technical foundation for the future FIDIC® EPC/Turnkey Projects (Silver Book) contract and World Bank Standard Procurement Documents for Works;
- iv. Prepare complete Request for Proposals comprising all documents required for international competitive procurement in accordance with World Bank Procurement Regulations;
- v. Provide technical support during bid evaluation, due diligence and contract negotiations to ensure GMP and regulatory compliance; and
- vi. Submit a unified package reflecting interlinkages between all technical components and ready for Client review before finalisation.

3.2.1.5 Final Report

A comprehensive report summarising the Report outlining project milestones, risk mitigation measures, procurement processes and lessons learnt

3.2.2 Task Two: Good Manufacturing Practice Certification Compliance

3.2.2.1 Inception Report

The Consulting Firm will hold an inception meeting, which will serve as the formal starting point of the assignment and will establish a common understanding between BioVax and the Consultant regarding the objectives, scope, deliverables, and implementation approach. This engagement will ensure strategic alignment, clarify roles and expectations required to deliver a successful GMP compliant human vaccines and biologicals fill finish manufacturing facility. In undertaking this task, the Consulting Firm will be expected to:

- i. Familiarise with all background documentation and preparatory work conducted to date, including but not limited to reports, studies, audits, and shall be responsible for carrying out initial reviews; and
- ii. Develop an inception report that clearly outlines the methodology, detailed implementation plan, sequencing of tasks, timelines, deliverables, and key milestones. This report will provide a shared roadmap for the assignment and form the basis for monitoring progress and ensuring the timely and successful completion of the consultancy; and

3.2.2.2 Biomanufacturing Assessment

Conduct a biomanufacturing readiness assessment, including personnel, infrastructure, utilities, equipment, and facility alignment with GMP expectations.

- i. Perform a comprehensive gap analysis and risk assessment across systems, processes, and compliance elements;
- ii. Prepare a site assessment report, documenting facility readiness, deficiencies, and corrective

action needs;

- iii. Assess workforce readiness, including staffing levels, competencies, training, and organisational maturity; and
- iv. Evaluate operational processes, identifying gaps in SOPs, workflows, validation status, and quality systems, and provide actionable recommendations.

3.2.2.3 Training Programme – Aseptic Simulation, GMP & PQS Competency

- i. Develop and deliver a comprehensive training programme covering aseptic manufacturing, cGMP requirements, PQS implementation, and ALCOA+ data integrity principles;
- ii. Conduct hands-on simulation training including aseptic gowning, material transfers, line interventions, and mock media fills;
- iii. Deliver role-specific training modules in critical areas incorporating ICH Q9 and ICH Q10 requirements for risk management, change control, deviations, and CAPA;
- iv. Carry out mock regulatory inspection exercises, including front-room/back-room simulations and documentation readiness drills;
- v. Prepare training materials, simulation modules, competency exams and refresher training schedules; and
- vi. Implement a structured train-the-trainer programme.

3.2.2.4 Vendor Pre-Qualification Framework

The employer shall prequalify vendors for the supply of goods and provision of services necessary to support its operational, regulatory, and strategic objectives, including but not limited to pharmaceutical raw materials, laboratory and quality equipment, utilities, engineering and facility services, regulatory and consultancy services, quality management systems support, cold chain infrastructure, and related technical services.

A structured, risk-based and GMP-aligned vendor prequalification and supplier qualification framework will therefore be required to ensure compliance with applicable regulatory and quality management standards. The Consultant will be required to:

- i. Review historical vendor pre-qualification processes;
- ii. Develop the Vendor's Prequalification Framework ensuring alignment with GMP, WHO TRS guidelines, Pharmaceutical Quality System requirements, Environmental Health and Safety, biosafety, and biosecurity requirements relevant to vaccine manufacturing operations; and
- iii. Evaluate technical capability and capacity during framework implementation

3.2.2.5 Master Documentation Development and Regulatory Alignment

- i. Develop a consolidated Master Document Index (MDI) for all engineering, qualification, validation, Pharmaceutical Quality System, and regulatory documents; and
- ii. Prepare a regulatory alignment plan mapping requirements for PPB GMP certification and WHO PQ readiness.

3.2.2.6 Pharmaceutical Quality System (PQS) Development and Implementation

- i. Develop the complete PQS documentation set (Quality Manual, SOPs, batch records, logs, Contamination Control Strategy, validation templates);
- ii. Establish change control, deviation/Corrective Action Preventive Action (CAPA), QRM, investigations, document control, audits, supplier qualification, and complaints systems per ICH Q10;
- iii. Implement Quality Risk Management (QRM) in accordance with ICH Q9(R1);
- iv. Implement Data Integrity controls aligned with ALCOA+ principles;

- v. Establish Continued Process Verification (CPV) and periodic review systems; and
- vi. Integrate Environmental Monitoring (EM) and Contamination Control Strategy (CCS) into PQS per Annex 1 requirements.

3.2.2.7 Qualification & Validation of Facilities, Utilities, and Equipment

- i. Oversee Facility Assessment Test and Site Assessment Test for all production and laboratory systems;
- ii. Lead execution of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ); and
- iii. Conduct cleanroom qualification including airflow testing, HEPA integrity, recovery studies, viable and non-viable monitoring, and pressure cascade verification.

3.2.2.8 Quality Control Laboratory Qualification, Analytical Method Transfer and Readiness

- i. Provide technical oversight and qualification protocols for laboratory equipment commissioning;
- ii. Develop protocols and oversight for analytical method transfer and validation (sterility, endotoxin, potency, identity, physicochemical); and
- iii. Develop and review validation protocols for Laboratory Information Management System (LIMS) to ensure audit trail integrity, workflow control, and data security.

3.2.2.9 Aseptic Process Qualification, Process Validation and Stability studies

- i. Conduct Aseptic Process Simulations (media fills) under worst-case conditions;
- ii. Execute engineering and technical batches for Technology Transfer alignment;
- iii. Conduct Process Performance Qualification (PPQ) batches for commercial readiness;
- iv. Conduct stability studies per ICH Q1A(R2); and
- v. Finalise lifecycle validation documentation including PPQ protocols, reports, Critical Process Parameters/Critical Quality Attribute justification, and control strategy documentation.

3.2.2.10 Dossier Preparation & Regulatory Submissions

- i. Prepare Chemistry, Manufacturing and Controls (CMC) sections of the dossier in CTD format.
- ii. Compile all modules required for product registration (process description, control strategy, PPQ data, stability data, analytical methods, facility information);
- iii. Prepare Site Master File, Validation Master Plan, CCS, and supporting GMP documentation for PPB licensing;
- iv. Conduct dossier completeness checks and develop responses to PPB queries; and
- v. Support preparation of documentation for WHO PQ, including readiness assessments and file packaging.

3.2.2.11 Business Process Reengineering (BPR)

- i. Map existing operational workflows;
- ii. Conduct gap analysis against cGMP, WHO PQ, and ICH Q10;
- iii. Redesign end-to-end operational workflows to improve efficiency and contamination control;
- iv. Propose organisational restructuring and competency requirements;

- v. Develop integrated operational frameworks with Key Performance Indicators for continuous improvement; and
- vi. Prepare a comprehensive BPR Report.

3.3 Time-Based Tasks

Provides continuous project management, technical, regulatory, and quality oversight of the EPC/Turnkey contractor and technology transfer processes for the establishment of the sterile fill-finish manufacturing facility for human vaccines and biologicals.

- i. Perform the duties of the Employer's Representative, including administering the contract, reviewing contractor submissions, and advising the Employer on compliance with the Employer's Requirements, GMP standards, and contractual obligations;
- ii. Coordinate all cross-functional activities across technology transfer sending unit and BioVax;
- iii. Provide structured reporting including monthly progress reports, dashboard updates, deviation notices, and corrective action tracking;
- iv. Integrate ESS/ESIA requirements into URS, validation protocols, SOPs, commissioning plans and workflows, and Pharmaceutical Quality System documents;
- v. Monitor contractor compliance with ESMP requirements including waste management, handling of hazardous materials, OHS, and community safety;
- vi. Provide periodic environmental and social compliance updates;
- vii. Develop and maintain a system of quality control and assurance for works;
- viii. Support regulatory interactions with the Pharmacy and Poisons Board (PPB) and ensure alignment with WHO technical expectations for Prequalification;
- ix. Carry out quarterly inspections during the Defects Notification Period and instruct the Contractor with regard to outstanding works and defects;
- x. Ensure preparation of the Final Statement (Account) by the Contractor as per the works contract and submit to the Client for final determination and certification; and
- xi. Oversee the orderly transition from construction and installation to qualification, validation, and operational readiness.

3.4 Close out Phase

The Consulting Firm will hold a close-out meeting, to serve as the formal conclusion of the assignment and a critical governance milestone for BioVax. In the close-out meeting, the Firm will purpose to review, validate, and consolidate the outcomes of the project, ensuring all agreed objectives are achieved and that BioVax is positioned to fully internalise and sustain the benefits of the engagement. The meeting will provide a structured forum for reflecting on implementation performance, confirming the completeness of deliverables, and facilitating institutional learning by capturing insights that will inform future projects.

In undertaking this task, the Consulting Firm will be expected to compile a comprehensive project final report that integrates technical, operational and implementation performance assessments, documents lessons learned, residual risks, and recommendations for future initiatives. The report will

incorporate any additional reporting requirements specified by BioVax and will serve as a reference for continuous improvement and future scaling efforts.

4 Duration and Location of the Assignment

The consulting services will be implemented over a cumulative period of thirty-six (36) months from contract commencement date.

Inputs by the consulting firm shall be based on implementation of the lumpsum deliverables (Task 1 shall have a duration not exceeding eight (8) months from commencement date and Task 2 shall have a duration not exceeding thirty-four (34) months from contract commencement) and time-based deliverables that shall have a duration not exceeding twenty-eight (28) months from the date of issuance of Commencement notice by the Client, which shall be issued following successful completion and acceptance of Task 1 Lumpsum deliverables.

The Consulting Services will generally be offered in Nairobi (Kenya) at the Kenya BioVax Institute offices. The Consultant's technical proposal shall describe their approach to delivering services, including any travel requirements

5 Reporting Requirements and Project Deliverables Timelines

5.1 Reporting

- a) 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 40779-00100. Nairobi. KENYA
[Tel: +254 775 751 639](tel:+254775751639)
Email: ceo@biovox.go.ke cc: hepr@biovox.go.ke

- b) 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 Lumpsum Deliverables

The consultants will be expected to deliver the following outputs. Periodic timelines and submission formats shall be determined in consultation with the Client:

Table 1: Reporting Requirements and Timelines for Submission of Lumpsum Deliverables

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
LUMPSUM DELIVERABLES				
TASK ONE: PREPARATION OF PRELIMINARY DESIGNS, EMPLOYER REQUIREMENTS AND CONSTRUCTION SUPERVISION				
1	Inception Report	This report shall summarise the Consultant's understanding of the assignment objectives and scope, present the proposed methodology and approach for conducting the assignment, provide a detailed work plan with activity schedules and milestones, present the responsibility assignment matrix, identify any issues or constraints that may affect the assignment, and propose solutions for addressing identified constraints.	Within 14 days of commencement of services	2 hard copies + 2 soft copies (USB) in PDF and MS Word formats
2	Stakeholder Consultation Workshop Report	This report shall document the proceedings of the first stakeholder consultation workshop held during the early stages of the assignment. The report shall include the date and venue of the workshop, list of participants, agenda and program, summary of presentations made by the Consultant, record of questions and comments raised by stakeholders, the Consultant's responses to stakeholder input, photographic documentation, and recommendations for incorporating stakeholder feedback into the design work. The workshop shall accommodate approximately thirty participants from national government agencies, county government, local communities, and civil society organisations.	Within 2 weeks following the first stakeholder workshop, approximately 2 months after commencement	2 hard copies + 2 soft copies (USB) in PDF and MS Word formats
3	Preliminary Concept Design Report	This report serves as the critical phase gate deliverable and shall present the recommended structural requirements and preliminary cost estimates.	2.5	4 hard copies + 4 soft copies (USB) in

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
				PDF and MS Word formats)
4	Draft Final Preliminary Engineering Design Report	Consolidated report comprising: <ul style="list-style-type: none"> • Draft Engineering Design Report; • Draft Materials Investigation Report; • Draft Geotechnical Investigation Report; • Draft Hydrological and Drainage Report; • Draft Structural Design Report; • Draft Engineer's Cost Estimates (confidential); • Draft Employer's Requirements and Bidding documents; • Specifications • Draft Bills of Quantities; • Draft Book of Drawings. 	3.5	2 hard copies + 2 soft copies (USB) in PDF and native formats
5	Final Engineering Design Report	Final versions of all components listed above incorporating the Client's comments, plus Computer Output of All Setting Out Data.	5	10 hard copies + 10 soft copies (USB) in PDF and native formats
6	Final Report	Report outlining project milestones, risk mitigation measures, procurement and tender evaluation processes and lessons learnt	8	2 hard copies + 2 soft copies (USB) in PDF
TASK TWO: GOOD MANUFACTURING PRACTICE CERTIFICATION COMPLIANCE				
1	Inception Report	This report shall summarise the Consultant's understanding of the assignment objectives and scope, present the proposed methodology and approach	Within 14 days of commencement of services	2 hard copies + 2 soft copies (USB) in PDF

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
		for conducting the assignment, provide a detailed work plan with activity schedules and milestones, present the responsibility assignment matrix, identify any issues or constraints that may affect the assignment, and propose solutions for addressing identified constraints.		
2	Biomanufacturing readiness assessment reports	2.1 Comprehensive reports documenting findings Client readiness. identifying potential risks in the following: Site Assessment Report	6	2 hard copies + 2 soft copies (USB) in PDF
		2.2 Workforce readiness report	6	2 hard copies + 2 soft copies (USB) in PDF
		2.3 Operational Processes gap analysis and risk assessment	6	2 hard copies + 2 soft copies (USB) in PDF
3	Training and Capacity Building reports	3.1 Training curriculum (GMP, PQS, aseptic behaviour)	12	2 hard copies + 2 soft copies (USB) in PDF
		3.2 Development and deployment of Aseptic simulation training modules on areas including gowning, interventions, mock media fills	12	2 soft copies (USB) in PDF and native format
		3.3 Competency assessments & training records	24	2 hard copies + 2 soft copies (USB) in PDF
		3.4 Train-the-trainer programme	24	2 hard copies + 2

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
				soft copies (USB) in PDF
4	Vendor Pre-Qualification Framework	4.1 Draft Vendor pre-qualification framework	8	2 hard copies + 2 soft copies (USB) in PDF
		4.2 Final Vendor prequalification framework	12	2 hard copies + 2 soft copies (USB) in PDF
5	Master Documentation	5.1 Draft Master Document Index	12	2 hard copies + 2 soft copies (USB) in PDF
		5.2 Final Master Document Index	34	2 hard copies + 2 soft copies (USB) in PDF
6	Pharmaceutical Quality System (PQS) Implementation	6.1 Draft Pharmaceutical Quality System Documentation and Implementation Status Reports	18	2 hard copies + 2 soft copies (USB) in PDF
		6.2 Final Pharmaceutical Quality System Implementation and Maturity Report	34	2 hard copies + 2 soft copies (USB) in PDF
7	Facility, Utilities and Equipment Qualification	7.1 Draft Facility, Utilities and Equipment Qualification and Validation Protocols and Oversight Reports (Factory and Site Acceptance Testing)	24	2 hard copies + 2 soft copies

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
	n & Validation reports			(USB) in PDF
		7.2 Final Facility, Utilities and Equipment Qualification and Validation Protocols and Reports	34	2 hard copies + 2 soft copies (USB) in PDF
8	Laboratory Qualification & Analytical Method Transfer	8.1 Draft Laboratory Qualification and Analytical Method Transfer Reports	24	2 hard copies + 2 soft copies (USB) in PDF
		8.2 Final Laboratory Qualification and Analytical Method Transfer Report	30	2 hard copies + 2 soft copies (USB) in PDF
9	Aseptic Process Qualification & Process Validation reports	9.1 Draft Aseptic Process Qualification , Process Validation and stability study Protocols (Media Fill, Engineering Batch, Process Performance Qualification and Stability Studies)	24	2 hard copies + 2 soft copies (USB) in PDF
		9.2 Final Aseptic Process Qualification, Process Validation and stability study Protocols and Reports	34	2 hard copies + 2 soft copies (USB) in PDF
10	Dossier Preparation & Regulatory Submissions reports	10.1Regulatory Pre-Submission Review Reports	18	2 hard copies + 2 soft copies (USB) in PDF
		10.2 Final Regulatory Submission Package and Regulatory Response Summary Report	30	2 hard copies + 2 soft copies (USB) in PDF

No.	Deliverable / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
11	Business Process Reengineering (BPR) report	11.1 Draft Business Process Mapping and Gap Analysis Report	28	2 hard copies + 2 soft copies (USB) in PDF
		11.2 Final Business Process Reengineering Report with redesigned workflows and performance indicators	34	2 hard copies + 2 soft copies (USB) in PDF

5.3 Timelines for submission of time-based deliverables

All reports and communications related to time-based deliverables covering Employers Requirements, Construction Supervision and Technology Transfer shall conform to a format agreed with Engineer/Client, including an executive summary, a table of contents, standard cover sheet with date and project details, submission letter showing those copied and actual date of submission.

Table2: Reporting Requirements and Timelines for Submission of Time-Based Deliverables

S. No.	Reports/Deliverable	Timeline for Submission	Copies	
			Hard Copies	Electronic Copy**
1.	Monthly Progress Reports	Within seven (7) calendar days after the end of the reporting month	3	2
2.	Quarterly Progress and Financial Appraisal Reports	Within seven (7) calendar days after the end of the reporting Quarter	3	2
3.	Contract Completion Report for Taking Over	Within fourteen (14) Calendar Days after issuance of Taking Over Certificate of the whole of the works	3	2
4.	As – built drawings	Within fourteen (14) Calendar Days after issuance of Taking Over Certificate or issuance of Certificate of Completion for whole of the works or sections of the works	3	2
5.	Operations and maintenance manual	Within fourteen (14) Calendar Days after issuance of Taking Over Certificate or issuance of Certificate of Completion	3	2

S. No.	Reports/Deliverable	Timeline for Submission	Copies	
			Hard Copies	Electronic Copy**
		for the whole works or sections of the works		
6.	Final Contract Completion Report at the End of Defects Notification / Liability Period	Within twenty-eight (28) Calendar Days after the submission of the Final Statement of Completion by the Contractor upon receipt of the Performance Certificate	3	2
7.	Any other reports required by the Client	As will be required	As will be required	As will be required

N.B ** the soft copies must be delivered in CD-ROM in Microsoft Word and PDF file for text document and in Auto CAD file for all drawings.

- a. **The Monthly Progress Reports** shall contain all the data necessary to serve as a formal record document of the monthly status of the works and consultant's contract, including but not limited to: the contract base data; the detailed status of all aspects of the works; progress against/compared to agreed program; colour progress photographs with detailed captions; typical test results against the specification criteria, plus all test results which do not meet specification and the action taken by the Consultant; details of the Site record keeping system established and available for audit; equipment mobilisation/demobilisation data against the agreed equipment list; equipment availability records; key professional staffing bar chart for both the Consultant and Contractor, by position, name and duration/days of deployment and a statement on compliance/deviations on staffing requirements; interim valuation of the works; payment status of both the Contractor and the Consultant; and full details of all claims, delays, requests for Extensions of Time, Contractors-Environmental Social Management Plan (C-ESMP) implementation progress (including closure status, challenges and proposed strategies to address the challenges of any reported incidents reported within the month) and any other information the consultants may consider necessary to include in the report.
- b. The **Quarterly Report** shall be a combination of monthly reports, including an overall financial appraisal of the project and a risk management section.
- c. **The Contract Completion Report (CCR)**: The CCR shall be submitted within fourteen (14) days after receipt of the Statement at Completion from the Contractor in accordance with the relevant Works contract.
- d. **Final Contract Completion Report (FCCR)** -The Consultant shall prepare and submit a Final Contract Completion Report (FCCR) within twenty-eight (28) calendar days after receipt of the Contractor's Final Statement and completion of contract close-out procedures
The FCCR shall constitute the definitive completion and contract-close-out record of the EPC/Turnkey Contract and shall contain:

Final Contract and Financial Summary

- Final Contract Price and reconciliation of the Final Statement;
- Summary of variations, claims, determinations, and dispute resolutions;
- Final Time for Completion and any delay damages applied;
- Status and recommendation on release of retention and performance security.

Testing, Commissioning and Performance

- Summary of Tests on Completion and performance tests;
- Confirmation that the Works meet required performance guarantees;
- Certification of operational readiness and compliance with Employer's Requirements.

Taking-Over and Asset Handover

- Record of Taking-Over of the Works by the Employer
- Details of transfer of operational control and responsibilities;
- Confirmation of handover of all Contractor-provided facilities and project resources.

Project Records and Documentation

A complete indexed and catalogued record of all project documentation handed over to the Employer, including but not limited to:

- As-built drawings and final design documentation;
- Operation and maintenance manuals;
- Site records, supervision reports, and inspection logs;
- Test results for materials, plant, and equipment;
- Environmental, social, health and safety compliance records;
- Warranties and guarantees;
- Photographic records of construction and completed works;
- Asset registers and equipment inventories.

The Consultant shall submit the above-mentioned Reports duly bound in sequential manner with table of contents upfront and cover titles on the front cover. The As-Built drawings should be prepared in A-1 size hard copy as well as in Computer - aided design (CAD) files specified by the Client. Specification of CAD shall be agreed with Client.

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 3 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 3: Payment Schedule

S/No	Milestone / Deliverables	Timelines for submission of deliverables after contract commencement (months)	% of Contract Amount
LUMPSUM DELIVERABLES			
TASK ONE: PREPARATION OF PRELIMINARY DESIGNS, EMPLOYER REQUIREMENTS AND CONSTRUCTION SUPERVISION			
1	Submission and Acceptance Inception Report	0.5	2%
2	Submission and Acceptance of Stakeholder Consultation Workshop Report	2.5	2%
3	Submission and Acceptance of Preliminary Concept Design Report	2.5	2%
4	Submission and Acceptance of Draft Final Preliminary Engineering Design Report	3.5	0
5	Submission and Acceptance of Final Engineering Design Report	5	10%
6	Submission and Acceptance of Final report	8	2%
TASK TWO: GOOD MANUFACTURING PRACTICE CERTIFICATION COMPLIANCE			
1	Submission and Acceptance of Inception Report	0.5	2%
2	2.1 Submission and Acceptance of Site Assessment Report	6	10%
	2.2 Submission and Acceptance of workforce readiness report		
	2.3 Submission and Acceptance of operational processes gap analysis and risk assessment report		
3	3.1 Submission and acceptance of Training and Capacity Building curriculum report	12	5%
	3.2 Submission and acceptance of aseptic simulation training modules report	12	
	3.3 Submission and acceptance of training and capacity building competency assessment report	24	5%
	3.4 Submission and acceptance of train-the-trainer programme reports	24	
4	4.1 Submission and acceptance of Draft Vendor Prequalification Framework	8	0%
	4.2 Submission and Acceptance of Final Vendor Prequalification Framework	12	5%
5	5.1 Submission and Acceptance of Draft Master Documentation Index	12	5%

S/No	Milestone / Deliverables	Timelines for submission of deliverables after contract commencement (months)	% of Contract Amount
	5.2 Submission and Acceptance of Final Master Documentation Index	34	5%
6	6.1 Submission and Acceptance of Draft Pharmaceutical Quality System Documentation and Implementation Status Reports	18	5%
	6.2 Submission and Acceptance of Final Pharmaceutical Quality System Documentation and Implementation Status Reports	34	5%
7	7.1 Submission and Acceptance of Draft Facility, Utilities and Equipment Qualification and Validation Protocols and Oversight Reports	24	5%
	7.2 Submission and Acceptance of Final Facility, Utilities and Equipment Qualification and Validation Protocols and Oversight Reports	34	5%
8	8.1 Submission and Acceptance of Draft Laboratory Qualification and Analytical Method Transfer Reports	24	2%
	8.2 Submission and Acceptance of Final Laboratory Qualification and Analytical Method Transfer Reports	30	3%
9	9.1 Submission and Acceptance of Draft Aseptic Process Qualification, Process Validation and stability study Protocols	24	5%
	9.2 Submission and Acceptance of Final Aseptic Process Qualification, Process Validation and stability study Protocols and Reports	34	5%
10	10.1 Submission and Acceptance of Regulatory Pre-Submission Review Reports	18	2%
	10.2 Submission and Acceptance of Final Regulatory Submission Package and Regulatory Response Summary Report	30	3%
11	11.1 Submission and Acceptance of Draft Business Process Mapping and Gap Analysis Report	28	0%
	11.2 Submission and Acceptance of Final Business Process Reengineering Report	30	5%
	Total		100%

6.1 Payment Schedule for Time Based Deliverables

The Client shall pay to the Consultant remuneration that shall be determined on the basis of time actually spent by each Expert in the performance of the Services after the date of commencing of Services or such other date as the Parties shall agree in writing; and reimbursable expenses that are actually and reasonably incurred by the Consultant in the performance of the Services.

7 Minimum Requirements for Consultant Qualification and Experience

7.1 Core Business and Years in Business

The consulting firm shall be legally registered/incorporated as a consulting entity and shall have its core business providing expertise in project management, preparation of preliminary designs, employers requirements, construction supervision, GMP compliance certification support and technology transfer projects oversight for pharmaceutical/biopharmaceutical/human vaccines and biologicals manufacturing companies, for a minimum period of ten (10) years.

7.2 Relevant Experience

The consulting firm shall demonstrate having successfully executed, completed and supported GMP compliance certification of at least one (1) assignment of similar nature, scope, scale, and complexity within the last ten (10) years.

Details of similar assignments shall be provided in the expression of interest, including the Client's name and address, scope of services, contract value, period of execution, and the consultant's role.

7.3 Technical and Managerial Capacity

The consulting firm shall demonstrate adequate technical depth, financial and business advisory capacity, and managerial capability to undertake this assignment, supported by submitted company profiles, organisational structures, and availability of suitably qualified experts.

8 Team Composition, Minimum Qualifications and Experience for Key Experts

The consulting firm shall have a multidisciplinary team of qualified and experienced professionals capable of delivering the full scope of this assignment, including project management, GMP compliance, technology transfer, qualification and validation, regulatory submissions, environmental and social safeguards integration, ICT systems, business process reengineering, and training. They should possess necessary resources to undertake services of such nature including equipment and software required to execute the assignment.

The team shall comprise Key Experts (who provide leadership and accountability) and Supporting Experts (who provide specialised technical input).

Key Experts shall be available throughout the duration of the assignment, while Supporting Experts may be mobilised as required in accordance with the approved work plan.

All experts shall have verifiable experience in GMP-regulated environments, with demonstrated experience in human vaccines and biologicals manufacturing, including sterile or aseptic operations where applicable.

8.1 Key Experts

8.1.1 Team Lead

- i. A minimum of a Masters degree in Engineering, Construction Management, Quantity Survey or a related field from an institution/academic institution in any country recognised in Kenya;
- ii. Minimum of ten(10) years general experience in project management and team leadership;
- iii. Minimum of successfully established at least one human vaccines and biologicals or pharmaceutical manufacturing facility in the last seven (7) years;
- iv. Must possess Project Management Professional certification
- v. Must hold a current annual professional practicing license from a relevant professional body any country duly recognised in Kenya.

8.1.2 GMP / Pharmaceutical Quality Systems Expert

- i. A minimum of a bachelor's degree in Pharmacy, Pharmaceutical Sciences, Chemical/Process Engineering, Regulatory Affairs, or related field; from an academic institution in any country recognised in Kenya;
- ii. Minimum of ten (10) years general experience in human vaccines and biologicals manufacturing,
- iii. Minimum of seven (7) years specific hands-on experience and responsibility for technology transfer, GMP implementation, validation, and regulatory compliance for sterile biological products including process parameter optimisation, analytical method validation, equipment qualification protocols, pharmaceutical quality systems establishment and cross-functional team coordination to ensure seamless knowledge transfer from sending units to receiving units while maintaining regulatory compliance and product quality standards;
- iv. Demonstrated experience facilitating feasibility studies, technical evaluation, multi-stakeholder engagement, manufacturing strategy development, greenfield or brownfield fill-finish projects, and early-stage facility development for at least one (1) biopharmaceutical initiative in Africa; and
- v. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.3 Biomanufacturing Expert

- i. A minimum of a bachelor's degree in Biology, Biotechnology, Chemistry, or a related field ; from an academic institution in any country recognised in Kenya;
- ii. Minimum ten (10) years of general experience supporting advanced biopharmaceutical manufacturers under stringent regulatory frameworks (FDA, EU Annex 1);

- iii. Minimum of six (6) years' specific experience supporting technology transfers for fill-and-finish operations;
- iv. Demonstrated ability to serve as liaison bridging validation, technology transfer, and operations teams with a strong foundation in bioprocessing and vaccine manufacturing principles, for regulated environments; and experience supporting biopharmaceutical manufacturing operations, including supply chain engagement for critical materials, consumables, single-use/aseptic fluid pathway technologies, and fill-and-finish equipment with focus on formulation, filling, inspection, and packaging of final drug product.

8.1.4 Regulatory Affairs & Product Registration Expert

- i. A minimum of a Bachelor's degree in Pharmaceutical Sciences, Regulatory Affairs, or related discipline from an academic institution in any country recognised in Kenya;
- ii. Minimum of ten (10) years general experience in regulatory affairs for pharmaceutical or human vaccines and biological products;
- iii. Minimum of seven (7) years specific experience in preparation of Chemistry Manufacturing and Controls (CMC) dossiers, GMP licensing submissions, and WHO Prequalification support;
- iv. Must be validly registered Pharmacist
- v. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.5 Vaccine and Biologicals Quality Control Expert

- i. A minimum of a bachelor's degree in Pharmaceutical analysis, Pharmaceutical Sciences, Biochemistry, Microbiology, Biotechnology, or a closely related discipline from an academic institution in any country recognised Kenya;
- ii. A minimum of ten (10) years of progressive experience in pharmaceutical quality control laboratories supporting pharmaceutical or human vaccine and biologicals manufacturing, with demonstrated experience in sterile product testing;
- iii. A minimum of five years specific experience in sterile product testing in pharmaceutical quality control laboratories supporting human vaccine and biologicals manufacturing;

8.1.6 Business Process Reengineering Expert

- i. Minimum of master's degree in Business Administration, Operations Management, or related discipline from an academic institution in any country recognised in Kenya.
- ii. Minimum of ten (10) years' experience in business process reengineering, operational finance, or business transformation within manufacturing environments.
- iii. Minimum of five (5) years' experience in business process reengineering within human vaccines and biologicals manufacturing environments;
- iv. Demonstrated experience supporting, Cost of Goods Sold (COGS) modelling and optimisation; Commercial readiness and sustainability of GMP-regulated facilities.

8.1.7 Chemical / Process Engineer

- i. A minimum of a Bachelor's degree in Chemical Engineering, Process Engineering, Pharmaceutical Engineering, or related discipline from an academic institution in any country recognised in Kenya.
- ii. A minimum of ten (10) years of general experience in pharmaceutical or biomanufacturing or aseptic manufacturing environments.
- iii. A minimum of five (5) years of specific experience in biomanufacturing environments
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.7 Procurement and Contracts Specialist

- i. Minimum of Bachelor's degree in Engineering, Supply Chain Management or Business Administration or related discipline from an academic institution in any country recognised in Kenya;
- ii. A minimum of ten (10) years of general experience in preparation of procurement documentation for infrastructure projects, contract administration, claims management, and dispute resolution
- iii. A minimum of five (5) years specific experience involving development of bidding documents and contract administration for projects requiring preparation of Employee Requirements for FIDIC-based EPC/Turnkey contracts and demonstrating capability to translate detailed technical designs into performance-based specifications suitable for EPC/Turnkey contract procurement;
- iv. Demonstrated experience in at least one (1 No.) assignment that involved coordination with environmental and social safeguards teams to integrate environmental and social requirements into procurement documentation;
- v. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.8 Environmental, Health & Safety (ESS/OHS) Expert

- i. A minimum of a Bachelor's degree in Environmental Science, Environmental Engineering, Occupational Health and Safety, Public Health, Industrial Hygiene, or related discipline from an academic institution in any country recognised in Kenya
- ii. A minimum of ten (10) years general experience in Environmental Assessment and ESMP implementation;
- iii. A minimum of seven (7) years of specific experience in conducting ESIA and supervising C-ESMP implementation in construction projects and donor funded projects in pharmaceutical or human vaccine and biologicals manufacturing environments;
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.9 Validation Engineer

- i. A minimum of a bachelor's degree in chemical engineering, Process Engineering, Pharmaceutical Engineering, or related discipline from an academic institution in any country recognised in Kenya
- ii. A minimum of ten (10) years of general experience in pharmaceutical or human vaccines and biologicals manufacturing, with demonstrated involvement in sterile/aseptic manufacturing environments;
- iii. A minimum of five (5) years of specific experience in process validation in human vaccines and biologicals fill-finish manufacturing;
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.10 Architect

- i. A minimum bachelor's degree in Architecture from an academic institution in any country recognised in Kenya
- ii. A minimum of ten (10) years' general experience in the architectural design of pharmaceutical or human vaccines, or biologics manufacturing facilities, including experience in cleanroom and sterile manufacturing environments;
- iii. A minimum of five (5) years specific experience in cleanroom design for sterile manufacturing environments;
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.11 Mechanical Engineer

- i. A minimum Bachelor's degree in mechanical engineering or related discipline from an academic institution in any country recognised in Kenya;
- ii. A minimum of ten (10) years' general experience in the design and implementation of mechanical systems for manufacturing facilities;
- iii. A minimum of five (5) years' specific experience in the design and implementation of mechanical systems for pharmaceutical, human vaccines and biologicals manufacturing environments;
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.12 Electrical Engineer

- i. A minimum bachelor's degree in electrical engineering or related discipline from an academic institution in any country recognised in Kenya.
- ii. A minimum of ten (10) years' general experience in the electrical systems design for manufacturing industries;

- iii. A minimum of five (5) years' specific experience in industrial electrical and control systems and safety standards for pharmaceutical, vaccine, or biotechnology manufacturing facilities.
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.13 Quantity Surveyor

- i. A minimum bachelor's degree in quantity surveying, Construction Economics, or Cost Engineering or related discipline from an academic institution in any country recognised in Kenya.
- ii. A minimum of seven (7) years' experience in cost estimation, budgeting, value engineering, and contract administration for industrial facilities;
- iii. A minimum of four (4) years' experience in cost estimation, budgeting, value engineering, and contract administration for pharmaceutical or human vaccines and biologicals manufacturing facilities.
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.14 Structural Engineer

- v. A minimum bachelor's degree in civil or structural engineering from an academic institution in any country recognised in Kenya.
- vi. A minimum of ten (10) years' general experience in the structural systems design and building codes and regulations;
- vii. A minimum of five (5) years' specific experience in structural systems design, building codes and regulations for pharmaceutical, vaccine, or biotechnology manufacturing facilities; and
- viii. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.15 Resident Engineer

- i. A minimum bachelor's degree in civil engineering or a related discipline from an academic institution in any country recognised in Kenya.
- ii. A minimum of ten (10) years' general experience in civil engineering;
- iii. A minimum of five (5) years' specific experience in structural systems design, building codes and regulations for pharmaceutical, vaccine, or biotechnology manufacturing facilities; and
- iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.2 Non-Key Experts

8.2.1 ICT / Computerised Systems Validation Expert

- i. A minimum of a Bachelor's degree in Information Technology, Computer Science, Information

Systems, Engineering, or related discipline from an academic institution in any country recognised in Kenya.

- ii. Minimum of ten (10) years in designing and supporting implementation of digital systems (ERP/MRP, LIMS, DMS, LMS, EMS/BMS) in manufacturing environments;
- iii. Minimum five (5) years hands on experience in implementing and validating GMP-supporting digital systems in pharmaceutical or human vaccine and biologicals manufacturing environments (ERP/MRP, LIMS, DMS, LMS, EMS/BMS),
- iv. Demonstrate strong knowledge of ALCOA+, GAMP 5, and data integrity requirements.

8.2.2 Sociologist/Community Expert

- i. A minimum of Bachelors degree in Sociology or related discipline from an academic institution in any country recognised in Kenya;
- ii. A minimum of ten (10) years general experience as a Sociologist;
- iii. A minimum of eight (8) years specific field experience in conducting ESIA, SEA and Gender Based Violence (GBV) in construction projects of a similar nature.

In addition to the proposed Key Staff, the Consultant is expected to provide non-key staff including works inspectors to supervise construction works during the construction period. The Consultant will be responsible for their office support staff on site and head office. The cost of any support staff not highlighted in the list but which the consultant considers necessary will be deemed to have been included in the Consultant's Financial Proposal.

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 4: Estimated Time Inputs for Key and Non-Key Experts

S/ No	Key/ Non-Key Experts	No.	Time Inputs (Staff-Months) LUMPSUM	Time Inputs (Staff- Months) TIME BASED	Time Inputs (Staff- Months) TOTAL
Key Experts					
1	Team Lead	1	8	24	32
2	GMP/ Pharmaceutical Quality Systems Expert	1	18	12	30
3	Biomanufacturing Expert	1	18	0	18
4	Regulatory Affairs and Product Registration Expert	1	12	0	12
5	Vaccine and Biologicals Quality Control Expert	1	18	0	18
6	Business Process Reengineering Expert	1	4	0	4
7	Chemical/Process Engineer	1	18	0	18

8	Procurement and Contracts Specialist	1	2	0	2
9	Environmental, Health & Safety (ESS/OHS) Expert	1	2	10	12
10	Validation Engineer	1	0	12	12
11	Architect	1	6	4	10
12	Mechanical Engineer	1	6	4	10
13	Electrical Engineer	1	6	4	10
14	Quantity Surveyor	1	6	4	10
15	Structural Engineer	1	6	4	10
16	Resident Engineer	1	0	18	18
Non-Key Experts					
17	Sociologist	1	1	6	7
18	ICT / Computerised Systems Validation Expert	1	0	6	6

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

The Client will:

- i. Provide all relevant information and documentation to the consultant that can assist in this assignment;
- ii. Provide contacts of key stakeholders;
- iii. Organise meetings with relevant stakeholders as may be required by the consultant;
- iv. Facilitate liaison with other program-implementing partners;
- v. Review and approve reports.

12 Obligation of the Consultant

- i. The Consultant shall be responsible for the provision of all the necessary resources to carry out the services including appropriate qualified staff and shall make arrangements for the establishment of office, supporting office equipment and furniture, vehicles, accommodation, utilities, communications, insurance and any other required resources and procurement of all maps required for the designs. The Client, from time to time during the performance of the contract, may second to the Consultant staff for training and capacity building
- ii. The consulting firm shall actively engage stakeholders incorporate their inputs where relevant, and be responsible for planning, coordinating, and delivering all agreed activities and outputs, including technical deliverables and reports, in accordance with GMP requirements and the approved work plan.
- iii. The consultant(s) shall make their own arrangements for travel, visa and accommodation. Any travel outside the project site, including domestic travel beyond Nairobi and

international travel outside Kenya, shall be reimbursed by the Client on an actual-cost basis, subject to prior written approval.

- iv. The Consultant shall bear all costs of report production, printing, reproduction, courier services, and submission. These costs are included in Contract price and no separate payment shall be made. The Consultant shall provide satisfactory explanation for any delayed submissions beyond specified timeframes and shall implement remedial measures to address delays.
- v. The consulting firm shall be answerable to the Chief Executive Officer and shall work in close collaboration with BioVax staff to ensure effective execution, knowledge transfer, and timely delivery of this consultancy.

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.