

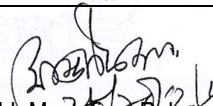


Government of the People's Republic of Bangladesh
Essential Drugs Company Limited
Ministry of Health and Family Welfare
Tejgaon I/A, Dhaka-1202.



Request for Expression of Interest (EOI) (International)

1	Ministry/Division	Ministry of Health and Family Welfare/Health Service Division
2	Agency	Essential Drugs Company Limited
3	Procuring Entity Name	Project Director, Establishment of Essential Biotech and Research Centre at Munshiganj.
4	Procuring Entity Code	Project Director
5	Procuring Entity District	Dhaka
6	Invitation for Expression of Interest for Selection of	Procurement of Consultancy firm (International) for Bid Documents Preparation, Monitoring, Supervision, and Validation for Vaccine, Therapeutics, and Diagnostics (VTD) facility on Turnkey basis
7	EOI Ref No	45.06.0000.000.015.14.0001.26.001, 27 October 2026
8	Date	29 October 2026
KEY INFORMATION		
9	Procurement Method	QCBS (90:10)
FUNDING INFORMATION		
10	Budget and Source of Funds	Development, RPL (Special Account)- Asian Development Bank (ADB)
11	Development Partners	Asian Development Bank (ADB)
PARTICULAR INFORMATION		
12	Project/ Programme Code	224398200
13	Project/ Programme Name	Establishment of Essential Biotech and Research Centre at Munshiganj (1 st Revised) Project
14	EOI Closing Date and Time	30 November 2026 (11:59 PM Manila Time)
INFORMATION FOR APPLICANT		
15	Brief Description of Assignment	The assignment involves hiring an international consulting firm to provide consultancy services to support the project planning, preparation of bid documents, procurement support, construction supervision, monitoring, commissioning, testing, and validation, etc., for an integrated, state-of-the-art manufacturing complex for Vaccines, Therapeutics, and Diagnostics (VTDs) and a research centre located at Sirajdikhan, Munshiganj.
16	Experience, Resources and Delivery Capacity Req'd	The prospective bidders are requested to refer ADB CSRN for detailed information and submission of EOI application by using the following link: https://selfservice.adb.org/OA_HTML/adb/xxcrs/jsp/ADBCsrnFwd.jsp?sel=23100
17	Other Details of Application	The prospective bidders are required to submit the EOI application in duly prescribed format on ADB CSRN (please note that there is no other platform) by using the mentioned link. For applying on ADB CSRN, prospective bidder has to register on ADB CSRN. After the registration, the bidder will be allowed to view and submit the EOI application (on line only) before the EOI Closing date and time. All prospective bidders are requested to refer ADB CSRN for any further update, modification, rescheduling of dates etc.
18	Association with foreign firms is	This is an international assignment. The prospective bidders are suggested to refer Qualification and Eligibility Criteria before EOI submission. Bidders may form JV or sub consultancy with other firms to meet qualification criteria.
19	Phasing of services	Please Refer TOR attached with the advertisement posted on ADB CSRN at mentioned link.
PROCURING ENTITY DETAILS		
20	Name of Official Inviting EOI	Md. Mostafizer Rahman (Joint Secretary)
21	Designation of Official Inviting Expression of Interest	Project Director, Essential Biotech and Research Centre at Munshiganj (1 st Revised)" Project
22	Address of Official Inviting Expression of Interest	Essential Drugs Company Limited., 395-397, Tejgaon I/A, Dhaka-1208.
23	Contract of Details of Official Inviting Expression of Interest	PABX: 02-41010771-3,02-41010779-80 G.P.O. Box No. 2447 , Email: vaccine@edcl.gov.bd
24	The Procuring entity reserves the right to reject all EOI's without assigning any reasons	


 Md. Mostafizer Rahman
 Project Director (Joint Secretary)
 Office of Project Director,
 Essential Biotech and Research Centre
 at Munshiganj.

TERMS OF REFERENCE

Subject: Consultant for Bid Documents Preparation, Monitoring, Supervision, and Validation for Lab Design and Oversight (Vaccines, Therapeutics, and Diagnostics (VTD) facility on Turnkey basis)

Reference /Package Number: EDCL/CS-01

A. Background

1. Bangladesh is emerging globally as a country of great promise and ambition. It has an inspiring story, an impressive track record of growth and development, and aspirations to become a middle-income country by 2031. Over the last decade, it has surfaced as one of the world's fastest-growing economies, emboldened by a demographic dividend, strong ready-made garment (RMG) exports, remittances, and a stable political and macroeconomic environment.
2. However, the COVID-19 pandemic jolted the entire world, including Bangladesh, significantly affecting the health of its population, healthcare systems, and economic activities, consequently reversing some of the gains achieved in the previous decade. The pandemic exposed the vulnerabilities of the countries that lacked vaccine manufacturing infrastructure. It emphasized the importance of vaccines, not only to curb the spread of infection and disease but also to increase reliance on local vaccine production.
3. The country also faces several outbreaks of different emerging and re-emerging infections, including cholera, dengue, chikungunya, malaria, meningitis, pneumonia, measles, rabies, and other diseases, most of which are vaccine-preventable. Besides this, the problem of antimicrobial resistance has reached alarming levels. As a result, in addition to vaccines, there is a need to strengthen diagnostics and therapeutic capacity by developing and manufacturing diagnostic kits (using molecular and serological test platforms) and quality-assured pharmaceuticals for the public to be self-reliant and well-prepared for pandemic/epidemic emergencies.
4. Thus, the Ministry of Health and Family Welfare (MoH&FW), Government of Bangladesh is committed to establishing a current Good Manufacturing Practices (cGMP) compliant State-of-the-art, integrated Vaccines, Therapeutics, and Diagnostics (VTD) manufacturing complex in Munshiganj in Bangladesh with financial assistance from Asian Development Bank (ADB) under the monitoring and supervision of Essential Drugs Company Limited (EDCL). The EDCL is a 100% state-owned advanced pharmaceutical manufacturing company. EDCL has three pharmaceutical manufacturing plants at Bogra, Dhaka, and Gopalganj and one condom manufacturing plant at Khulna. EDCL is a key manufacturer of injectable products, intravenous fluids, sterile, and penicillin antibiotics; supplies 70% of the medicine requirements of the country's public health system; and is the leading manufacturer of sterile products. So far, the EDCL has completed feasibility studies, secured project finance, and acquired land beside at BSCIC Chemical Industrial Park (BCIP) in Sirajdikhan, Munshiganj.

B. Brief Description of ADB Vaccines, Therapeutics, and Diagnostics (VTD) Manufacturing and Regulatory Strengthening Project in Bangladesh

1. The Government of Bangladesh (GOB) has received loan support from the Asian Development Bank (ADB) for the VTD project. The project will provide the Government of Bangladesh with financing to establish domestic vaccines, therapeutics, and diagnostics (VTD) manufacturing capacity and strengthen the regulatory capacity of the

national regulatory authority. The project will also support the research and development of novel vaccines and biosimilars. It aims to strengthen pandemic preparedness, improve vaccine supply security, and reduce dependence on external supply for key vaccines (including in the event of future outbreaks). The availability of indigenously manufactured selected safe and efficacious VTD in Bangladesh will help reduce the disease burden of selected vaccine-preventable diseases. The proposal under the project will (i) construct a VTD manufacturing facility, (ii) establish capacity for VTD manufacturing, and (iii) strengthen the national regulatory authority's (Directorate General of Drug Administration-DGDA) capacity for VTD regulation.

2. The project is aligned with the following impact: pandemic preparedness increased, and the disease burden due to selected vaccine-preventable diseases in Bangladesh reduced. The outcome of the project will be the availability of domestically VTD manufactured selected safe and efficacious VTD in Bangladesh improved.

Output 1: Manufacturing facility for vaccines, therapeutics, and diagnostics established.

3. The project will construct a VTD manufacturing facility and warehousing unit with gender equality, social inclusion-responsive, and climate-resilient features under direct monitoring and supervision of Essential Drugs Company Limited's (EDCL) at BSCIC Chemical Industrial Park (BCIP) in Sirajdikhan, Munshiganj. An in-house research and development center will be established to develop and improve access to diagnostics and biological therapeutics. A lean, agile, and green approach will be adopted to ensure operational, economic, and environmental efficiency, including with respect to waste management. The manufacturing facility will aim to receive World Health Organization (WHO) Good Manufacturing Practices (GMP) certification. The facility will be "ready to operate," with a capacity to manufacture 300 vials per minute (58 million annually).

Output 2: Capacity for vaccines, therapeutics, and diagnostics manufacturing established.

4. The project will support setting an assembly line for at least five rapid diagnostic kits and a packaging line for at least five biosimilar therapeutics. The research and development center established under Output 1 will facilitate technology transfer and sourcing of raw materials for diagnostic kits and biosimilar manufacturing. The project will support collaboration between the research and development center, leading universities in Bangladesh, and international technical partners to promote knowledge sharing and innovation.
5. Under output 2, the analytical transfer method and production line will be completed for at least five fill-and-finish vaccines in campaign mode, sourced from manufacturers that are WHO-prequalified or approved by maturity level 4 or a stringent regulatory authority. Full-cycle manufacturing of at least two selected vaccines will be operationalized by developing a seed bank, master cell bank, and working cell bank. The project will commission necessary equipment and orient and train 95 technical staff (of whom at least 25% will be women) in VTD manufacturing. The output will also support the DGDA's validation of diagnostic kits, therapeutics, and vaccines.

Output 3: DGDA's capacity to regulate vaccines, therapeutics, and diagnostics strengthened.

6. The output will strengthen a national control laboratory by constructing an additional lab and training center in Dhaka to improve DGDA's institutional capacity according to WHO regulations and standards. It will reinforce the post-marketing surveillance systems of

DGDA, safety monitoring of pharmaceutical products, and adverse events reporting. This will include support for (i) strengthening laboratory quality management and regulatory inspection systems and (ii) improving testing capacity modalities, information technology systems, and logistics in compliance with WHO's GBT. The legal, clinical trials, consumer protection, and intellectual property regulatory framework will be strengthened to enable international collaboration and technology transfer. The project will also facilitate DGDA to resolve outstanding self-assessment of corrective and preventive actions and submit closure reports to WHO based on the GBT to achieve at least ML3 and WHO GMP certification for the national control lab. It will improve DGDA's capacity to conduct audits of secondary packaging units and grant import licenses for biosimilar therapeutic finished products. DGDA will be strengthened to issue certificates of analysis, testing, and batch release for at least five fill-and-finish vaccines, which may include COVID-19 vaccines.

C. Objective and Purpose of this Assignment

7. The EDCL(Client), on behalf of MoH&FW, Government of Bangladesh (GoB) intends to hire a Consultant for Bid Documents Preparation, Monitoring, Supervision, and Validation of Vaccines, Therapeutics, and Diagnostics (VTD) Manufacturing Facility in Bangladesh (International Firm) to achieve project Outputs 1 and part of Output 2. The VTD manufacturing facility is proposed to be designed, built, commissioned and handing over for operation to the client by a suitable, experienced construction agency on a design-build/turnkey basis. To achieve this objective, the consultant will assist and closely work with EDCL & other agencies of the Government of Bangladesh, in Preparation of a Bidding Document for hiring of a turn-key constructing agency for establishing manufacturing facility for VTD and later on for the Monitoring, Supervision, and Validation of VTD Manufacturing Facility after the contract signing.
8. The Consultant must assist EDCL as an interface for technology-transfer agreements for Vaccines Therapeutics and Diagnostics (VTD) as well as for OEM, R&D centre etc. This would be inclusive of interface management support at every stage.
9. The broad Scope of Work of the Consultant, proposed in various stages, is as follows:

Stage I: (Pre- Construction)

- I) To prepare the bidding document on behalf of EDCL for hiring a constructing firm for the design, build, commissioning and handing over for operationalization (Operationalization here means commissioning, performance testing, training and handover to EDCL) of the integrated complex on the turnkey (EPC- Engineering, Procurement, and Construction) basis for the manufacturing of Vaccines, Therapeutics, and Diagnostics (VTDs) by using relevant ADB's Standard Bidding Document and under FIDIC contract based on Yellow or Silver book as selected by EDCL with ADB concurrence.. For preparing the bidding document, the consultant will be required to submit a Contract Strategy Report that recommends the FIDIC form, risk allocation, bidding procedure and merit point criteria. It should weigh EDCL's need to control the design for GMP/regulatory compliance, market appetite and expected competition, the price premium for transferring risk, and EDCL's capacity to administer the contract.
- II) To provide support to EDCL in preparing and approval of bid document from ADB, managing the bidding process, evaluation, award, and signing of contracts with the turnkey constructing firm.

Stage II: (During Construction, Commissioning and Operation)

- III) To assist EDCL in Monitoring, Supervision, and Validation of VTD manufacturing facility.

Stage III: (Defect Liability Period)

- IV) To assist EDCL in Monitoring, Supervision, and Validation during the defect liability period of the VTD facility.

D. Scope of Work

Details of deliverables, including the expected timelines are mentioned under Scope of Work as given below in Table -1.

Table 1 :

S.No.	Scope of Work	Expected Output / Outcome	Indicative Timeline*
Stage I (Pre- Construction): Assist EDCL in preparing Contract Strategy, design basis and Employer's Requirement, bidding document, managing bidding process, award and signing of contract with turnkey constructing firm (Duration – 12 Calendar Months, Fixed cost)			
I. To prepare the bidding document on behalf of EDCL for hiring constructing firm for design, build, commissioning and operationalization of the integrated complex on the turnkey (EPC- Engineering, Procurement and Construction) basis for the manufacturing of Vaccines, Therapeutics and Diagnostics (VTDs) by using relevant ADB's Standard Bidding Document and FIDIC contract.			
P1	Collect and compile the available project related information and documents-DPP/RDPP etc, required for preparing the bidding document for Engineering, Procurement and Construction (EPC) mode. Review all works contract documentation, including checking for completeness, consistency and adequacy of documentation	1. Inception Report (within one month of commencement): It will include scope of Work of the assignment, Approach and methodology, Work and personnel schedule, important issues if any for information of EDCL. 2. Prepare Contract Strategy Report, containing Design Basis and User Requirements (products and capacities, relevant technologies for suitable production of priority vaccines, monoclonal antibodies, biosimilars and therapeutics & Diagnostics, process flows, layouts, room data sheets, cleanroom grades, containment, utilities, URS for key equipment which align with project goals and local contexts.	T + 4 Months (T denotes commencement date of assignment)
P2	Contract Strategy Report;		
P3	Employer's Requirement		
P4	Preparing the draft Bidding document in consultation with EDCL	3. Employer's Requirements by covering GMP/regulatory basis (WHO TRS, EU GMP Annex 1, WHO prequalification readiness); CQV requirements and responsibilities; automation, computerised-system validation and data integrity; design stage-gate reviews; Tests on Completion and performance guarantees; training, O&M manuals and spares. Products and capacities, Process flows, layouts, room data sheets, cleanroom grades, containment, utilities, URS for key equipment etc. (value engineering and constructability), within the approved project budget.	

		4. Draft Bidding Document by using Standard Bidding document of ADB for turnkey (EPC) contracts, by using relevant ADB's Standard Bidding Document and under FIDIC contract based on Yellow or Silver book as selected by EDCL with ADB concurrence and ensuring Compliance with Environmental, Health and Safety Guidelines (EHSG) and other Good International Industry Practice (GIIP).	
II. To support EDCL in conducting the bidding process and hiring of the turnkey constructing firm			
Q1	Support the EDCL In finalization of bidding document after seeking approval of ADB and completing procurement process.	Assisting EDCL in finalization of bidding document, assisting in holding pre-bid meeting, finalization of bid document, bid opening, and assisting in bidding process	T + 12 Months
Q2	Assist EDCL in procurement process		
Stage II (Design, Construction, Commissioning and Handover): To assist EDCL in Monitoring, Supervision, Validation of VTD manufacturing facility, the Consultant will act as the Engineer, as per the FIDIC . (Duration – 34 Calendar Months, Time-Based).			
R1	Planning and Designing • Identification of Requirements of survey and investigations. • Review of Survey and investigation results and assist EDCL in approving of Project designs and drawings-Conceptual, layout, plan, architectural design, structural design, Basic and Detail Designs in 2D, 3D and Animated formats , AutoCAD designs etc. • Review of design parameters and assist EDCL in approving the design parameters. • Review the Technical Specifications submitted by Turnkey constructing agency and assist EDCL in approving the same. • Review the work plan and process flow (including stage wise construction) and assist EDCL in approving the same. • Review the Product wise volumes requirement for both drug substance (DS) as well as drug product (DP) for all the	1. Quarterly progress reports. 2. Relevant documents as per requirements under various stages. 3. Documents required to be submitted by the Consultant during Planning and Designing stage, such as -review of the design basis and of the design parameters of the VTD facility etc. 4. Reviewing of documents submitted during Construction and Operation and Commissioning phases by EPC constructing agency and to assist EDCL in approving of Project designs and drawings-Conceptual, layout, plan, architectural design, structural design, Basic and Detail Designs in 2D, 3D and Animated formats, AutoCAD designs, work plan, product-wise production and QC areas etc 5. Assist EDCL in ensuring compliances related to QAQC, QMS safeguard, safety, licenses, permits etc 6. Assist EDCL In establishing Knowledge Transfer Platform including Preparation of a Standard Operating Procedures (SOPs) Manual for long-term operational, management and maintenance efficiency for the VTD facility.	Post Completion of 1 st stage +34 months

	required VTDs. Black (Central) and clean Utilities requirements and calculations for electricity, raw water, clean water, water for injection, pure steam, effluent calculations etc • Review the Safeguard, Safety (which includes fire safety also) and Health related parameters and mitigation mechanism and assist EDCL in approving the same. • Review of relevant domestic and international Law, Regulations, Codes, and Standards/ statutory compliances including license permit and NOC requirement for establishing and operationalization of VTD facility and assist EDCL in decision making. • Review of inspecting and testing requirements including Factory Acceptance Test (FAT), Site acceptance Test (SAT) etc and assist EDCL in determination of mechanism, test frequency and documentation. • Assist EDCL in finalizing and setting up of efficient and effective project performance and monitoring system (PPMS) by using latest project monitoring software. • Assist EDCL in finalizing Project Progress Reporting and Contract Review Meeting Mechanism with associated formats. • Assist EDCL in finalizing payment related formats in accordance to payment milestones of Turnkey Constructing agency. • Assist EDCL in finalizing suitable Quality control mechanism and system by	7. Regular refresher and on the job training sessions for EDCL staff and relevant stakeholders. 8. All relevant documents/reports as per requirement of EDCL and Scope of Work. 9. Concept note for Setting up of an efficient PPMS.	
--	---	---	--

	involving reputed third-party inspectors. Assist EDCL in setting up Dispute Board (DB) and mechanism of Arbitration.		
R2	Project Monitoring and Supervision during Construction - Review and assist EDCL in approval of the contractor's proposed designs/drawings - Monitor the construction activity and ensure that it is in compliance with the approved plan. - Review the quality tests done for all the items & for the material used for the construction work. - Ensure that the Contractor delivers its Environmental, Health and Safety (EHS) obligations under its contract (see Annex 1) - Review and monitoring of safeguard, Health and safety related compliances. - Review invoices of Constructing agency and assist EDCL in determining payable amount and in dealing contract variation and contract related interpretations. - Assist EDCL in setting up an efficient Project Performance and Monitoring system for regular reviewing of the project progress and performance and analysis. - Ensure that the contractor strictly adheres to the contract conditions, specifications, compliance requirements, project schedule, reporting and testing requirements and to assist EDCL for taking appropriate actions whenever there is a breach of contract or misconduct by the contractor	- Periodical PPMS reports. - Audit Report. - QA, QC and QMS reports. - SOP and Operation and Management Plan. - Risk Management Plan reports. - Periodical project performance assessment reports. - Periodical EHS and EMP status reports. - periodical reports on Net Zero concept status. - Training Reports - Review as built drawing after completion of the project.	

	in accordance with contract conditions. • Assist EDCL in finalizing Standard operating procedures (SOP), training requirement and management plan of VTD facility for operational-readiness and CQV tasks of turnkey Constructing agency. • Assist EDCL in finalization of Site Delineation, Use, Access, and Possession Details for CQV tasks and operational-readiness in consultation with turnkey constructing agency. • Assist EDCL in Describing to the widest and deepest possible extent all work of others than the Contractor (Employer's other contractors and consultants, Employer's Personnel, etc.) which will interface with the activities of the Contractor for CQV tasks and operational-readiness under the Contract to avoid possibility of Contractor's claim for Unforeseeable Cost caused by interfaces. • Assist EDCL in finalizing Laws, regulations, codes and Standards required to be complied with by the Contractor for CQV tasks and operational-readiness. . • Assist EDCL in finalizing safeguard, safety, health related compliances for CQV tasks and operational-readiness.. • Assist EDCL in determining Permits/licenses those to be obtained: - by the Employer, and- by the Contractor Ideally in a tabulated format to make clear who is to obtain what under the Contract, how and under which sequence/timing		
--	---	--	--

	for CQV tasks and operational-readiness,. • Assist EDCL in determining Frequency, contents and format of reporting an dmeeting for CQV tasks and operational-readiness . • Assist EDCL in determining Equipment and Personnel requirements for CQV tasks and operational-readiness . • Assist EDCL in determining QA (Quality Assurance), QC (Quality Control) and QMS (Quality Management system) requirements for CQV tasks and operational-readiness . • The consultant shall develop a detailed Risk Management Plan identifying potential risks such as construction delays, budget overruns, regulatory compliance challenges, and technological failures for CQV tasks and operational-readiness . • The plan should include a risk mitigation strategy, early warning mechanisms, and corrective actions to ensure project continuity. A dedicated risk monitoring mechanism should be part of the Project Performance and Monitoring System (PPMS) for CQV tasks and operational-readiness. • Supervision and monitoring of building and associated services at regular frequency as per approved Net zero concepts for CQV tasks and operational-readiness . • Periodical reports on Net Zero building concepts such as Sustainability Compliance Reports to ensure adherence to green and energy-efficient building standards . • Assist EDCL in Operational readiness of –		
--	--	--	--

	✓ Contractor training of EDCL staff, O&M manuals, spares and service contracts ✓ Tests on Completion and any performance-guarantee tests ✓ Clear CQV responsibilities: the contractor shall execute commissioning and IQ/OQ under an agreed validation master plan; EDCL owns PQ and process validation; the consultant reviews protocols and witnesses key tests. ✓ EDCL's operating SOPs and GMP documentation ✓ Regulatory licensing (DGDA, DoE) • Review 'As-built drawings'		
<u>R3</u>	Project Monitoring and Supervision during Commissioning and Operation • Prepare variation reports/orders whenever required and submit them to the client for approval before giving relevant instructions to the contractor. • Conduct regular and periodic performance checks to ensure compliances according to approved Operation and Management plan and SOP. • Assist Auditing body in performance of duty. • Review compliance status of law/regulations/codes/standards/permit/license requirements and ensure timely compliances. • Review compliance status of inspection and testing requirements and ensure timely compliances. • Review compliance status of safeguard, health and safety	1. Variation reports. 2. Periodic audit and performance assessment reports. 3. Long-term maintenance and operational guidelines. 4. Compliance status of laws/regulations/inspections/testings/EHS etc. 5. Handover of Relevant documents and reports after project completion.	

	requirements and ensure timely compliances. • Review compliance status of QA, QC and QMS (Quality Management System) requirements. • Assist EDCL in determining list of documents/reports/assets to be handed over after completion of Commissioning and Operation. • Implement a long-term maintenance & operational sustainability strategy. • Define the handover process from the constructing agency to EDCL, ensuring operational readiness post-project completion for one year. • Review compliance status of handing over requirements.		
<u>R4</u>	Knowledge Transfer and Capacity Building Review the document development history, review and recommend Process know-how, and associated control strategies suitable for biotech project. • Provide risk mitigation strategies, address operation challenges, including progress preparation and final completion reports with recommendations. • Assist EDCL In establishing Knowledge Transfer Platform including: • Preparation of a Standard Operating Procedures (SOPs) Manual for long-term operational, management and maintenance efficiency for the VTD facility. • Assist EDCL to get regulatory licenses from DGDA as per following guideline of WHO compliance facility.	1. Knowledge Transfer Platform. 2. SOPs/Manuals for long term operational, maintenance and management efficiency etc 3. Training Report	

	- Assist EDCL to get license for DoE, DoF, OCIB and others as per necessary. - Regular refresher and on the job training sessions for EDCL staff and relevant stakeholders.		
Stage III (Defect Liability Period): To assist EDCL in Monitoring, Supervision, Validation of VTD manufacturing facility during Defect Liability period. (Duration – 4 Calendar Months after completion of Stage II or till end (if extended), whichever is later, Time-based)			
<u>S1</u>	Monitoring the completed works. - Monitoring the performance of the VTD manufacturing facility at Sirajdikhan, Munshiganj, including its process equipment, utilities and systems. - Identification of defects/issues (if any) by monitoring of the activities and to work closely with the turnkey contractor to address the defects/issues. - Extend support for analytical method transfer documentation assessment for VTDs fill-finish operations.	Completion Report	Post Completion of Stage II+ 4 Months
<u>S2</u>	Perform regular inspections of the works during the defect liability period		
<u>S3</u>	Final Closure - Assist EDCL in facilitating the project handover upon successful completion of the project. Assist in preparation of final accounts of the project after the completion of the defect liability period of the project. - Assist EDCL in Issuance of certificate of making good defects, final completion, and final payment certificate.		

*** T is the commencement date as indicated in the Notice to Proceed (NTP)**

E. Duration and Location of Services

1. The Stage I activities shall be completed within 12 (twelve) months from the commencement date as mentioned in the Notice to Proceed (NTP) under the Contract.

- The Consultant shall have to perform activities of this stage at Dhaka in close association with EDCL and other offices of the Government of Bangladesh.
2. The consultant may be required to visit the VTD site as per the requirement during this stage.
 3. Stage II activities (envisaged to be completed in 34 months from commencement date) shall be performed after the mobilization of the Turnkey Constructing agency during the Design, construction, commissioning, and handing over of the VTD facility.
 4. Stage III shall be performed after the completion of stage II activities. The consultant will perform the activities of stages II and III from the project site of VTD.

F. Payment terms

The Consulting Firm may submit an invoice as per the schedule in Table 2, cited below.

Table 2: Payment terms for the Consulting Firm

S. No.	Deliverables	Payment in %age of the Total Contract Value
Stage I (12 Months), Fixed Cost (Limited to 13% of the total contract value)		
1	Assistance in preparation of bid document and Approval of the bid Evaluation Report	13%
i	Submission of Inception Report (10% of fixed cost)	
ii	Contract strategy and Design basis (25% of fixed cost)	
iii	Preparation of draft bidding document (30% of fixed cost))	
iv	Approval of bidding document by ADB (20% of fixed cost)	
v	Preparation of bid evaluation report (15% of fixed cost)	
	Total (Stage I: Fixed Cost)	13%
	Note: EDCL will have to approve or revert with comments on deliverables within 15 days of submission date.	
Stage II (34 Months post stage I completion), Time-Based		
3	Monthly invoice along with Monthly progress report	As per approved rates
Stage III (4 months post stage II completion), Time-Based		
4	Monthly invoice along with Monthly progress report	As per approved rate
	Total (Stage II and III: Time-Based Cost)	Up to 87% of the contract value

Payment shall be released after the approval of the deliverables by the competent authorities.

G. Qualification and Eligibility Requirement

1. As the construction of the VTD manufacturing facility at Sirajdikhan, Munshiganj, including its process equipment and utilities, is the most vital component of this project and this requires specific technical expertise for preparing design basis , employer's requirement .The consultant will also be required to review the designs submitted by the turnkey constructing agency.
2. The firm should have experience of designing, monitoring, supervision, and validation of at least two completed owner's-engineer, PMC or CQV assignments for cGMP biologics or vaccine facilities approved by WHO-PQ, a stringent regulator or an NRA at ML3 or above, plus experience administering FIDIC design-build or EPC contracts.
3. The Consultant should have good experience of supervising VTD facility center, including determining technical specifications of building, equipment, office equipment, IT equipment etc.
4. Joint Venture/ sub consultant are allowed to participate. However the consultant and its affiliates, who have been part of TOR formulation shall not be allowed to participate.
5. Experience of external financing project of ADB/World bank etc shall be preferred.

H. Consulting Firm Team Composition

The list of the key experts is provided in Table 3 below. The Consultant shall engage non-key/support staff to complete the assignment as per the job requirement.

Table 3: Indicative List of Key Experts

S. N.	Position	Type	Man Months (Tentative)			Total Man Months (Intermittent) for All Stages
			Stage* I	Stage II	Stage III	
1	Team Leader (1)	International	08	21	02	31
2	Project Manager (1)	National	08	32	04	44
3	Resident Engineer - Civil (1)	National	02	31	02	35
4	Lead Architect (1)	International	02	08	00	10
5	GMP, Regulatory, Quality & Validation Expert (1)	International	01	20	0.5	21.5
6	Vaccines Process Expert (1)	International	01	12	0.5	13.5
7	Biotherapeutics Process and diagnostic Expert (1)	International	01	10	0.5	11.5
8	Cleanrooms, HVAC & Utilities Expert (1)	International	01	21	0.5	22.5
9	Electrical & Power Systems Engineer (1)	National	02	16	01	19.0
10	Veterinary & Biosafety Expert (1)	International	01	07	0.5	8.5
11	QC Expert (1)	International	01	16	0.5	17.5
12	Procurement Expert (1)	International	08	03	01	12.0
13	Environment & Safeguards Specialist (1)	National	01	03	0.5	4.5
14	QMS (QA & QC) and Compliance Expert (1)	International	01	15	00	16
15	Net Zero Expert (1)	National	02	06	00	08
16	Mechanical and Plumbing Expert	National	02	16	01	19

*Stage I-man months are indicative in numbers as the payment is deliverable based; therefore, Consultant is free to mobile the Experts as per the requirement.

I. Qualification and Experience of Key Experts of the Consultancy Team

Table 4: Indicative Qualifications of Key Experts

S.No	Expert	Preferred Qualification Requirements	Preferred Experience	Requirement /Expected Deliverables
1	Team Leader	He/ she shall be an engineer with a minimum qualification of a master's degree in civil engineering/bio technology/pharmaceutical/chemical	He/she must have at least 15 years of cumulative experience in biopharmaceutical facility design and construction supervision and execution of at least three (3) projects of Vaccines, Therapeutics, and	1. Lead the team and shall be fully responsible for fulfillment of the scope of work on behalf of the consultant. 2. Lead the team in the preparation of the Bidding document for hiring EPC contractor and assisting EDCL in successful completion of the procurement process till award of

		from a reputed institute.	Diagnostics (VTD) related manufacturing plant of similar magnitude, and complexity in the last ten (10) years as per international standard The experience of working on externally financed project will be preferred.	the project to selected EPC contractor. - Review the design, CQV/validation lead , FAT, SAT and key decisions. - Lead the team for implementation of VTD project and during defect liability period. - Guide the team and EPC contractor in the timely implementation of the project. - Oversee the smooth integration of the of the information and inputs received from rest of the team of experts. - Coordination and liaison with client and EPC constructing agency. - Taking any action under a civil works contract designating the Consultant as "Engineer",. - Support in knowledge transfer and training of the EDCL staff on equipment & manufacturing process. - Extend PMP support - Integration & Timeline Management (The Master Schedule) - Provide Scope & Technical Change Control. - Provide Strict Quality Governance & Biopharma Compliance. - Ensure Cost and quality control oversight.
2	Project Manager	He/ she shall be an engineer with a minimum qualification of a Bachelor's degree in civil engineering/bio technology/pharmaceutical/chemical from a reputed institute. Master's degree in the above streams will be an added advantage.	He/she must have at least 10 years of cumulative experience in biopharmaceutical facility design and construction supervision and execution of at least three (3) projects of Vaccines, Therapeutics, and Diagnostics (VTD) related manufacturing plant of similar magnitude, and complexity in the last ten (10) years as per international standard The experience of working on externally financed project will be preferred.	- Coordinate with the teams and shall be fully responsible for fulfillment of the scope of work on behalf of the consultant and the client. - In absence of TL, the project manager will work as TL. - Coordinate with the teams in the preparation of the Bidding document for hiring EPC contractor and assisting EDCL in successful completion of the procurement process till award of the project to selected EPC contractor. - Coordination with the teams for implementation of VTD project and during defect liability period. - Support and assist the teams and EPC contractor in the timely implementation of the project. - Coordinate and oversee the smooth integration of the of the information and inputs received from rest of the team of experts. - Coordination and liaison with client

				and EPC constructing agency. 8. Taking any action on the advice of the team leader under a civil works contract designating the Consultant as “Project Manager”, for which action, pursuant to such civil works contract, the written approval of the Client as “Employer” is required. 9. Support in knowledge transfer and training of the EDCL staff on equipment & manufacturing process. 10. Extend PMP support - Integration & Timeline Management (The Master Schedule) 11. Provide Scope & Technical Change Control. 12. Provide Strict Quality Governance & Biopharma Compliance. TOR_Consultant for Monitoring, Supervision and Validation (13. Ensure Cost and quality control oversight
3	Resident Engineer - Civil	Must hold a degree in Civil Engineering from the reputed institute. Post graduate in structural engineering shall be an added advantage.	He /She must have a minimum of ten (10) years of supervision of civil construction work related to industrial/ chemical/pharmaceutical plants. The experience of handling of at least 1 project related to Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants industrial/chemical / bio chemical/pharmaceutical projects shall be preferred. The experience of working on externally financed project shall be preferred.	1. To assist TL/EDCL in monitoring and supervision of VTD construction complex. 2. To assist TL/EDCL in preparation of quantity assessment, estimates, 3. Responsible for overall construction management, quality assurance and administration of the EPC contract. 4. Supervise the construction work as per design and quality standards. 5. Contract management and Performance Monitoring of the contract. 6. Assist EDCL in finalizing of construction supervision schedule of EPC contract with timing and resources identified including stage level permissions. 7. To Monitor the construction method by assessing the adequacy of the contractor's input materials, labor, equipment and construction methods; 8. To review and monitor the detailed construction drawings of EPC contractor. 9. To Assist in third party inspections, as decided by EDCL; 10. To Assist the EDCL in interim and final certification of the bills of payment;

				11. To Assist the EDCL in issue of completion certificates. 12. To assist in preparing Project Completion Report and progress reports. 13. To assist EDCL in contract interpretation, variation, time extension and in resolving contractual issues during implementation. 14. Any other construction activity required as per the requirement and not covered in above points.
4	Lead Architect	He/she must be a registered architect with a degree in architecture from a reputed institute.	He/she must have at least ten (10) years cumulative experience in architectural practice of, planning, and designing of industrial building works, with at least five (5) years of working experience of the biopharmaceutical industry after registration as an architect. He/she must have served in a similar position in at least two (2) projects of similar magnitude and complexity within the last ten (10) years. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	1. To assist TL in all architectural matters as per the requirement. 2. Assist TL in preparation of indicative layout and architecture designs for bidding purpose. 3. Review the architectural plans/designs/drawings/specifications etc submitted by EPC contractor and to assist EDCL in finalizing the architectural designs/drawings and layouts/ specifications etc. 4. Review the final master plot plan (2D and 3D versions in auto-cad and pdf formats) with all the necessary details submitted by EPC contractor and assist EDCL in according necessary approvals.
5	GMP, Regulatory, Quality and Validation Expert	Must hold a postgraduate degree in Pharmaceutical , Biotechnology, or related Chemical field from a reputed institute. Certifications such as Lean Six Sigma Green Belt, PMP (Project Management Professional), and certifications in Good Manufacturing Practices (GMP) from recognized bodies like WHO,	Minimum of 15 years of experience of handling at least 2 projects in designing, commissioning, and Operation of cGMP-compliant Vaccines, Therapeutics, and Diagnostics (VTD) production facilities, including BSL-2 and BSL-3 laboratories. Experience with WHO-PQ and/or stringent regulatory authorities (USFDA/EU) preferred. Having international regulatory inspection exposure with direct involvement in at least one WHOPQ regulatory	1. To assist TL in determining relevant broad design parameters, process designing, flow design, quality standards, section design etc as required for preparation of the bidding document., 2. To review the Good Manufacturing Practices (GMP) submitted by EPC contractor during implementation , commissioning and operation of the VTD facilities and assist EDCL in approval, monitoring and supervision including CQV , Validation lead etc. 3. To assist EDCL in providing expert opinion in scaling up production from pilot to commercial scale, considering technology transfer in alignment with ICH Q5A (Quality of Biotechnological Products).

		PIC/S, or FDA shall be preferred.	inspection. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language	4. To assist EDCL in providing expert opinion on international regulatory requirements, including WHO TRS, FDA 21 CFR Part 211. 5. To assist EDCL in determining the production capacities for the identified product portfolio. 6. Supervise a project-wide Quality Risk 7. Management (QRM) framework. 8. Review technical specifications and factory acceptance test (FAT) protocols for specialized biological equipment like bioreactors, formulation vessels, lyophilizers, and automated filling lines. 9. Establish lot-release and batch certification, advise on technology transfer and regulatory submissions and interactions with DGDA, WHO and other relevant regulatory authorities. 10. Support in knowledge transfer and training of the EDCL staff on regulatory aspects.
6	Vaccines Process Expert	Must hold a postgraduate degree in Pharmaceutical , Biotechnology, or related Chemical field from a reputed institute. Certifications in current Good Manufacturing Practices (cGMP) for vaccines from recognized bodies like WHO, PIC/S, or FDA shall be preferred.	Minimum of 15 years of experience of handling at least 2 projects in vaccines manufacturing which would include exposure to upstream and downstream processes. Experience in commissioning, and Operation of cGMP-compliant Vaccines, Therapeutics, and Diagnostics (VTD) production facilities, including BSL-2 and BSL-3 laboratories. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language	1. To assist TL in determining relevant broad design parameters, process designing, flow design, quality standards, section design etc. as required for preparation of the bidding document., 2. To determine the required vaccines manufacturing processes and integrate the requirements in the bidding document. 3. Align the processes based on identified vaccines manufacturing platforms and provide inputs for technology transfer during the bidding process. Monitor and supervise the vaccines manufacturing process during project implementation phase and defect liability period. 4. To review the Good Manufacturing Practices (GMP) submitted by EPC contractor during implementation , commissioning and operation of the VTD facilities and assist EDCL in approval, monitoring and supervision. 5. To assist EDCL in providing expert opinion in scaling up production from pilot to commercial scale, considering technology transfer in alignment with ICH Q5A (Quality of

				Biotechnological Products). 6. To assist EDCL in providing expert opinion on international regulatory requirements, including WHO TRS, FDA 21 CFR Part 211. 7. To assist EDCL in determining the production capacities for the identified product portfolio. 8. Assist and provide inputs related to technology transfer related aspects. 9. Support in knowledge transfer and training of the EDCL staff on equipment & manufacturing process.
7	Biotherapeutics Process and diagnostic Expert	Must hold a postgraduate degree in Pharmaceutical , Biotechnology, or related Chemical field from a reputed institute. Certifications in current Good Manufacturing Practices (cGMP) for biotherapeutics from recognized bodies like WHO, PIC/S, or FDA shall be preferred.	Minimum of 15 years of experience of handling at least 2 projects in biotherapeutics / biosimilars manufacturing which would include exposure to upstream and downstream processes. Experience in commissioning, and Operation of cGMP-compliant, biotherapeutics, and Diagnostics (VTD) production facilities, including BSL-2 and BSL-3 laboratories. IVD regulatory and quality requirements, including ISO13485, ISO 14971, applicable WHO guidance and relevant national regulatory requirements shall be preferred. Experience in biochemical, molecular and immunodiagnostics preferred. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	1. To assist EDCL in determining relevant broad design parameters, process designing, flow design, quality standards, section design etc. as required for preparation of the bidding document., 2. To determine the required biotherapeutics manufacturing processes and integrate the requirements in the bidding document. 3. Align the processes based on identified biotherapeutics manufacturing platforms and provide inputs for technology transfer during the bidding process. Monitor and supervise the biotherapeutics manufacturing and diagnostic process during project implementation phase and defect liability period. 4. To review the Good Manufacturing Practices (GMP) submitted by EPC contractor during implementation, commissioning and operation of the VTD facilities and assist EDCL in approval, monitoring and supervision. 5. To assist EDCL in providing expert opinion in scaling up production from pilot to commercial scale, considering technology transfer in alignment with ICH Q5A (Quality of Biotechnological Products). 6. To assist EDCL in providing expert opinion on international regulatory requirements, including WHO TRS, FDA 21 CFR Part 211. 7. To assist EDCL in determining the production capacities for the identified product portfolio. 8. Assist and provide inputs w.r.t

				technology transfer related aspects. 9. Support in knowledge transfer and training of the EDCL staff on equipment & manufacturing process.
8	Cleanrooms, HVAC & Utilities Expert	He/ She must hold a Bachelor's degree in mechanical / electrical engineering from the reputed institute.	Minimum of 15 years of experience as cleanrooms, HVAC and utilities for projects of similar nature and scale. Specialist of handling at least 2 projects in designing, commissioning, and managing Operation related to cGMP-compliant Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	1. To assist in preparation of bidding documents. Support in the review the cleanroom, HVAC and Utilities designs submitted by the contractor during implementation, of the VTD facilities and assist EDCL in approval, monitoring and supervision. 2. To assist EDCL by providing inputs w.r.t the cleanroom design and validation, HVAC system design and validation, Utilities designs, review and validation. 3. Assist in contamination control measures for manufacturing viral, bacterial, and recombinant vaccines, biotherapeutics and diagnostics.
9	Electrical & Power Systems Engineer	He/ She must hold a Bachelor's degree in electrical engineering from the reputed institute.	Minimum of 15 years of experience as electrical and power systems for projects of similar nature and scale. Specialist of handling at least 2 projects in designing, commissioning, and managing Operation related to power and electrical requirements for various aspects of cGMP-compliant Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	1. To review the electrical and power related designs submitted by the contractor during design and implementation, of the VTD facilities and assist EDCL in approval, monitoring and supervision of the same. 2. Suggest designs and ideas towards application and integration of various sources of power like, electricity from regular and renewable sources. 3. Provide suggestions for designs related to computer systems, CCTV, cameras, fire systems including automation, computerised-system validation and data-integrity.
10	Veterinary & Biosafety Expert	He/ She must hold a Master's degree in veterinary science / biotechnology / life sciences from the reputed institute.	Minimum of 10 years of experience w.r.t. animal house design and operations for projects of similar nature and scale. Specialist of handling at least 2 projects in designing, commissioning,	1. The expert shall ensures that the animal house design and physical architecture complies with global regulatory standards (such as GLP, WHO, & CCSEA). 2. Layout and Workflow Integrity: Review floor plans to verify strict separation between clean and dirty

			and managing operations related to animal house for breeding and testing purposes. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	corridors. Ensure distinct segregation between R&D areas (where novel or modified strains are tested) and QC manufacturing testing areas (where standardized pharmacopeia assays occur). 3. Species-Specific Isolation: Validate that separate, dedicated rooms are planned for different animal species (e.g., mice, rats, guinea pigs, rabbits) to prevent inter-species disease transmission or pheromone-driven stress. 4. HVAC & Environmental Controls: Review specifications for HVAC systems. The expert will verify that the design allows 10 to 15 air changes per hour (ACH), 100% fresh air intake (no recirculation), and strictly controlled differential pressures to contain airborne biological hazards. 5. Biosafety Containment: Evaluate containment levels for handling live pathogens. Determine if the design adequately integrates Animal Biosafety Level 2 (ABSL-2) or ABSL-3 zones required for vaccine challenge-exposure studies. 6. Support System Sizing: Review architectural plans for crucial ancillary areas: quarantine rooms, automated cage/bottle washers, double-door pass-through autoclaves, feed/bedding storage, necropsy rooms, and dedicated diagnostic labs. Licensing and Accreditation: Guide the facility through local registrations and global credentials (such as AAALAC International accreditation or compliance with OECD GLP principles). 7. Support in knowledge transfer and training of the EDCL staff on equipment & animal house related aspects.
11	QC Expert, Analytical, Microbiology & Molecular Laboratory/Facility Expert	He/ She must hold a Master's degree in biotechnology / life sciences from the reputed institute. PhD in relevant	He/she must have at least 10 years of cumulative experience in QC related aspects. The experience should be w.r.t biopharmaceutical facility design and construction supervision and execution of at least two (2) projects	1. Provide strategic oversight, compliance enforcement, design verification, and validation during the facility's design, construction, commissioning, and qualification phases. 2. Review architectural plans to ensure complete separation between live-viral lines (vaccines)

		streams will be an added advantage.	of Vaccines, Therapeutics, and Diagnostics (VTD) related manufacturing plant of similar magnitude, and complexity in the last ten (10) years as per international standard The experience of working on externally financed project will be preferred.	and non-viral platforms (biotherapeutics) to prevent cross-contamination. 3. Review design specifications for HVAC systems, differential pressure zones, and airlocks to ensure they meet ISO cleanroom classes aligned with aseptic processing requirements. 4. Review and verify that the proposed QC testing laboratories (chemical, microbiological, and containment areas like BSL-2/BSL-3) are appropriately isolated with adequate unidirectional workflows. 5. Evaluate and approve URS documents for highly specialized testing systems (e.g., HPLC, mass spectrometers, automated endotoxin systems, sterility isolation units, and digital RT-PCR blocks). 6. Participate in technical evaluations of equipment vendors and contract manufacturing/testing sites to confirm their quality capabilities. 7. Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) frameworks for all critical facility systems. 8. Supervise the validation testing of critical manufacturing utilities, ensuring the Water-for-Injection (WFI) loops, Pure Steam, and specialized process gases meet strict pharmacopeia metrics. 9. Supervise the baseline EM strategy, establishing the location map and limits for non-viable particulate and microbiological sampling across critical zones. 10. Monitor and assist in technology transfer related aspects.
12	Procurement Expert	Must hold a degree in Engineering Management, Business Administration, or equivalent field from a reputed institute. The relevant certifications in procurement or bidding	He /She must have a minimum of ten (10) years of handling procurement/bidding matters. The experience of handling of at least 2 projects related to Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants industrial/chemical / bio-chemical/ pharmaceutical projects	1. To assist the team in all procurement and bidding related matters as per the requirement. 2. Assist EDCL in FIDIC based procurement process from preparation of bidding document till signing of contract with EPC contractor of VTD facility. It includes assisting EDCL in holding of Prebid meeting, preparation of Bid Evaluation reports, issuance of LOA and Contract signing etc.

		management shall be preferred.	shall be preferred. The experience of working on externally financed project specially ADB project is must. the experience of preparation of bidding document by using EPC document of ADB based on FIDIC contract shall be preferred.	
13	Environment & Safeguards Specialist	He/she must be a Master's degree holder in Environmental Engineering or equivalent field from the reputed institute.	He /She must have a minimum of ten (10) years of handling Safeguard matters. The experience of handling of at least 2 projects related to Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants industrial/chemical / bio-chemical/ pharmaceutical projects and supporting in health and safety matters shall be preferred. The experience of working on externally financed project will be preferred.	1. To assist TL in all Safeguard (Environmental, Resettlement, Gender, Health, Safety and Fire related) matters as per the requirement. 2. Assist TL in Safeguard details for bidding purpose. 3. Review the Safeguard Reports (EIA/EMP/Resettlement/Gender Action/ Safety/health protection etc) submitted by EPC contractor and to assist EDCL in compliance monitoring and guiding EPC contractor in implementing corrective measures. 4. To prepare periodic Safeguard Compliance reports of project as required for submission to ADB. 5. To review compliance documents demonstrating adherence to local, national, and international environmental regulations and standards. 6. Evaluations of the site's environmental conditions, including soil, water, and existing flora and fauna. 7. To review and assist in monitoring of compliance requirements for handling, storing, and disposing of hazardous and non-hazardous waste generated during execution and operation. 8. To assist EDCL in Identification and analysis of potential environmental risks associated with the manufacturing process and how to mitigate them. 9. To review and assist in analysis of the EPC contractor's practices to promote sustainability, including energy use, resource conservation, and lifecycle assessments. 10. Any other relevant safeguard related activity not covered in above points.

14	QMS (QA & QC) and Compliance Expert	He/ She must hold a Master's degree in pharmaceutical sciences / biotechnology / life sciences from the reputed institute.	He/she must have at least 10 years of cumulative experience in QMS related aspects. The experience should be w.r.t biopharmaceutical facility design and construction supervision and execution of at least three (3) projects of Vaccines, Therapeutics, and Diagnostics (VTD) related manufacturing plant of similar magnitude, and complexity in the last ten (10) years as per international standard. The experience of working on externally financed project will be preferred.	1. Provide oversight, compliance assurance, and strategic alignment. 2. Monitor and ensure a QMS framework that complies with WHO TRS (Technical Report Series), USFDA 21 CFR Parts 210/211/600/820, EU GMP Annex 1 (for sterile biologicals), and ISO 13485 (specifically for diagnostics). 3. Review the overarching Quality Manual, Site Master File (SMF), and high-level Standard Operating Procedures (SOPs) prepared by the engineering, procurement, and construction (EPC) contractors. 4. Supervise a project-wide Quality Risk Management (QRM) framework following ICH Q9 guidelines to mitigate contamination, cross-contamination, and data integrity risks from the design phase onward. 5. Review facility layouts to ensure strict segregation of cleanroom classes (Grade A to D), unidirectional personnel/material flows, and containment for biohazards (BSL-2/BSL-3 zones if applicable). 6. Supervise the quality assurance protocols for high-risk utilities, including Water for Injection (WFI) systems, Pure Steam, and HVAC systems crucial for environmental monitoring. 7. Review technical specifications and factory acceptance test (FAT) protocols for specialized biological equipment like bioreactors, formulation vessels, lyophilizers, and automated filling lines. 8. Review, or approve the VMP covering all facility systems, manufacturing lines, and diagnostic assay kits. 9. Monitor and verify the execution of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols. 10. Oversee the structural QMS prep for validating complex biological assays, sterility testing methods, and aseptic process simulations (media fills). 11. Act as the primary quality liaison
----	-------------------------------------	--	--	---

				between the project owner, EPC contractors, and international regulatory inspectors. 12. Issue formal quality observations to contractors, monitor remediation timelines, and report quality metrics directly to project steering committees. 13. Monitor and assist in technology transfer related aspects. 14. Support in knowledge transfer and training of the EDCL staff on QMS related aspects.
15	Net Zero expert	Must hold a degree in Architect from the reputed institute. He/ She should have EPD Certifications, Green Building Certifications and other relevant documents. shall be an added advantage.	Minimum of 7 years' Experience in infrastructure projects He/ She should have the experience of delivering Net Zero Building Projects	1. Work under guidance of the team leader. 2. Designing of building and services by following Net Zero Building concepts, i.e Green Building concept, water conservation, use of non-conventional energy sources, energy conservation and efficiency, low pollution, waste water recycling and reuse, hazard/disaster mitigation and all modern building design principles to ensure that the VTD complex performs the utility in most efficient manner. 3. Supervision and monitoring of building and associated services at regular frequency as per approved Net zero concepts. 4. Periodical reports on Net Zero building concepts such as Sustainability Compliance Reports to ensure adherence to green and energy-efficient building standards.
16	Mechanical and Plumbing Expert	He/ She must hold a Bachelor's degree in mechanical engineering from the reputed institute.	Minimum of 15 years of experience as MEP Specialist of handling at least 2 projects in designing, commissioning, and managing Operation related to cGMP-compliant Vaccines, Therapeutics, and Diagnostics (VTD)/industrial/chemical plants. The experience of working on externally financed project will be preferred. The incumbent must have fluency in English language.	1. To review the MEP designs submitted by EPC contractor during implementation, of the VTD facilities and assist EDCL in approval, monitoring and supervision. 2. To assist EDCL by providing inputs w.r.t the cleanroom design and validation, HVAC system design, and contamination control measures for manufacturing viral, bacterial, and recombinant vaccines.

Note: EHS Code of Conduct Requirement - The Standard Code of Conduct Form Annex 2 should be signed by each Expert to indicate that they have:

1. received a copy of the code;

2. had the code explained to them;
3. acknowledged that adherence to this Code of Conduct is a condition of employment; and
4. understood that violations of the Code can result in serious consequences, up to and including dismissal, or referral to legal authorities.

J. Implementation Arrangements

The Consultant's contract will be delivery-based (fixed cost basis) during stage I and input-based during the remaining two stages and shall be administered by EDCL under MoH&FW of the Government of Bangladesh. The Consultant will mobilize promptly after signing the Contract and will compile, prepare, and submit all required reports according to the delivery milestones agreed in the contract.

K. Maintenance of Accounts and Project Monitoring

- The Consultant shall keep accurate and systematic accounts and records in respect of the Services and make them available to EDCL and ADB for inspection and audit, as provided in the contract.

L. Project Monitoring & Reporting

- EDCL will monitor the implementation of the project as per the designed format for the project.
- EDCL will review monthly/quarterly progress reports and advise or suggest such measures, as deemed fit, from time to time to ensure proper execution of the project.
- **EHS Reporting Requirements**
 - (i) Immediately notify the Client of any failure by the Contractor to comply with its Environment, Health and Safety obligations;
 - (ii) Immediately notify the Client of any allegation, incident or accident, which has or is likely to have a significant adverse effect on the environment, the affected communities, the public, Client's Personnel, Contractor's Personnel or Experts. Confidentiality of full details should be maintained for sensitive cases. The Consultant shall provide full details of such incidents or accidents to the Client within the timeframe agreed with the Client;
 - (iii) Immediately inform and share with the Client any immediate notification related to Environment, Health and Safety incidents provided to the Consultant by the Contractor, and as required of the Contractor as part of the Progress Reporting.
 - (iv) Share with the Client in a timely manner the Contractor's Environment, Health and Safety metrics, as required of the Contractor as part of the Progress Reports.

M. Reporting Requirement and Time Schedule

All reports as mentioned in Table 5 below are to be submitted to Project Director, EDCL

Table 5 : Reporting Requirements

S.No.	Name of Report and Content	Frequency (Maximum time period)	Type
1)	Inception Report	After one month of commencement of assignment	1 soft copy and 2 printed copies
2)	Draft Bidding Document	Within 3 month of contract commencement date	1 soft copy and 3 printed copies
3)	Monthly Progress Report (MPR) during stage II and III activities of previous	By 7 th of every next month	1 soft copy and 2 printed copies

	month covering all major activities of EPC contractor and performance report of consultant team with necessary attachments.		
4)	Quarterly Progress Report (QPR) during stage II and III activities of previous quarter covering all major activities of EPC contractor and performance report of consultant team with necessary attachments.	By 7 th of succeeding month of previous quarter	1 soft copy and 2 printed copies
5)	Comments on designs, drawings, layouts, proposal for approval submitted by EPC contractor for Client approval with detail justification and relevant supporting documents/references.	Within 7 working days from the date of receipt of proposal	1 soft copy and 2 printed copies
6)	Payment Invoices received from EPC contractor to be examined, reviewed and suitably recommended in light of contract conditions and actual performance.	Within 7 working days from the date of receipt of invoice	1 soft copy and 2 printed copies
7)	Closure Report covering entire scope of work, mile stones achieved, action points required to be implemented by Client.	Within 1 month after completion of assignment	1 soft copy and 2 printed copies
8)	Any other report/confidential report required by the Client	Immediately/as soon as possible as per the requirement /nature of criticality of the report	As required by the Client

N. Client's Input and Counterpart Support

- EDCL will provide all relevant project-related available data, reports, and documents for the successful completion of the contract.
- The consultant will have access to consultation with all relevant officials of EDCL and other agencies of the Government of Bangladesh.
- The consultant will be provided with a fully furnished office with network facilities for smooth functioning at the VTD site.

O. Consultant's Responsibility

- Out of Pocket Expenses- Per diem, travel cost etc. shall be part of the Contract Cost.
- Except the key experts, cost of any Non key experts and support staff required like office manager/accounts officer or office assistant etc, shall have to be borne by the Consultant as part of the Contract cost.
- Any Cost which is not covered under Client's support shall be borne by the consultant unless any such cost is agreed during the contract negotiations.

Annex 1: Environmental, Health and Safety (EHS) Obligations

Ensure that the Contractor delivers its EHS obligations under its contract. This includes, but is not limited to the following:

1. Review the Contractor's Environment, Health and Safety Management Plan, including all updates and revisions at frequencies specified in the Contractor's contract (normally not less than once every 6 months);
2. Review all other applicable contractor's documents related to Environment, Health and Safety aspects including the health and safety manual, security management plan, etc;
3. Review and consider Environment, Health and Safety risks and impacts of any design change proposals and advise if there are implications for compliance with project requirements;
4. Undertake audits, supervisions and/or inspections of any sites where the Contractor is undertaking activities related to the Works, to verify the Contractor's compliance with Environment, Health and Safety requirements with and without contractor and/or Employer relevant representatives, as necessary, but not less than once per month
5. Undertake audits and inspections of Contractor's accident logs, community liaison records, monitoring findings and other Environment, Health and Safety related documentation, as necessary, to confirm the Contractor's compliance with Environment, Health and Safety requirements;
6. Agree remedial action/s and their timeframe for implementation in the event of a noncompliance with the Contractor's Environment, Health and Safety obligations.
7. Ensure appropriate representation at relevant meetings including site meetings, and progress meetings to discuss and agree appropriate actions to ensure compliance with Environment, Health and Safety obligations;
8. Check that the Contractor's actual reporting (content and timeliness) is in accordance with the Contractor's contractual obligations.
9. Review and critique, in a timely manner, the Contractor's Environment, Health and Safety documentation (including regular reports and incident reports) regarding the accuracy and efficacy of the documentation.
10. Undertake liaison, from time to time and as necessary, with project stakeholders to identify and discuss any actual or potential Environment, Health and Safety issues.
11. Establish and maintain a grievance redress mechanism including types of grievances to be recorded and how to protect confidentiality

Annex 2: Environmental, Health and Safety Code of Conduct for Consultant's Personnel

We are the Consultant, [enter name of consultant]. We have signed a contract with [enter name of Client] for [enter description of the Works]. These Works will be carried out at [enter the Site and other locations where the Works will be carried out]. Our contract requires us to implement measures to address environmental, health and safety risks related to the Works.

This EHS Code of Conduct is part of our measures to deal with environmental, health and safety risks related to the Works. It applies to all our staff, laborers and other employees at the Works Site or other places where the Works are being carried out. It also applies to the personnel of each JV Partner, Sub-Consultant and any other personnel assisting us in the execution of the Works. All such persons are referred to as "Consultant's Personnel" and are subject to this EHS Code of Conduct.

This EHS Code of Conduct identifies the behavior that we require from all Consultant's Personnel.

Our workplace is an environment where unsafe, offensive, abusive or violent behavior will not be tolerated and where all persons should feel comfortable raising issues or concerns without fear of retaliation.

REQUIRED CONDUCT

Consultant's Personnel shall:

1. carry out his/her duties competently and diligently;
2. comply with this EHS Code of Conduct and all applicable laws, regulations and other requirements, including requirements to protect the health, safety and well-being of other Consultant's Personnel and any other person;
3. maintain a safe working environment including by:
 - (a) ensuring that workplaces, machinery, equipment and processes under each person's control are safe and without risk to health;
 - (b) wearing required personal protective equipment;
 - (c) using appropriate measures relating to chemical, physical and biological substances and agents; and
 - (d) following applicable emergency operating procedures.
4. report work situations that he/she believes are not safe or healthy and remove himself/herself from a work situation which he/she reasonably believes presents an imminent and serious danger to his/her life or health;
5. treat other people with respect, and not discriminate against specific groups such as women, people with disabilities, migrant workers or children;
6. report violations of this EHS Code of Conduct; and
7. not retaliate against any person who reports violations of this EHS Code of Conduct, whether to us or the Employer, or who makes use of the grievance mechanism for Consultant's Personnel or the project's Grievance Redress Mechanism.

RAISING CONCERNS

If any person observes behavior that he/she believes may represent a violation of this EHS Code of Conduct, or that otherwise concerns him/her, he/she should raise the issue promptly. This can be done by call [] to reach the Consultant's hotline (if any) and leave a message.

The person's identity will be kept confidential, unless reporting of allegations is mandated by the country law. Anonymous complaints or allegations may also be submitted and will be given all due and appropriate consideration. We take seriously all reports of possible misconduct and will

investigate and take appropriate action. We will provide warm referrals to service providers that may help support the person who experienced the alleged incident, as appropriate.

CONSEQUENCES OF VIOLATING THE ENVIRONMENTAL, HEALTH AND SAFETY CODE OF CONDUCT

Any violation of this EHS Code of Conduct by Consultant's Personnel may result in serious consequences, up to and including termination and possible referral to legal authorities.

FOR CONSULTANT'S PERSONNEL

I have received a copy of this EHS Code of Conduct written in a language that I comprehend. I understand that if I have any questions about this EHS Code of Conduct, I can contact [enter name of Consultant's contact person(s) with relevant experience)] requesting an explanation.

Name of Consultant's Personnel: [insert name]

Signature: _____

Date: (day month year): _____

Countersignature of authorized representative of the Consultant:

Signature: _____

Date: (day month year): _____