**REPUBLIC OF TÜRKİYE**

**MINISTRY OF HEALTH**

**General Directorate of Public Health (GDPHe)**

**TÜRKİYE PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES PROJECT**

**(P180781)**

**TERMS OF REFERENCE (TOR) FOR**

**CONSULTANCY SERVICES**

**VACCINE PRODUCTION CENTER PROJECT IN ANKARA**

**(Ref: TPPHEP/HSGM/2025/CS/L.1.1/QCBS/1)**

**1. BACKGROUND**

The Republic of Türkiye has applied for a loan equivalent to USD 250 million from the International Bank for Reconstruction and Development (IBRD) to finance the Türkiye *Preparedness* for *Public Health Emergencies Project* (P*180781)*. Part of the proceeds will be applied to payments for goods, works, related services and consultancy services to be supplied under this project.

The Project consists of the following components:

Component 1: Strengthen vaccine production capacity

This component will focus on preventing infectious diseases by enabling access to vaccines through local and regional vaccine manufacturing and production, which proved critical during COVID-19. It will continue efforts initiated in 2020 for the equipment of the Ankara VPC. Specifically, it will finance procurement of medical and technical equipment required for the operation of the VPC. All new medical and technical equipment will comply with energy-efficiency standards that go beyond standard practice and result in a substantial reduction in GHG emissions. This subcomponent will also support technical assistance (TA) to define and prioritize the research agenda for vaccine manufacturing technologies – with particular consideration of climate-sensitive diseases and the impact of climate on changing infectious disease risks – to align manufacturing regulations to international standards, and to support the completion of the WHO Pre-Qualification (PQ) process, as well as to procure and establish physical components required for design, supply, and installation needs to meet WHO PQ requirements and to train and support capacity building of VPC staff.

Component 2: Strengthen national and subnational capacities for detection of and response to health emergencies

This component will finance the development and expansion of critical core capacities across health and public health systems at all levels to strengthen emergency readiness for a wide range of potential threats. The primary anticipated threats are outbreaks, climate shocks, and humanitarian emergencies, including earthquakes. Activities will target systems, workforce training, and institutional capacities, and will incorporate enabling and cross-cutting capabilities and approaches including integrated and digital solutions to facilitate improvements of core PPR capacities. A OH approach across animal, human, climate change, and environmental sectors is also critical to addressing the broad range of potential threats. To the extent possible, OH principles will be adopted throughout Project subcomponents and selected activities. The OH approach will focus on strengthening enabling activities such as: (i) OH governance and coordination; (ii) OH related capacity building; and (iii) infectious disease related info-sharing and system interoperability. This entails: (i) establishing a functioning OH coordination mechanisms at national and selected provinces; (ii) developing and implementation of OH annual work plans; (iii) developing and disseminating of annual OH reports; (iv) exploring Info-sharing mechanisms; and (v) conducting dissemination activities such as national OH conference. This component will be delivered through a combination of TA, capacity building, and provision of critical goods and equipment.

* Sub-component 2.1: Early warning and surveillance

This subcomponent will support strengthening the surveillance system and public health intelligence at all levels to improve early and accurate detection of potential hazards. Multisectoral coordination for OH will be incorporated, where possible and appropriate, including activities in EWS, data sharing and information exchange, and joint workforce capacity building. Climate change is a primary impetus and focus of this activity. The subcomponent will therefore incorporate climate and meteorological indicators in EWS and surveillance systems, and prioritize relevant interventions for climate-sensitive diseases, including vector-borne and waterborne diseases. This subcomponent will also apply a strategy of active systems-based performance assessment and improvement that optimizes timeliness, sensitivity, and cost efficiency to counter realized threats. Activities will reinforce bidirectional information flow and a feedback loop by supporting reporting, analysis, and communication of surveillance data to inform public health action. Specifically, this subcomponent will support the following activities.

* 1. Prioritization and planning for greater impact.
  2. System performance, expansion, and improvement to increase surveillance and EWS performance in detecting potential threats.
  3. Workforce skills.
  4. Critical hardware.
  5. Information systems and data.
* Sub-component 2.2: Laboratory and diagnostic systems

This subcomponent will support strengthening of laboratory systems and diagnostics capacities to detect and monitor infectious and environmental hazards, especially at periphery. The laboratory system will similarly be assessed through active performance improvement, with a specific focus on facilitating timely, accurate diagnostic validation, including:

* 1. Improved planning.
  2. System performance and improvement.
  3. Workforce skills.
  4. Critical hardware.
* Sub-component 2.3: National planning and emergency response coordination for emergency-ready health systems

This subcomponent will strengthen national preparedness planning for health emergencies and enhance the resilience and response capacity of the health system against health emergencies. It will facilitate delivery of critical public health functions across the workforce of all allied health professions, reinforce governance of key capacities for emergency coordination, and test these capacities through a learning curriculum of simulated and practical exercises. The primary anticipated threats are outbreaks, climate shocks, and humanitarian emergencies, including earthquakes. Climate change, which is fueling emergence and spread of infectious diseases in the country, including zoonotic diseases, waterborne diseases, and vector borne diseases, is one of the primary impetuses and focal areas of the component. Specifically, this subcomponent will support the following activities.

* 1. National preparedness and response planning.
  2. Workforce skills and system performance improvement.
  3. Critical hardware support.
  4. Coordination and governance.

Component 3: Project management and monitoring, and institutional capacity

This component will support routine project management, including coordination of technical activities in all components, fiduciary functions, audits of project financial statements, environmental and social (E&S) compliance, and regular monitoring of and reporting on implementation. This component will also support MoH’s institutional capacity during a period of one (1) year starting at the Project Effective Date. It will finance project operating costs, including translation, interpretation, equipment supporting costs, and staffing costs of the Project Management Support Unit (PMSU).

Component 4: Contingent Emergency Response (no funds allocated).

The objective of this Contingency Emergency Response Component (CERC) is to improve the Government’s response capacity in the event of an emergency.

The COVID-19 pandemic has emphasized the importance of vaccines to curb the spread of the infection and the disease. It is essential for developing countries to develop local vaccine production capacities to reduce dependence on imports and ensure vaccine security. Türkiye is well positioned to develop local vaccine production capacities for pandemic preparedness and long-term health system flexibility. With a population of around 86 million and a birth capacity of around 1.2 million per year, Türkiye has a well-established Expanded Program on Immunization (EPI) program that has a good vaccination coverage.

The Government has taken strong steps to strengthen the local capacity for manufacturing of vaccines.

Meanwhile, TİTCK achieved in October 2023 the ML3 against the WHO Global Benchmarking Tool [GBT] for medicines and vaccines manufacturing. This is a true asset for the country and for the project and is further evidencing the strong steps which the government has already taken to strengthen and support the local capacity for manufacturing of vaccines.

The Ministry of Health (MoH) of the Republic of Türkiye is implementing a state-of-the-art vaccine production project to strengthen national biosafety, vaccine production capacity and pandemic preparedness. This will support the country to develop systems for simultaneously procuring, developing and locally producing vaccines to meet the demands of national immunization needs alongside exporting vaccines.

This Project will be based on the following conditions locally for all processes related to the development and production of vaccines.

* Research and Development Laboratory; Biosafety Level (BSL)- II and III:

Development of Novel & Contemporary Vaccines - Having a provision to set up a ‘Research and Development’ lab in the facility to initiate fast track development of vaccines at pilot scale and up to pre-clinical trials and do the scale up from the Laboratory to this facility for clinical trials product registration and commercial scale manufacturing (BSL II and III).

This would include support of an Experimental research (Invivo, Invitro) for R&D as well as testing of locally produced vaccines.

* Cell Banking

Preparation of host cell Master Cell Bank, Working Cell Bank, Master Seed Lot and Working Seed Lots for the vaccine to be studied.

* Bulk Production

The production process of different types of vaccines, domestic production of active ingredients based on the product categories and capacities that the country will need and future planning of capacities for export.

* Formulation, Fill-Finish and Quality Control (QC)

Advanced filling lines for different types of vaccines (lyophilized and/or liquid) [With multiple presentations; Vials (Single and Multi-dose) and pre-filled syringes].

* Central Warehouse:

For all the required material for production, operation of the facility and storage of raw materials and finished goods. The warehouse will be a state-of-the art technology product with advanced cold storage facilities and automated systems for material handling.

The types of vaccines that are intended to be produced in the proposed facility are as follows

* + National immunization needs
  + Travel vaccines
  + Pandemic preparedness and development of new vaccine technologies

The Government of Republic of Türkiye intends to build a new "Vaccine Production Center (VPC), Experimental Animal Production Center, R&D and a laboratory at BSL 2 & 3 and ABSL 2 & 3 level" in Ankara.

The consultancy services for the VPC will be funded under Component 1 of the Türkiye Preparedness for Public Health Emergencies Project.

VPC is being constructed in Balıkhisar Neighborhood of the Akyurt District in Ankara on the parcel number 215173/1 with a 76,412,99 m2 area.

**I - Location of VPC**

VPC is planned to be established in the Balıkhisar Neighborhood of the Akyurt District in the Ankara Province (Figure 1).

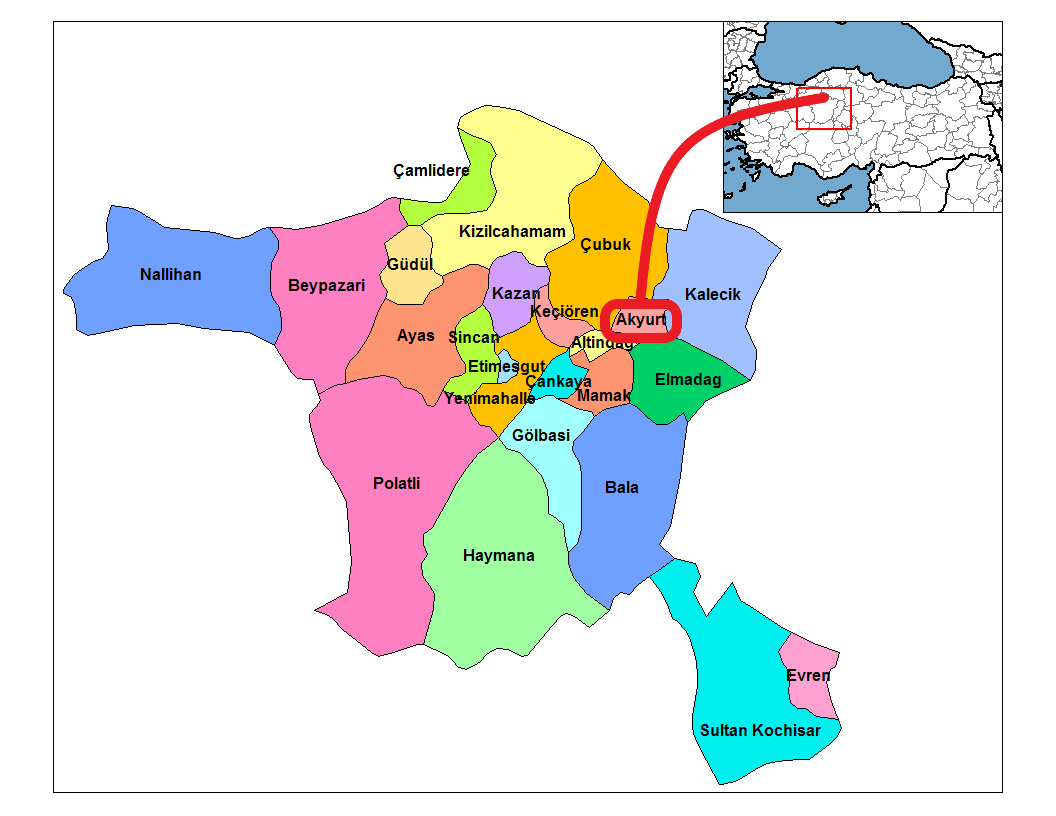


Figure 1: Map of Ankara and Akyurt

The Project area is owned by the Ministry of Health. There is a warehouse constructed on the parcel and being used currently to store equipment related to vaccines. This is the parcel where VPC will be constructed. The adjacent parcel is also allocated for GDPH and currently being used as a vaccine warehouse, including -80 and -20 degree cold storages where COVID-19 vaccines are currently being stored. Since the parcel is currently being used, infrastructure of energy, water, waste water and road systems in the Project area will be used. Satellite view of the Project area and its surroundings is provided below.



Figure 2 : General View of VPC Parcel in Ankara

Distance of the Ankara Province center to the Project area is approximately 20 km. Esenboğa Airport is located approximately 3 km away from the Project area. The nearest settlement to the Project area is the Balikhisar Neighborhood which is located approximately 3 km southeast of the Project area. In 1 km diameter, the closest places are Otonomi (off-road vehicle sales point), YDS (well-known shoe manufacturer particularly for people working in Health and Safety sector), Isbir Bedding, OSYM (national exam center), Borusan Automotive and MAN Turkey. The closest housing area is located 500 meters away across Özal Boulevard, which is a bird's eye view of the highway (Figure 3). In addition, for the last years pharmaceutical and medical device companies such as Vilsan Veterinary and Pharmaceutical Industry, Turkish Pharmaceutical and Serum Industry, TTS Turktıpsan A.Ş, Turkish Plast Medical Products A.Ş. have started to operate in the region. The area started to become ***bio-technology investment zone***. According to Akyurt Municipality Zoning Plan, the area was approved as "Serum Area".



Figure 3 : Structures in 1 km Diameter for Ankara Vaccine Center

II - Description of VPC

In the scope of the VPC, which is subject to consultancy services of this ToR, a complex will be constructed by the Ministry of Health including (i) a vaccine production center, (ii) an experimental animal production center, (iii) R&D center and (iv) laboratory at BSL 2 & 3 and ABSL 2 & 3 level.

The main project complex area consists of the following buildings and units:

* Administrative Building (Storages, security, cafeteria, administrative office, guest house),
* Research and Development (R&D) Building (including Biobank),
* Experimental Animals Production/Test Building,
* Vaccine Production and Storage Buildings (including bacterial and viral pilot-scale production areas and quality control laboratories),
* Loading/Unloading Area (located north of the production buildings),
* Waste Centre,
* Technical Buil
* Security Building, and
* Observation Towers.

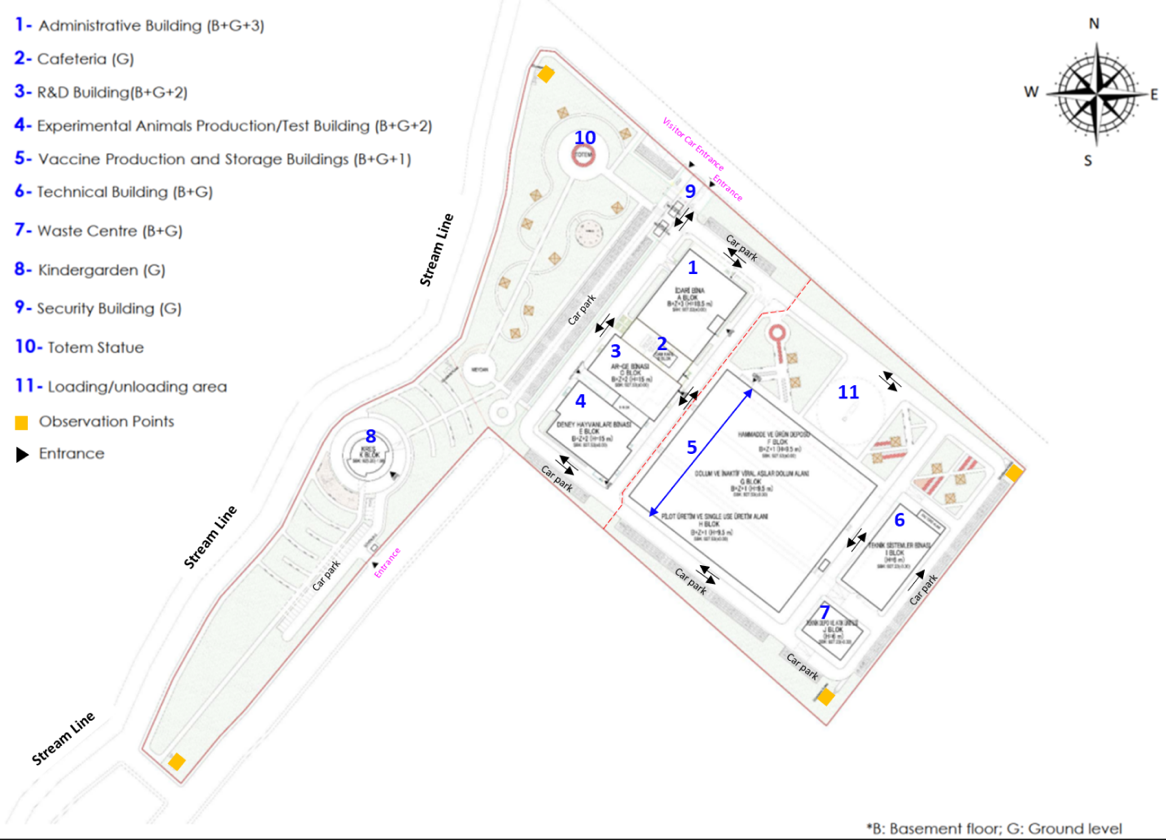
**IMPORTANT NOTE**

At the date of issuance of these Terms of Reference, the choice of the vaccines and of the vaccine manufacturing processes which will be hosted in the ‘Vaccine Production and Storage Buildings’ have not been finalized yet.

Therefore, the following plan and detailed list of buildings are currently considered tentative.

Also important, to limit the potential constrains which the construction could cause on the proper implementation of these future vaccine processes, the consultancy firm will have to pay particular attention to providing solutions for these new buildings that will maintain a high degree of flexibility in terms of surface area, lay-out, functionalities, segregation, access to clean utilities, etc…

In addition to the units listed above, a recreational area is planned to be developed within the Project site. The recreational area will establish a buffer zone between Çubuk Stream and the main project complex. A kindergarten, which will be used only by operational staff, is planned to be built within the recreational area. Additionally, a totem statue will be positioned within the recreational area close to the entrance. The remaining portions of the recreational area will consist of landscaping and rest areas.



Figure‑4: Tentative Project Plan (MoH has been studying to finalise the plan.)

The project buildings will have a tentative total floor area of 21,446 m2. All buildings in the main project complex area (including the Waste Building and Technical Building) are designed to be interconnected through galleries (4x4 m wide) to be constructed in the basement to facilitate and secure operational management. All buildings to be constructed within the scope of the project are planned to have rooftop solar energy panels for energy production. Project components to be constructed and their floor area/operation areas are presented in the table below. Please note that the figures are tentative.

Table: Project components and tentative footprint/activity areas (The construction footprint areas are tentative, retrieved from project document presenting layouts, building details, surface areas and floor plans prepared by Mesart Mimarlık ve İnşaat A.Ş.)

| Building No. | Building Name | Footprint area (m )2 | Total operation area (m )2 |
| --- | --- | --- | --- |
| 1 | Administrative Building (Basement + Ground + 3 floors + Attic) | 2,142.00 | 10,714.09 |
| 2 | Glass Cafeteria (Ground floor) | 206.92 | 206.92 |
| 3 | Research and Development Building (Basement + Ground Floor+ 2 Floors + Attic) | 1,941.95 | 5,968.63 |
| - | Indoor Parking Lot (Basement) | 171.72 | 171.72 |
| 4 | Experimental Animals Production/Test Building (Basement + Ground Floor+ 2 floors + Attic) | 1,842.98 | 7,231.40 |
| 5 | Vaccine Production and Storage Buildings (Consisting of six blocks) (Basement + Ground Floor+ 1 Floor + Attic) | 11,262.53 | 31,272.97 |
| 6 | Technical Building (Basement + Ground + Attic) | 1,676.25 | 3,366.90 |
| 7 | Waste Building (Basement + Ground Floor + Attic) | 617.76 | 1,262.06 |
| 8 | Kindergarten (Ground floor) | 502.83 | 502.83 |
| 9 | Security Building (Ground floor) | 160.97 | 160.97 |
| - | Kindergarten Security Building (Ground floor) | 8.75 | 8.75 |
| - | Observation Towers (x5) | 138.5 | 138.5 |
| - | Galleries | 980.11 | 980.11 |
| **-** | **TOTAL** | **21,446.35** | **61,985.85** |



The architectural design of the project requires seismic isolation method to be applied in the blocks to be constructed as Vaccine Production and Storage Buildings to ensure elimination of biosafety risks in case of an earthquake event. The Administrative Building, R&D Building and Experimental Animals Production/Test Building are designed to have raft foundations that will also be protective against seismic risks.

There will also be open outdoor parking areas in the main project complex area and a recreational area dedicated to both employees and visitors.

A landscaping study has been undertaken by the Ministry of Health including proposed number of trees and shrubs to be planted, amount of vegetative soil to be laid down and the types and details related with plant species. It is proposed that total of 2,005 trees (including leaved and coniferous trees), 1,510 shrubs, 6,950 seasonal plants and 123 volubilate plants will be planted within the Project site (including parcel 1555-4 and recreational area) forming a total planted area of approximately 20,000 m2.

The whole project site will be fenced with security walls fitted with razor wires and CCTV cameras. The site will consist of two phases (zones) with different security levels; (i) Phase I includes the Administrative, R&D and Experimental Animals Production/Test Buildings and (ii) Phase II includes the Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area. Phase II will be protected at a higher security level and there will be a secondary security check for entry from Phase I to Phase II by both vehicles and pedestrians.

There will be two different entrance-exit points dedicated for cars/pedestrians and trucks which will provide safe access to the campus. Additionally, different entrance-exit doors in the buildings for services, animal and material transfers are allocated in the design of Phase I.

III. Current Status of the Construction Site

The tender for the shell and core construction of the VPC building will be conducted by the General Directorate of Health Investments from general budget resources. The supervision services for the construction works will also be carried out by the General Directorate of Health Investments.

Currently, the construction works of the following buildings are completed.

* Administrative Building (Storages, security, cafeteria, administrative office, guest house),
* Research and Development (R&D) Building
* Experimental Animals Production/Test Building,

The bidding process and the construction works for the shell and core construction of the VPC building are expected to be completed in 8 months in accordance with Public Procurement Law procedures by the General Directorate of Health Investments. To shorten the time for the completion of shell and core buildings, steel construction is preferred.

In addition, the Ministry will commence the preparation of the technical specifications for the design, supply and installation bidding for the Research and Development (R&D) and Experimental Animals Production/Test Building immediately. The technical part of this bidding document is being prepared by the MoH experts. The Consultant is expected to review these technical parts before MoH commences the DSI bidding for R&D and Experimental Animal Production/Test Building.

IV. Consultancy Services Task Completed for VPC

The contract for consultancy services for the situation and needs analysis for the Vaccine Production Center Project was executed and completed by the end of December 2023. The output of the services “VPC Project Situation and Needs Assessment Final Report” is updated and presented as Annex 1 of this TOR, a guide for the Vaccine Production Center project.

This report suggests the vaccine types to be produced based on situation analysis, needs assessment, capacity planning, economic and financial analysis and defines the manufacturing capacity of the VPC.

**2. PURPOSE OF THE CONSULTANCY SERVICE**

The Government of Republic of Türkiye intends to build a new "Vaccine Production Center (VPC), Experimental Animal Production Center and a laboratory at BSL 2&3 and ABSL 2 & 3 level" in Ankara. Consultancy services for the VPC will be financed under Component 1 of the Türkiye Preparedness for Public Health Emergencies Project (PPHE).

The objective of this Project is to provide support in strengthening the bio-pharmaceutical and healthcare sector. By localizing manufacturing of vaccines and by adopting international best practices, the Ministry of Health will ensure vaccine security and continuous vaccines supply for the country in the long run.

Ministry of Health would like to use the proceeds of the World Bank (IBRD) loan to undertake consultancy services defined in this ToR.

The Ministry of Health will be the main owner of the Project and the site and will be referred to as MoH. “Project Consultant” will be referred to as “Consultant” for short. The Consultant will provide consultancy to the MoH within the scope of the Vaccine Production Center regarding the scope of the Design, Supply and Installation Contractor, including the basic and conceptual design, preparation of work plans, preparation of all specifications, all tender processes, execution of contracts, commissioning of the entire facility and certification processes and the Defects Liability period with the Project Manager, Engineer, technical experts etc. staff. The key task for the Consultant will be consulting MoH on the overall management of the VPC project and suggesting all technical and engineering decisions in the management of the contract for the execution of the VPC project. The Consultant will act on behalf of the MoH, supervise, monitor and report on the project performance of the MoH's contractor and subcontractors until the turnkey commissioning of the VPC.

The Consultant will be required to obtain prior approval from the MoH in all cases for (including but not limited to) the following matters; (a) contents of technical specifications for design, supply and installation bidding documents, (b) change orders and amendments both in terms of quantities and in particular those related to financial results, (c) time extensions and (d) approval of materials, etc.

**3. SCOPE OF SERVICES, TASKS AND EXPECTED OUTCOMES FOR *LUMP-SUM CONTRACT***

**3.1. Scope of Services**

It is planned by the MoH to construct a new facility (all processes will operate on a commercial scale) that will be fully functional and meet the current and future demands for production of vaccines required for national immunization program and a potential for exports.

The Consultant will carry out consultancy services for vaccine production center in Türkiye. The Consultant will provide support for project management, concept, preliminary design, engineering and supervision services for the 'Vaccines Production Project' for an appropriate vaccine’s portfolio including national immunization needs, travel vaccine and pandemic preparedness.

The Consultant will carry out services related but not limited to Design (including Concept and Preliminary Design), Project Management (design, supply, installation, certification processes and commissioning phases) up to GMP (Good Manufacturing Practices) and GLP (Good Laboratory Practices) audits and approval at the site located in Akyurt, Ankara.

The facility will provide the required infrastructure, manpower and space compatible with modern technology in accordance with the requirements of national and international standards with the capacity to meet the primary vaccine needs of our country.

Table: Minimum List of Activities and Facilities

|  |  |
| --- | --- |
| Facilities/ activities of the project | Functional units /activities |
| Design vaccine manufacturing block | The Cleanroom, Change Room & Growning Area |
| Cell Culture Production area |
| Vaccine Production |
| Vaccine Purification: |
| Formulation |
| Dry heat sterilization room |
| Aseptic Fill *&* Finish |
| Lyophiliz ation room |
| Preparation and Washing area room |
| Autoclaving room |
| Labelling and packaging |
| Quality Control (QC & QA) suite |
| Washing area |
| Day store and quarantine areas |
| Tool rooms |
| In process quality control rooms |
| Antigen Warehouse with Cold Chain Areas |
|  |
| Design warehouse | Raw material warehouse with cold chain areas |
| Antigen storage where cold chain areas are located |
| Work in progress warehouse with cold chain areas |
| Finished goods warehouse with cold chain facility |
| Packaging and ancillary materials warehouse |
| Sampling room |
| Design utilities areas and identify required utilities along their capacity | Direct impact utilities such as water treatment plant and its distribution network and heating ventilation and air conditioning areas networks, black and clean utilities: black steam, clean steam, purified water, WFI, clean compressed air, clean nitrogen (if applicable), electricity and other relevant |
| Design workshop areas | Maintenance areas |
| Prepare list of equipment and machineries | Identifies capacity, and user requirement specification |
| ldentify Technologies and Advice on Vaccine Selection  selection | ldentify appropriate technologies and advice in vaccine selection for local  manufacturing |
| Prepare HR Plan and Training Modalities for Vaccine Manufacturing | Prepare HR plan required for the facility in the short and long term and indicate how the required human resource can be filled in through short and long term trainings. |
|  |  |

The Consultant is expected to undertake the tasks below:

# Task 1: Review of documents

* Review the existing designs (architectural, structural, civil, mechanical, plumbing and electrical, etc.),
* Submit to the MoH the design analysis, plans, specifications, etc. requested by the MoH and covering the requirements in line with all national and international standards required by the Project,
* Ensure that construction drawings also provide necessary trunking and ducting that will accommodate the centralized Information Technology system on the building and across the roads and at all necessary external surroundings,
* Ensure the accessibility to buildings and additional internal facilities for physically challenged persons is appropriately allocated. This should go in line with consideration of the best practice and positive legal regulations in Türkiye regarding the rights of the disabled persons,
* Provide support on issues such as architectural design of the facility, equipment selection and layout, flow chart of the facility.
* All required information (design analysis, proposed changes and revised specifications) will be provided to the Consultant by the MoH for review.
* The Consultant must have knowledge of the following codes and technical criteria and those specified here. This list does not cover all required certification. This list will be updated with the Consultant as needed.

|  |  |
| --- | --- |
| **Standard** | **Scope** |
| WHO Laboratory Biosafety Manual, 4th Edition, 2020 | BSL-2/BSL-3 facility installation, validation and certification |
| WHO Laboratory Biosafety Manual 4th Edition 2020  National Microbiology Standards  HSGM (Halk Sağlığı Genel Müdürlüğü – Directorate General for Public Health) Laboratory Safety Guide 2021 2nd version | Laboratory biosafety training  Risk assessment  Laboratory design and management  Use of personal protective equipment  Use of primary protective device/equipment  Decontamination and waste management  Biosecurity program management |
| CEN/CWA 15793 Laboratory Biorisk Management Standard  ISO 35001: 2009 Biorisk management for laboratories | WHO Biorisk management and training program  It determines the processes for identifying, assessing, mitigating, controlling and monitoring risks associated with hazardous biological substances. |
| DIN 1946  DIN EN 1886  EUROVENT  EN 12237:2003 | Requirements regarding air conditioning system, ventilation for buildings, heat ventilation, refrigeration strength and leakage of circular sheet metal ducts   1. DIN 1946 Ventilation and Air Conditioning (for the healthcare sector) 2. DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance 3. EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and Refrigeration products) 4. EN 12237:2003 Ventilation for Buildings. Channel system. Strength and Leakage of Circular Sheet Metal Ducts |
| Standards of Accreditation in Health – Laboratory Kit | "SAS Laboratory Kit" that describes Standards of Accreditation in Health. This set was developed for laboratories consists of two parts including standards, assessment criteria and guidelines. Standards of Accreditation in Health-Laboratory Kit was developed for medical laboratories such as microbiology, biochemistry, pathology, immunology and genetics. |
| TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments | Clean room certification: Identification of clean room class, HEPA filter system sealing, air flow, number of air change, room pressure difference, room temperature and humidity, room sound level tests |
| TS EN 12128: 2002: Bio-Technology Research-Development and Analysis Laboratories - Safety levels, risk areas, locations and physical safety rules for micro-biology laboratories) | This standard is structured on ISO 3864 (Safety colors and signs), ISO 7000 (Graphical symbols for use on equipment), ISO 8995 (Principles of visual ergonomics-The lightning of indoor work systems) |
| TS EN 12469 Biotechnology – Performance Criteria regarding Microbiological Safety Cabinets | Certification of biological safety cabinets |
| TS EN 12347 Biotechnology – Performance Criteria for Steam Sterilizators and Autoclaves | Autoclave validation |
| Prevention of Biologic Factors Exposures  Regulation (In compliance with European Union: Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work) | Regulates the minimum provisions regarding the prevention and protection of health and safety risks that may arise from the exposure of employees to biological factors in the workplace. |
| US CDC-NIH “Biosafety at Microbiological and Biomedical Laboratories (BMBL)” | The BMBL is a manual published jointly by the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC) that lays out the code of practice for biosafety and biocontainment in the U.S. The BMBL is referenced in the Select Agent Regulations​ and is used in many professional and academic laboratories. |
| World Bank Group’s Environmental, Health and Safety Guidelines |  |
| GMP |  |
| GLP |  |
| AAALAC |  |
| Local Permits (Ministry of Agriculture, Ministry of Environment, regulations of TITCK, municipality permits etc.) |  |
| Biosafety Level Certifications |  |

# Task 2: Product Portfolio Details / Tender Documentation Services

* Review details of the product portfolio provided by MoH and determine equipment list accordingly,
* Review the equipment needs of the facility in consultation with the MoH and provide recommendations regarding the optimal technical solutions to address the identified needs,
* Work together with the MoH to assess laboratory needs and develop technical specifications for laboratories that match the identified needs with quality, including the latest technology and price expectations,
* Provide technical support in product and process technology selection, acquisition and proper transfer and also advise in identification of equipment required along with their capacity and list,
* Provide support for the preparation of technical specifications and assist in bidding document preparation for the selection of Design, Supply and Installation Contractor, all required bill of quantities, work-item based cost estimate and sample contract forms,
* Participate in pre-bid meeting during the bidding process and provide support for answers to the question/clarification requests raised by the prospective bidders regarding the bidding documents,
* Provide answers to questions, if needed, during the execution of design, supply and installation bidding and assist MoH to make amendments / corrections on any errors or faulty designs that have been identified,
* The design work should constitute complete sets of all necessary engineering structural designs and detailing of the structures and services required. This will involve electrical installation, telephone services, Local Area Network systems (LAN), Closed Circuit Television Systems (CCTV), alarm systems, fire fitting systems, internal access roads, parking facilities, sewerage systems, solid waste and disposal systems, storm water drainage systems, water treatment and distribution systems, heating, ventilation and air conditioning system (HVAC system) and other direct and indirect impact utilities.
* Ensure that the reviewed specifications and bill of quantities for all these services are appropriate,
* Consider design assumptions, design calculations and specifications and ensure their compliance with the applicable codes and regulations,
* Ensure appropriateness of the designs with the selected materials and their specifications from design alternatives,
* Ensure that the design should take regards of the constructability of the project, means method and techniques employed,
* Conduct a market research to identify potential suppliers (prominent manufacturers/ distributors) for the required medical equipment and laboratories,
* Provide support for the preparation of bidding documents,
* Provide support for the evaluation of bids and the clarification of the technical aspects to the bidders,
* Ensure that the inputs requested by the MoH are provided through all processes, including the contract award phase of the tender,
* Ensure that the necessary and appropriate equipment for the vaccine production facility is identified, the procurement process is coordinated and the installation is realized.

# Task 3: GMP/GLP

The following will be performed by the Consultant on the 5 P’s of GMP which helps comply with necessary standards throughout the entire production process.

* 1. People Planning Programme
* Plan, provide and evaluate the necessary trainings to ensure that all employees strictly comply with production processes and regulations.
* Plan, provide and evaluate product-specific GMP trainings to all employees to fully understand their roles and responsibilities to ensure that all employees strictly comply with production processes and regulations.
* Create necessary control and internal audit plans to evaluate their performance, help increase their productivity, efficiency and adequacy and ensure sustainability.
  1. Products Planning Programme
* Provide the necessary business plans of the products made to pass tests, comparisons and quality assurance. Business plans should ensure that primary materials, including raw products and other ingredients have clear specifications at each stage of production.
* Provide workflow plans complying with the standard methods for packaging, testing and allocation of sample products.
  1. Processes Planning Programme
* Document the appropriate, clear and consistent process planning.
* Ensure that the plans are distributed to all employees.
* Establish regular evaluation programs to ensure that all employees comply with existing processes and meet the organization's required standards.
  1. Procedures Planning Programme
* Provide the procedures planning programme including all the guidelines for undertaking a critical process or part of a process to achieve a consistent outcome.
* Ensure the distribution and continuous monitoring of the plans to all employees.
* Prepare the procedures that can be reported and investigated in case of any deviation from the standard procedures.
  1. Premises Planning Programme
* Provide the premises planning prepared to promote cleanliness to prevent cross-contamination, accidents and even deaths.
* Establish the plans for all equipment to be properly located or stored and calibrated regularly to ensure they are fit for purpose to produce consistent results to avoid the risk of equipment failure.

The Consultant is expected to undertake the following tasks for GLP:

GLP regulations set out rules of good practice and should be designed to help researchers carry out their work in accordance with their own pre-established plans and standardized procedures.

GLP texts and plans, regardless of their origin, should be prepared to emphasize the importance of the following five points;

1. Resources: organization, personnel, facilities and equipment

2. Characterization: test items and test systems

3. Rules: study plans (or protocols) and written procedures

4. Results: raw data, final report and archives

5. Quality assurance.

The consultant will perform following SOPs for all GMP and GLP plannıng programmes.

1. Create Standard Operating Procedures (SOPs)
2. Enforce / Implement SOPs and work instructions
3. Document procedures and processes
4. Validate the effectiveness of SOPs
5. Design and use working systems
6. Maintain systems, facilities, and equipment
7. Develop job competence of workers
8. Prevent contamination through cleanliness
9. Prioritize quality and integrate into workflow
10. Conduct GMP audits regularly

# Task 4: Technology Platforms/Assessment and Recommendations

* In consultation with the MoH, review the needs of the entire facility according to the vaccine technology platform to be used and make recommendations on the best technical solutions to meet the identified needs, together with alternative solution proposals including installation cost, production cost, sustainability and applicability criteria,
* In consultation with the MoH, identify relevant technologies available and applicable for the planned local vaccine manufacturing and provide advice on the selection of technologies and vaccines,
* Prepare the technical specifications regarding the technology platforms to be supplied, by taking the needs and technical capabilities into account,
* Collaborate with the MoH to assess the needs of the technology platform and develop technical features that address the identified needs and quality, including the latest technology and price expectations,
* Conduct a market research to identify potential suppliers (leading manufacturers/ distributors) for the needs of full-cycle technology platforms such as inactivation, live attenuated, recombinant, glycoconjugation and VLP (Virus like particuls),
* Support the planning, implementation and reporting of validation and qualification processes to determine and verify the performance of the vaccine production facility,
* Plan the requirements for the vaccines to be produced on each technology platform, including equipment, equipment requirements (gas, temperature, electricity, etc.), consumables to be used, chemicals, etc. according to the production volume, taking into account the order and delivery times and expiration dates for 2 years following the end of the project,
* Ensure that the necessary in-process controls and quality control tests for the vaccines to be produced on each technology platform are carried out within the facility.
* Provide support to the preparation of bidding documents and participate in the assessment of the proposals in terms of technology platforms.

# Task 5: Human Resources Planning

# Define and elaborate an organizational structure for the VPC in consultation with the MoH,

# Define all processes and process integrations related to "administrative, R&D laboratory, experimental animal laboratory, production facilities, as well as facility management such as security, cleaning, gardening, maintenance and repair" in accordance with the defined organizational structure of the Vaccine Production Center.

# Provide a Human Resources Plan for the facility on block by block basis,

# Provide a document that indicates the required number and type of skills for the facility and human development strategies that can be implemented in short and long term considering a fully integrated vaccine manufacturing facility,

# Plan the recruitment on an annual basis in accordance with project phases,

# Create the compensation system of the Vaccine Production Center and determine the optimum salary ranges for each job position.

# Provide recommendations for regulatory and procedural improvements that comply with the international best practices and principles of ethics, merit, equality, justness, transparency, diversity, inclusivity and responsiveness,

# Provide recommendations regarding selection/recruitment, promotion, transfer/ assignment and performance assessment within the framework of the legislation. The assessment will be conducted through a desktop review of legal and procedural frameworks in force, consultations/discussions held with the HR staff and senior decision-makers and overall supervision of work practices,

# Recommend regulatory and procedural amendments and specific capacity-building activities that are expected to support the modernization process as well as the identification of the modern tools that will be taken under consideration,

# Provide guidance to the selected staff regarding their capacity and capability in relevance to the implementation of the new systems/tools in order to improve individual performance management and achieve a merit-based personnel management system,

# Establish the corporate performance management system of the Vaccine Production Center and prepare the performance management system converted from corporate performance to individual performance for each job position in the Center.

# Identify compatibilities and incompatibilities with international best practices,

# Identify the strengths and the areas in need of improvement to be assessed by the MoH,

# The main focal points of the position papers and research will be meritocracy, integrity, efficiency, transparency, accountability, diversity and inclusivity, which are the fundamental principles of reform. Gender considerations and people with disabilities (PWD) are to be particularly considered during the review process,

# Develop tools that will support the improvement of the system.

# Task 6: Training

# Prepare the training plan for the Vaccine Production Center,

# Provide services for the creation and implementation of personnel training programs for the training and authorization of the personnel to be employed at the facility,

# Provide training plans related with the vaccine development and manufacturing process other than equipment trainings,

# Supervise the trainings to be provided by technology transfer partners,

# All the trainings will be certified with acceptable certificates,

# As a result of these trainings provided by the consultant, the relevant personnel should be competent enough to carry out commercial scale productions in the facility, and the training programs should be revised when necessary to ensure that the facility is operational with these personnel.

# Provide support for staff training, process validation, quality management system and for the facility to become operational upon obtaining the necessary regulatory approvals.

# Task 7: World Health Organization (WHO) Certification

# The WHO Production guidelines cover all the operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labeling and relabeling, to the completion of the finished product.

# Good manufacturing practices (GMP) are part of a quality management system to ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

# Good Laboratory Practices (GLPs) are quality management programs ensuring that testing in a preclinical or product development context is performed using reliable methods and excellent record-keeping, which enables companies to provide accurate and auditable data to regulatory institutions.

# Provide technical assistance to the MoH, including performing all the necessary tasks to be performed by the Contractor from start to finish until VPC (Vaccine Production Center) produces at least one vaccine which (i) receives authorization from Türkiye’s National Regulatory Authority, the Turkish Medicines and Medical Device Agency, and (ii) is subsequently submitted to WHO for Pre-Qualification,

# Ensure that the necessary approvals are obtained for the required licensing processes, quality control standards and safety protocols as compliance with relevant regulations and local legal requirements crucial for the establishment of a vaccine manufacturing facility,

# Prepare the roadmap and guideline for the entire WHO certification process for the project.

# Task 8: Other Tasks

# Provide guidance to the MoH Project Team from the commencement of the project through programming, design and bidding documents and provide realistic estimations on potential costs,

# Undertake the overall project planning,

# Work in coordination with the Ministry of Health Vaccine Production Project Management Office.

# Analyze the existing vaccine production facility/facilities to determine space needs at the current service level and to come up with a conclusion that includes an estimation of future space needs to maintain the right balance of space in a constantly evolving environment. This will include an assessment of the existing site, programming and conceptual budgeting for project and civil costs.

# Looking for ways to incorporate renewable energy sources and ensuring regulatory compliance.

# Analyze data from energy audits and assessments and develop recommendations for saving energy and reducing electricity, gas or water usage.

# Recommend solutions for cutting energy bills, reduce pollution and greenhouse gas emissions and using less energy to perfom the same task, that is, eliminating energy waste.

# Maintain records and data, promote programs that encourage efficiency and renewable energy, initiate changes to improve current use, and assist with the planning of the VPC Project.

# Minutes of all meetings will be prepared in English and Turkish and will be submitted to the MoH within one week after the meeting.

# The Consultant must describe in its technical proposal the system of quality assurance and how they will support experts on site with all required logistical support. Quality control of reports in terms of content, standardized layout and quality of language is a key aspect of quality assurance. In addition, the Consultant must describe the technical and managerial capability of the company (provide the structure of the organization, general qualification and number of permanent staff).

# Work Plan

# The Consultant shall prepare a detailed work plan for undertaking the assignment. The detailed work plan/implementation program for this assignment shall be submitted as follows:

# 7 (seven) months for the preparation of facility design and bidding documents preparation for the Design, Supply and Installation bidding, (Phase 1)

# 6 (six) months for the implementation of Design Supply and Installation (DSI) biddings,

# 8 (Eight) months for the bidding process and construction works for the shell and core construction of the manufacturing blocks,

# 24 (twenty-four) months for the supervision, contract management and monitoring services for the Design, Supply and Installation (DSI) contracts (equipment procurement, installation, small construction works, human resources plan implementation, technology transfer etc.), (Phase 2)

# 12 (twelve) months for Defects Liability Period (DLP) for the small construction works under DSI contracts.

# The shell and core construction of the vaccine production center facility is planned to be completed by the end of 2025. The implementation of the DSI biddings and implementation of the DSI contracts will be carried out simultaneously with the other activities related to technology transfer and HR.

# The overal project period including the Defects Liability Period will be 49 (forty-nine) months. The Consultant is expected to commence the services immediately after signing the contract.

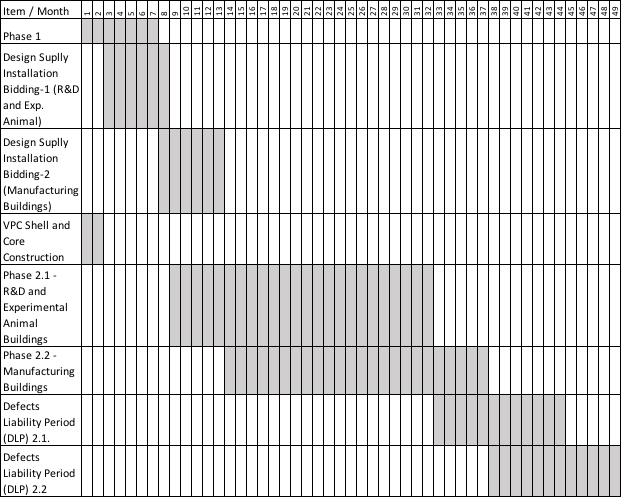
# The time allocated for Phase 1 is 7 months. At least 4 months duration for the design and 2 months duration for the completion of the bidding documents is required. The bidding documents will be cleared by the World Bank and approved by the MoH before the national and international publication of the procurement notices for DSI biddings. One month duration is added for the necessary approval stages before publication of the procurement notices.

# MoH plans to carry out two seperate DSI biddings. One is planned for R&D and Experimental Animals Production/Test Buildings and one is planned for the Vaccine Manufacturing Buildings.

# The procurement notices will be published at least 6 weeks until the bid submission deadline to enable prospective bidders for the successful preparation of their bids. Considering that the Design, Supply and Installation biddings are international biddings with use of "rated criteria, single stage, two envelope” after the bid submission and opening, the bid evaluation process including the preparation of the bid evaluation reports, World Bank’s no-objection and MoH approvals are expected to be completed in 3,5 months.

# An additional one-month duration is added for the necessary approval stages before the contract award and signing. Finally, the minimum duration required between the completion of Phase 1 (Design completion, bidding documents preparation) and commencement of Phase 2 (Supervision and Contract Management) is 6 months.

Tentative Timeline



# Under normal conditions, the scheduled bidding and construction period is 8 (eight) months for shell and core construction of VPC manufacturing building. The Consultant will not be responsible for the supervision of contruction works during the contruction period. The scheduled contract period for Design, Supply & Installation for R&D and Experimental Animals Production/Test Buildings (Phase 2.1) and Design, Supply & Installation for Vaccine Manufacturing Buildings (Phase 2.2) is 24 (twenty-four) months and the defects liability period for small construction works under these contracts is 12 (twelve) months.

# Cost Estimates

# A detailed cost estimate and summary of the project shall be submitted showing total cost for establishment of Vaccine Production Center (construction, equipment and technology transfer). In order to establish a fair and reasonable estimate of the project cost, the Consultant shall ensure a prepared unit price is analyzed for each item using basic elements (labour, materials, equipment, tools, overheads, on-site costs, profit, etc.), and the cost of all taxes (direct or indirect, duties, levies and fees) to be indicated separately. The cost estimates shall also include the cost for implementation of Environmental and Social Management Plan (ESMP). The Consultant will be required to advise on cost effective and fit for purpose design in relation to MoH budget.

# The Consultant should plan to meet the requirements of national and international regulations on waste management and environmental impacts. During the establishment of the Vaccine Production Center, the Consultant should provide advice on energy efficiency, waste management and environmental impact mitigation to ensure the long-term sustainability of the facility.

**4. SUBMISSION REQUIREMENTS FOR OUTPUTS**

Outputs for each task will be submitted to and approved by the MoH. The Consultant must obtain approval for each output before moving on to subsequent tasks. The table below summarizes the outputs and includes an indicative timeline.

|  |  |  |
| --- | --- | --- |
| **Task** | **Expected Reports and Deliverables** | **Due Date for Submission**  (calendar months after effectiveness of the contract) |
| 1 | Inception Report | 0,5 months |
| 2 | Documentation Review Report | 1,5 months |
| 3 | Pilot GMP/GLP Guidelines and Planning Programme Report | 4 months |
| 4 | Technology Platform/Assessment Report | 3 months |
| 5 | Tender Documentation Report - 1  (Review, recommendations and clearance for technical specifications prepared by MoH for Design, Supply and Installation bidding for R&D and Experimental Animal Laboratories ) | 1 months |
| 6 | Tender Documentation Report - 2  (Submission of technical specifications for Design, Supply and Installation bidding and Conceptual and Basic Design for the Vaccine Manufacturing Buildings) | 4 months |
| 7 | Human Resources Management Plan | 3 months |
| 8 | WHO Certification Report | 4 months |
| 9 | Training Plan | 4 months |
| 10 | Phase 1 Completion Report | 6 months |

**Reports to be requested from the Consultant:**

* Inception Report

The Consultant shall submit an inception report within two weeks after the signing of the contract for the assignment. The Consultant shall present to MOH consolidated work plan outlining methodologies, staff schedule and the project plan to ensure the quality of the services.

The inception report should address the following;

* Methodology and details of any additional points to be considered in the project required.
* The detailed work program indicating time, duration and personnel as well as the inter-relationships between activities,
* Proposed methodology for tracking compliance with applicable technical specifications environmental laws and regulations, and site-specific Environmental and Social Management Plan (ESMP).
* Reports for Good Manufacturing Practice (GMP)
* Reports for Good Laboratory Practices (GLP)
* Project Progress Reports: Regular reports showing the current status of the project, its overall progress, how much of the identified milestones have been completed and future milestones.

Principles of Reporting

All documents and outputs must be prepared in both English and Turkish.

* Report Format : A4 or A3, preferably A3 size when appropriate including scaled down drawings.
* Drawing Format : A1 size (unless otherwise required or agreed upon)
* Drawing Scale : Must be agreed upon with MoH.

The Consultant will upload all outputs to the online platform addressed by the MoH and provide an electronic copy (an external hard disk) of all the above-mentioned outputs in addition to 3 printed copies. Metric weighing and measuring system will be used. Drawings will be submitted as per the format, labeling, batching and detailing as requested by the MoH.

**5. FACILITIES PROVIDED BY THE CONSULTANT**

The Consultant is responsible for putting together a supervision and design group that has experience in the preparation of architectural, structural, electrical and mechanical designs for infrastructure works. This group will be a fully functional team consisting of project management, architecture, mechanical and technical device consultants. This team will also cover electrical engineering, cost estimation and cost-benefit analysis to provide support for the improvement of the bidding documents. Therefore, the Consultants will individually identify the staff to be assigned to the preparation of the designs and documents, specifying the positions intended to be appointed for each staff member.

The Consultant must ensure that their professional staff have access to adequate support and equipment. All costs for equipment, administrative and logistical support including but not limited to the below required for the providing the services shall be covered by the Consultant and included in the financial proposal.

* All costs arising from the activities of its personnel during the contract period, including accommodation, per diem allowance, transportation, insurance, etc. .
* Equipment, office supplies and hardware and software to ensure monitoring is fully functional.
* All communication costs, including fax, e-mail, phone, etc.
* All costs incurred for the vehicles, services and logistical support, and incurred during preparation, copying, printing, etc. of documents and drafts which are required for the implementation of the contract.
* Excellent command of written and spoken English and Turkish is required. If the Consultant requires translation and interpretation services, the Consultant shall make the necessary arrangements and will be responsible for the accuracy of the translation.
* Documents related to the project (contracts, specifications, reports, etc.) will be translated when requested by the MoH.
* The Consultant is obliged to obtain all necessary permits, approvals, to pay all fees and contributions and to arrange all other things necessary for the work of its professional staff assigned at its own expense for the performance of this Contract.

**6. TIME TABLE**

This assignment is expected to begin in the last quarter of 2025 and will be completed within a period of 7+6 months. The Consultant will provide support during the Design, Supply and Installlation bidding stage envisaged as 6 months.

**7. SUPPORT TO BE PROVIDED BY MoH TO THE CONSULTANTS**

MoH provides current inputs, project data, reports, etc. regarding the Vaccine Production Project.

- VPC Project Situation and Needs Assessment Final Report

- The existing designs (architectural, structural, civil, mechanical, plumbing and electrical, etc.)

- Product portfolio details.

- Process technology selection.

**8. TEAM COMPOSITION AND QUALIFICATION REQUIREMENTS FOR THE KEY STAFF**

The Consultant will establish a team with proven technical and managerial competence and experience.

Alternative professional staff will not be proposed. Only one curriculum vitae (CV) will be submitted for each position. All experts who have a crucial role in implementing the contract are referred to as key experts.

**8.1. Consultant's Profile:**

The staff to be provided by the Consultant shall be sufficient to perform the services under this contract. The timing and inputs of each professional staff member shall be in accordance with the agreed program for the delivery of services and appropriate to the project. The Consultant shall employ only such key staff whose curriculum vitae or certificates or professional registration have been reviewed and approved by authorizing bodies and thereafter MOH. Staff employed must be relevant to the project with intended actual participation in the project. There should be a clear breakdown of all staff members that intend to be involved in the projects in terms of man month realistically to the actual individual executing a particular task.

The Consultant must be capable of providing fully competent expertise in the following disciplines on as need basis as listed in 8.2. In preparing proposals, the Consultant must provide Curriculum Vitae for all positions indicated in 8.2., the experts and their qualifications for Phase 1.

**8.2. Team Composition and Qualification Requirements for the Key Staff**

The working language of the project is English. All the team members assigned by the Consultant must possess proficiency in English language. Day-to-day communication language will be Turkish and English at the field level to ensure smooth communication among all participants, direct or indirect, of the Project.

All key and support staff will be mobilized immediately after the contract signature.

The Consultant's team will include at least the following qualified engineers and other professionals competent to perform the duties described in this Terms of Reference.

In addition, support staff for the administrative services will be proposed as required (experts, clerks, drivers, secretary etc.).

* K-1 / Team Leader (TL)
* K-2 / Project Manager (PM)
* K-3 / Design Architect
* K-4 / Mechanical Engineer
* K-5/ Electrical and Electronics Engineer
* K-6 / Environmental Expert
* K-7 / Social Expert
* K-8 / Cost and Planning Expert
* K-9 / Regulatory Expert
* K-10 / Biosafety Expert
* K-11 / GMP and GLP Expert
* K-12 / Medical Device Specialist (MDS)
* K- 13 / Animal Experiment Specialist
* K-14 / Quality Assurance Specialist
* K-15 / Licensing Specialist
* K-16 / Laboratory Expert
* K-17 / Human Resource Expert
* K-18 / Training Specialist
* K-19 / Energy Efficiency Expert
* K-20 / Process Engineer (Black & Clean Utilities Specialist)
* K-21 / Vaccine Production & Quality Expert
* K-22 / Vaccine Quality Control Specialist
* K-23 / Sterility Assurance Specialist

The Consultant will provide adequate personnel in terms of expertise and time allocation, as well as the necessary equipment to complete the activities required within the scope of work and ultimately achieve the project's objectives in terms of time, cost and quality.

The Project Manager and experts will collaborate with other consultants and attend meetings when requested by the MoH.

The Consultant’s team must at least have following experience and qualifications requirements:

**Team Leader (TL) (1)**

The Team Leader is responsible for the overall contract coordination and quality control of contract implementation. TL will ensure that the engagement of experts is agreed with the MoH and that they are engaged on time to deliver the project outputs. The expected role of the Team Leader is to guide the project from a strategy and policy perspective. This role will last until the plant is operational and GMP approval is obtained.

* Bachelor's degree in Pharmaceutical Sciences, Microbiology, Biotechnology, pharmaceutical engineering, or any other discipline relevant with the project.
* Master's degree in business management or project management.
* Proven expertise and experience in vaccine manufacturing strategy, vaccine portfolio planning, project planning and review of vaccine manufacturing project, design and review of architectural and engineering services for exterior and interior design for a vaccine manufacturing facility/project.
* Minimum 15 years of experience in consultancy services in complex projects in the sector for International Financial Institutions (IFI) funding, preferably the World Bank.
* Minimum 5 years of work experience in consultancy services for vaccine production.
* Minimum 2 completed projects in the field of health sector.
* Previous work experience in a relevant field in a public or private sector company in Türkiye is an asset.
* Knowledge of English language.

**Project Manager (PM) (1)**

The Project Manager is responsible for overall contract coordination and quality control of contract implementation, management of timelines, budget oversight and communication. The Project Manager coordinates all team members, will ensure that the assignment of Experts is agreed with the MoH and project deliverables are delivered on time.

The Project Manager is expected to provide operational management and coordination with all stakeholders. This will last until the plant is operational and GMP approval is obtained.

* Bachelor's degree in Pharmaceutical Sciences, Microbiology, Biotechnology, pharmaceutical engineering or any other discipline relevant with the project.
* Master's degree in business management or project management.
* Minimum 10 years of professional experience in biological/biotechnological active substance production and sterile finished product, pharmaceutical production facilities.
* Minimum 12 years of experience in consultancy services in complex projects in the sector for International Financial Institutions (IFI) funding, preferably the World Bank.
* Minimum 2 completed projects in the field of health sector.
* Good knowledge of design and technical documentation requirements of the projects tendered under the tendering procedures and rules of IFIs, preferably the World Bank.
* Have a good knowledge of the requirements of Turkish legislation regarding design, construction, engineering, environmental and social issues is an asset.
* Knowledge of English language.

**Design Architect (1)**

The Design Architect is expected to develop conceptual and basic architectural designs and layouts for the Vaccine Production Center.

* University degree in architecture.
* Master's degree in a relevant field will be an asset.
* Experience in developing architectural designs and layout plans for the vaccine facility.
* Minimum 10 years of professional experience
* Minimum 5 years of experience in similar works.
* Experience in the design processes of any pharmaceutical production facility from the very beginning.

**Mechanical Engineer (1)**

The Mechanical Engineer is expected to review the mechanical aspects.

* University degree in mechanical engineering.
* Experience in ventilation systems (HVAC) design, installation, qualification and maintenance processes.
* Master's degree in a relevant field will be an asset.
* Experience in supervising mechanical aspects, including conceptual and basic designs
* Minimum 10 years of professional experience
* Minimum 5 years of experience in similar works.

**Electrical & Electronics Engineer (1)**

The Electrical Engineer is expected to review the electrical and electronics aspects.

* University degree in electrical & electronics engineering
* Master's degree in a relevant field will be an asset.
* Experience in building management systems (BMS) design, installation, qualification and maintenance processes.
* Experience in supervising electrical/electronic aspects, including conceptual and basic designs
* Minimum 7 years of professional experience
* Minimum 5 years of experience in similar works.

**Environmental Specialist (1)**

The Environmental Specialist is expected to recommend and oversee environmental norms and compliances for the facility.

* University degree in environmental engineering.
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of professional experience.
* Experience in recommendation and supervision of environmental norms and compliance.
* Minimum 3 years of experience in similar works, especially working knowledge of the World Bank Environmental Framework.

**Social Specialist (1)**

The Social Specialist is expected to recommend and oversee social norms and compliances for the facility.

* University degree in Social Sciences.
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of professional experience.
* Experience in recommendation and supervision of social norms and compliance.
* Minimum 3 years of experience in similar works, especially working knowledge of the World Bank Social Framework.

**Cost and Planning Engineer (1)**

The Cost and Planning Engineer is expected to prepare the cost details and financial plans for the project. This task will last until the end of the first phase of the project.

* Bachelor's degree in commerce, economics, statistics, civil engineering
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 2 years of experience in similar works, especially in the development of comprehensive scope of works, bill of quantities, timelines and budgets.

**Regulatory Expert (1)**

The expert shall be responsible for understanding and implementing relevant regulations and legal requirements. The Regulatory Expert manages the facility's licensing processes and ensures compliance with legal requirements. Regulatory Expert is expected to audit and recommend GMP and GLP aspects for the facility. This task will last until GMP & GLP approval is obtained for the facility and laboratory respectively.

* Master's degree in pharmaceutical sciences, pharmaceutical engineering, regulatory affairs, biotechnology, microbiology, biochemistry and virology sciences, or any other discipline relevant with the project.
* Proven track record of successfully consulting on similar projects involving construction of vaccine production center or similar facilities.
* In-depth knowledge and understanding of vaccine manufacturing processes, regulatory compliance requirements specific to vaccine manufacturing plants, clean room designs, HVAC systems, process flow optimization, equipment layout and utilities required for vaccine production.
* Familiar with Good Manufacturing Practices (GMP), regulatory guidelines and quality control standards specific to vaccine production facilities.
* Expertise in facility design and layout for vaccine manufacturing plants.
* Well-versed in regulations set forth by regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other relevant authorities.
* Proven track record in the country is an asset.

**Biosafety Specialist (1)**

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences, pharmaceutical engineering
* Registered Biosafety Specialist (to an internationally recognized biosafety association)
* Certified Workplace Safety Specialist
* Minimum 5 years of experience as a biosafety consultant
* Minimum 10 years of experience at least in 3 labs as an ABSL-3/BSL-3/BSL-2 biosafety expert
* Experience in review and approval of ABSL-3 / BSL-3 / BSL-2 facility designs
* Experience in supervising constructions of ABSL-3 / BSL-3 / BSL-2 facilities
* Experience in commissioning biosafety facilities
* Field training experience in biosafety and animal biosafety

**GMP (Good Manufacturing Practices) / GLP (Good Laboratory Practices) Expert (1)**

* Bachelor's or Master's degree in medicine, veterinary medicine, pharmacy, biology or chemistry
* Certified training on GLP, GMP issues
* Experience in conducting facility inspections and providing training in terms of GLP and GMP
* Having at least 5 years of experience as a GLP and GMP consultant
* Experience in clean room facility design review and approval.
* Experience in supervising the construction of clean room facilities.

**Medical Device Specialist (1)**

* Bachelor's or Master's Degree in Pharmaceutical Sciences, Microbiology, Biotechnology Biomedical or pharmaceutical engineering with at least 10 years of experience in this field
* Minimum 10 years of experience in preparation of technical specifications and installation of laboratory devices
* Experience in conducting FAT and SAT, supervision of equipment installation, verification and commissioning.
* Minimum 5 years of experience in similar works.

**Animal Experiment Specialist (1)**

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences or Veterinary Sciences.
* Master's degree in a relevant field will be an asset.
* Relevant experience in animal experiments on vaccines
* Minimum 8 years of professional experience
* Minimum 3 years of experience in similar works, especially working knowledge of WHO (World Health Organization) certification and GLP.

**Quality Assurance Specialist (1)**

A person who ensures the implementation of GMP/GLP standards and oversees quality control processes. The quality assurance specialist conducts audits to ensure the compliance of the facility and takes corrective measures when necessary. This task will last until the end of the project.

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences or Pharmaceutical Engineering or other relevant discipline related to the project
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of experience in pharmaceutical industry quality management systems and quality risk management processes.
* Experience in recommendation and supervision of quality assurance elements for the facilities

**Licensing Specialist (1)**

The expected task of the Licensing Specialist is to supervise and recommend licensing activities for the facility. This task will last until the end of the project.

* Bachelor's or Master's Degree in Business Administration, Law, or Pharmaceutical Sciences.
* Master's degree in a relevant field will be an asset.
* Experience in recommendation and supervision of licensing activities.
* Minimum 5 years of professional experience.
* Minimum 3 years of experience in similar works.

**Laboratory Expert (1)**

Experts responsible for conducting laboratory tests and analyzing the results in projects following GLP processes.

* Bachelor's or master's degree in veterinary, genetics, bioengineering, pharmaceuticals, biology, chemistry engineering or molecular biology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience in laboratories.
* Minimum 6 years of experience in similar works.

**Human Resources Expert (1)**

* Bachelor's or master's degree in business, phychology or sociology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 6 years of experience in similar works.

**Training Specialist (1)**

The person responsible for training and authorization of staff. The specialist ensures that employees are trained and informed in accordance with GMP/GLP standards.

* Bachelor's or master's degree in the fields of veterinary, genetics, bioengineering, pharmaceuticals, biology, chemistry engineering or molecular biology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 6 years of experience in similar works.

**Energy Efficiency Expert (1)**

* Master’s degree in science, engineering, economics, business administration or equivalent areas,
* Minimum 10 years of relevant experience in the energy sector.
* Proven experience in at least two of the following areas: energy efficiency, energy sector economics, energy sector policy and regulation, energy and climate policy, renewable energy, transmission and distribution infrastructure, utility financial analysis and/or utility reform, power pools and regional integration.

**Process Engineer (Black & Clean Utilities Specialist) (1)**

The Process Engineer will be responsible for designing, optimizing, and validating production processes in a vaccine manufacturing facility, with a strong focus on Black and Clean Utilities. This role includes overseeing HVAC, sterilization, process validation, and ensuring compliance with GMP, WHO, EMA, FDA, and TİTCK standards. The specialist will play a key role in maintaining cleanroom integrity, contamination control, and process efficiency in vaccine production.

* Bachelor’s degree in Mechanical Engineering, Chemical Engineering, Industrial Engineering, or a related field.
* Master’s degree in Process Engineering, Bioprocess Engineering, Pharmaceutical Engineering, or a relevant discipline is preferred.
* Minimum 10 years of professional experience in pharmaceutical, vaccine, or biopharmaceutical production processes.
* Minimum 5 years of experience in Black and Clean Utilities, HVAC, and cleanroom design and operation.
* Strong knowledge of HVAC, cleanroom validation, and airflow dynamics.
* Experience with sterilization processes (autoclave, VHP, dry heat, gamma irradiation).
* Understanding of GMP-compliant facility design and process engineering principles.
* Proficiency in process modeling, equipment validation, and energy efficiency in pharmaceutical manufacturing.

**Vaccine Production & Quality Expert (1)**

The Vaccine Production & Quality Expert is responsible for technical oversight of vaccine development, production, and quality control. This role involves ensuring compliance with biosafety standards, sterility assurance, and GMP-compliant manufacturing techniques. The expert will oversee vaccine formulation, purification, filling, and stability studies while ensuring adherence to WHO, EMA, FDA, and TİTCK quality standards.

* Bachelor’s degree in Pharmacy, Bioengineering, Biomedical Engineering, Chemical Engineering, Molecular Biology and Genetics, Microbiology, Biochemistry, or a related discipline.
* Master’s degree in Pharmaceutical Technology, Biotechnology, Bioprocess Engineering, Microbiology, Biochemistry, Virology, or a related discipline (preferred).
* Extensive experience in vaccine production, including upstream and downstream processing, formulation, adjuvants, and filling processes.
* Knowledge of bioprocess engineering, cell culture, fermentation, and purification techniques used in vaccine production.
* Expertise in GMP-compliant aseptic techniques, sterilization methods (autoclave, dry heat, gamma irradiation, vaporized hydrogen peroxide - VHP).
* Experience in sterility assurance, contamination control, and biosafety standards for vaccine manufacturing.
* Proficiency in analytical method validation for vaccines, including HPLC, ELISA, PCR, and potency assays.
* Knowledge of cleanroom classification (ISO 14644) and environmental monitoring in vaccine production facilities.
* Experience in vaccine R&D and technology transfer projects.

Vaccine Quality Control Specialist (1)

The Vaccine Quality Control Specialist is responsible for ensuring the quality, safety, and efficacy of vaccines through rigorous quality control (QC) testing and compliance with international regulatory standards. This role involves conducting microbiological and analytical testing, method validation, stability studies, and contamination controlwhile ensuring adherence to WHO, TİTCK, EMA, and FDA guidelines. The specialist will work closely with sterility assurance, quality assurance, and production teams to maintain the highest quality standards in vaccine manufacturing. The expert will also focus on antigen production, formulation, purification, and stability studies to ensure high-quality vaccine development.

* Bachelor’s or Master’s degree in Microbiology, Biochemistry, Biotechnology, Pharmacy, Chemistry, Chemical Engineering, or Molecular Biology.
* Certified training in GMP, GLP, and WHO prequalification processes (preferred).
* Minimum 10 years of experience in vaccine or biopharmaceutical quality control.
* Minimum 5 years of hands-on experience in QC laboratory testing, including microbiological and analytical methods.
* Expertise in sterility, endotoxin, mycoplasma, and potency assays.
* Experience in HPLC, ELISA, PCR, and other advanced analytical techniques.
* Knowledge of environmental monitoring, contamination control, and stability testing.
* Familiarity with WHO PQS (Prequalification of Vaccines), TİTCK, and international vaccine quality standardsaccording to WHO guidelines.
* Proficiency in QC method validation and analytical method transfer.
* Experience in data integrity, deviation management, and CAPA (Corrective and Preventive Actions).
* Knowledge of cleanroom classification, biosafety, and quality risk management.
* **Antigen production** processes, including **recombinant protein production, viral vector production, inactivated or live attenuated vaccine manufacturing.**
* **Upstream and downstream processes,** such as **bioreactor operation, cell culture techniques, filtration, and purification.**
* **Antigen stabilization and formulation** to ensure vaccine efficacy and longevity.

Sterility Assurance Specialist (1)

The Sterility Assurance Specialist is responsible for ensuring the sterility of vaccines and pharmaceutical products through cleanroom management, aseptic processing, and contamination control. This role involves implementing sterility testing, sterilization validation, risk assessments, and environmental monitoring in compliance with WHO, TİTCK, EMA, and FDA guidelines. The specialist will work closely with quality control and production teams to maintain sterility assurance at all manufacturing stages.

* Bachelor’s or Master’s degree in Microbiology, Biochemistry, Biotechnology, Pharmacy, Chemistry, or Chemical Engineering.
* Certified training in GMP, GLP, and WHO prequalification processes (preferred).
* Minimum 10 years of experience in pharmaceutical or vaccine production with a focus on sterility assurance.
* Minimum 5 years of hands-on experience in aseptic processing, cleanroom management, and contamination control.
* Expertise in environmental monitoring, bioburden testing, endotoxin testing, and sterility testing.
* Familiarity with WHO, TİTCK, EMA, and FDA sterility assurance guidelines.
* Experience in cleanroom classification (ISO 14644), airflow visualization studies, and HEPA filtration validation.
* Knowledge of aseptic techniques and sterilization methods (autoclave, dry heat, gamma irradiation, vaporized hydrogen peroxide - VHP).
* Proficiency in media fill validation, disinfectant qualification, and risk-based sterility assurance strategies.
* Experience in CAPA (Corrective and Preventive Actions), deviation management, and root cause analysis.

\* Experience in Similar Works includes the following:

- Develop detailed designs and technical specifications, consulting services for the construction of healthcare projects such as hospitals, vaccine production facilities etc. for the key staff within the scope of all duties.

- Understand the requirements for establishing a vaccine production facility, including but not limited to the following:

* 1. Platform technology and production process
  2. Biosafety levels and containment
  3. Up-to-date GMP and GLP requirements
  4. WHO Pre-Qualification Process

Please note that similar works requirement is not applicable for Training Specialist and Human Rresorces Expert.

**Technical Support Staff:**

Support staff for technical services with minimum three (3) years of professional experience shall be proposed additionally as required (architects, surveyors, mechanical and electrical technicians/junior engineers, OHS personnel, etc.)

**Administrative Support Staff:**

Support staff for the administrative services shall be proposed additionally as required (clerks, drivers, secretary, etc.)

**TERMS OF REFERENCE (TOR)**

**FOR TIME-BASED CONTRACTS:**

**CONSULTANCY SERVICES FOR**

**VACCINE PRODUCTION CENTER PROJECT IN ANKARA**

**9. SCOPE OF SERVICES, TASKS AND EXPECTED OUTCOMES FOR TIME-BASED CONTRACT:**

**9.1. Scope of Services:**

The Consultant will be required to carry out supervision and commissioning services for all design, supply and installation related activities under scope of the Design, Supply and Installation (DSI) contract and supervise corrective works to eliminate defects arising during the Defects Liability Period for small contruction works under DSI contract if the MoH requires the Consultant's review and advice.

**9.2. Description of the Consultant’s Tasks**

The Consultant shall be responsible as the Project Manager to provide details and instruct the Design, Supply and Installation (DSI) Contractor whenever it necessitates during the course of the works and execute the services in accordance with recent laws and regulations (including the ESMPS). Significant issues shall be subject to approval of the MoH as indicated in the General Conditions (GCC) or Special Conditions (SCC) of the DSI Contract.

The Consultant’s Key Experts shall check and review the existing designs for their applicability to the site/project. If any revision is needed in existing designs, a report will be provided to the MoH. If the revision needs to be approved, the approval will be obtained by the Consultant. All costs of the approval belong to the Consultant.

The Consultant shall provide sufficient, qualified and experienced staff to ensure propoer supervision of the works and engineering services both during the contract period and during the Defects Liability/Maintenance Period.

**General Tasks:**

* + Carry out project management; project planning, budget management, creating timelines and resource allocation services within the scope of the project.
  + Advise the MoH on project implementation.
  + Supervise and monitor the project at all stages and in accordance with pre-agreed milestones.
  + Ensure that the works are carried out by the Contractor in a professionally acceptable manner and in accordance with the requirements of the relevant regulatory authorities.
  + Approve Contractor's proposed designs/drawings for temporary works.
  + Examine and approve various plans and programs submitted by the Contractor.
  + Control the Contractor's and sub-contractors' site personnel at all grades for suitability.
  + Check and approve the site installations, equipment plants that are to be used by the Contractor to execute the works and safety.
  + Check the suitability of sub-contractors as they arrive on site.
  + Check materials and equipment for conformity with the contract specifications by physical inspection and by gathering the manufacturers and suppliers' certificates of conformance.
  + Verify the Contractor's purchasing schedules so that materials and equipment necessary for the swift advancement of the works are available when needed, thus ensuring the work keeps to the establishment programme.
  + Provide continuous liaison with the MoH on all possible changes on the designated scope and budget of works.
  + Record all claims and submit recommendations to the MoH.
  + Measure authorized changes and agreed quantities and cost with the Contractor.
  + Estimate the cost effect of proposed changes before issue instructions. These changes must be communicated to the MoH for approval and a change order must be issued.
  + Advise the parties under the Contract on any dispute arising under the Contract to ensure that disputes are resolved amicably as soon as possible without affecting the project.
  + Ensure that the Contractor strictly adheres to the contract, specifications and bills of quantities in the execution of the works and advise the MoH on the appropriate actions to be taken whenever there is a breach of contract or misconduct by the Contractor.
  + Prepare monthly/periodic project reports as per formats approved by the MoH.
  + Detailed quarterly reports to be submitted within 14 days of the end of each quarter. Quarterly reports should include description of project activities illustrated by progress/completion photographs, status of any delays and contractual claims and details of all latest financial projections, an electronic copy and 4 copies to be submitted to the Project Coordinator.
  + Arrange for site meetings attended by all concerned parties and/or any other management meeting as may be deemed necessary. A summary/ draft of minutes in bullet form or description an action format must be presented in two (2) days' time after the meeting. Final minutes in approved format should be circulated within five (5) days.
  + A Quality Assurance Manual, detailing all QA/QC procedures, to be submitted within ten (10) days of commencement of services, 4 copies to be submitted to the Project Coordinator.
  + Review and approve as-built drawings, operation & maintenance manuals where applicable and submit documents in hard and electronic copies to the MoH.
  + Monitoring the completed works after completion up to defects liability period. Issuance of certificate of making good defects, final completion and final payment certificate.
  + Prepare variation orders whenever required and submit them to the MoH for approval before giving relevant instructions to the Contractor.
  + Facilitate the project handing over upon successful completion of the project.
  + Prepare and submit to the MoH the final payment certificate for the completed works.
  + Prepare a final report. The report in addition to all aspects of the project should include lesson learned as a reference to future project execution and management.
  + Approve return of performance security to the Contractor after final acceptance.
  + Perform regular inspection of the works during Defects Liability Period.
  + On completion of the contract, ensure the MoH acquires certificate of occupancy from relevant authority.
  + Perform all duties that may be required to be performed pursuant to any Contract signed between the MoH and the Contractor where the Consultant is designated as the "Project Manager" in the Contract in question.
  + Provide consultancy services to conduct the medical equipment, machinery and furnishing with qualified personnel approved by the MoH.
  + Include the reliability, quality, performance, maintenance requirements, calibration, and validation of the equipment supplied by the Contractor in the quality assurance program and provide supervision and control through the SOP preparation processes.
  + Supervise and foresee all aspects of the delivery, installation and commissioning of various components of medical equipment, machinery, furnishing and systems to ensure strict compliance with the drawings and contract documents, subject to any express or implied terms contained in the Contract signed between the MoH and the Contractor.
  + Determine the criteria, planning and procedure for all necessary tests and inspections of materials, equipment, furnishing, facilities and workmanship, as well as their commissioning, and will provide supervision and control for these tests and compile records of all these tests and compare the results with the specifications, standards or performance criteria guaranteed by the suppliers or the Contractor.
  + Hold weekly and monthly meetings with the Contractor, inform the MoH about the progress of the activities, attend meetings reasonably arranged by the MoH and will provide any information or evidence reasonably requested by the MoH at any public meeting or investigation that may be held in connection with the Project.
  + Interpret the drawings and specifications and to liaise with the Contractor as necessary to ensure compliance with the Contract and work schedule.
  + Check the Contractor's valuations for progress payment and prepare the necessary documents in accordance with the Conditions of Contract used and will also be responsible for agreeing with the MoH on the payable amount on each payment document. Procedure and presentation of the documents, supporting documents etc. will be discussed and agreed with the MoH.
  + Review and report any payment request submitted by the Contractor within 2 weeks from receipt of such request. The report on any request will include (but not limited to) the findings, justifications, cost-benefit analysis, any potential impacts on the approved work plan and final decision on any variations.
  + Review existing designs, plans, technical specifications, quantities, etc. for quality and prepare any additional documents and detailed designs (if necessary) that will minimize change orders during the installation phase. However, if it is deemed necessary by the Consultant or the MoH to make changes to any of the Contract Documents, Plans or Specifications (for reasons not attributable to the contractors), the Consultant will prepare these changes in a timely manner, supporting these with the necessary calculations, details and time and cost implications and will submit these to the MoH for approval. The consultant will indicate whether the changes will cause any delay in the work schedule and therefore whether the Contractor will be entitled to any extension of time, supporting it with the necessary documentation. Upon receipt of MoH written approval, the Consultant will promptly modify existing designs or procure additional designs, plans, drawings and specifications as required or deemed necessary for satisfactory completion of the contracts. In addition, the Consultant will review and approve the Contractor's and manufacturers' drawings and, where appropriate, incorporate these drawings into the overall design and review any changes that may be requested by the Contractor during the works. The Consultant will fully inform the MoH about the cost and time impact and other consequences of any suggestions (revisions, recommendations, etc.). MoH will not be responsible for the consequences of situations for which no prior information is provided.
  + Examine, evaluate and respond all correspondence from the Contractor within one week at the latest. Any requests from the Contractor within the scope of the project will be evaluated and the necessary recommendations will be forwarded to the MoH within two weeks at the latest.
  + Due to continuity of services or other reasons, some works may be carried out by the Contractor at night-time hours instead of day-time hours. In this case, the Consultant, MoH and Contractor will arrange the employment of their own experts accordingly, without incurring any additional costs.
  + Support the project meetings to be managed by the MoH, both virtual and physical meetings held with the participation of the MoH representative(s). For the meetings, presentation material containing the relevant content of each sub-project for the meetings will be prepared by the Consultant and forwarded to the relevant stakeholders. The content of each presentation for each sub-project is subject to MoH review and approval.
  + Help resolve any disputes or differences that may arise between the MoH and the Contractors in a timely manner. In case of litigation and arbitration, assist in the preparation of documents required by the MoH.
  + Since shell and core construction works will be inspected by the General Directorate of Health Investments, the Consultant will cooperate and attend meetings when requested by the MoH.
  + Have a local office in Ankara for administrative communication matters (writing letters, printing or drawing the project document, etc.).
  + Supervise solutions for cutting energy bills, reduce pollution and greenhouse gas emissions and using less energy to perfom the same task, that is, eliminating energy waste.
  + Supervise records and data collection, promotion programs that encourage efficiency and renewable energy, changes to improve current use.
  + Supervise the installations of energy efficiency solutions such as solar energy panels.
  + During the technology transfer process, provide guidance for business development, marketing and commercialization of the product or process, marketing strategies.

## Task 1: Execution of contract supervision and commissioning services

It is estimated that this task will take approximately 36 months from the signature of the DSI contract to the completion of the final acceptance of the contract, including the Contractor's provisional acceptance and defect liability periods for small works.

Consultant’s responsibilities (included but not limited to) for this task are summarized as follows:

**Carry out contract supervision services and commissioning services**

* + Allow working with counterpart staff from MoH for the duration of the consultancy services.
  + Prepare a management, control and supervision plan of the project and it is expected that the counterpart staff will be fully integrated within the consulting operations for capacity building.
  + Supervise all phases of the contract and sign the relevant parts of the payment documents specified in the contract.
  + Conduct monthly (more frequent if necessary) site visits with MoH and project team on a regular basis.
  + Prepare monthly field visit reports.
  + Conduct contract management; evaluate work schedules, monitor contractor's progress on the project; ensure project deadlines are met, proactively identify issues and propose solutions; ensure installation and works comply with design specifications and best practices.
  + Ensure that the Contractor's progress is in accordance with the work plan.
  + Check the Contractor's progress payments (including timesheets and other documents) and issue documentation according to the Contract Conditions used and will also be responsible for agreeing with the MoH on the payable amount on each payment document. Presentation of documents, supporting documents etc. will be discussed and agreed with the MoH.
  + Supervise the implementation of Environmental and Social Management Plans (ESMPs), including supervision on proper removal, packaging and transportation and disposal/interim storage of hazardous materials, use of personal safety equipment and monitoring in line with the requirements of the design and Environmental Mitigation and Monitoring Measures based on the Environmental and Social Management Framework.
  + Take the necessary precautions on environmental, social and security issues. In this context, in addition to the Environmental and Social Management Plans (ESMPs) prepared based on the ESMF, the most up-to-date Turkish environmental and safety regulations to be taken into account, especially during the inspection of works. Monitor/evaluate the Contractor's activities in accordance with site-specific ESMPs (including environmental, social, occupational health and safety, community safety, complaints etc. received, if any), include ESMP issues and complaints (if any) in monthly progress reports and provide feedback to the MoH.
  + Ensure compliance with all health and safety measures by the Contractor in accordance with the monitoring and reporting requirements of the relevant authorities and the World Bank.
  + Responsible to follow up all necessary permits, approvals, payment of all fees and contributions during the contract period.
  + Responsible for the quality, safety, and security of the submitted designed works and specifications.
  + Responsible for obtaining all necessary work permits (if applicable) and cover all necessary costs for his/her expatriates and any other necessary consent from relevant statutory bodies.
  + Provide risk assessment in accordance with environmental, health and safety policies.
  + Ensure the compliance of the Contractor's drawings with the specifications of the contract, and subsequently approve such drawings and participate in all site meetings.
  + Prepare and submit the required reports as per these terms of reference.
  + Finalize evaluation of all the outstanding claims from the Contractor and prepare and issue the final payment certificate (final account) and final completion cetiificate.
  + Review performance security validaty and recommend the return of performance security and retention money, if any.
  + Support MoH regarding the compliance of the project with the investment plan. Support the MoH to justify the differences in case of deviations.

**Assess the completion of the works up to the commissioning stage and during the defect liability period for small works and ensure commissioning**

* + Prior to the issuance of the Provisional Acceptance Certificate, supervise the Contractor's fulfillment of their obligation to remove all excess materials, debris, garbage and temporary works.
  + Upon completion of the works, ensure that the contractor removes all facilities, equipment and materials other than those necessary to complete the incomplete or remedial works and facilities required by the Consultant during the Defects Liability Period.
  + Prepare and issue the commissioning/provincial acceptance certificate in consultation with the MoH following successful completion of the contract, provided that any defects or deficiencies have been successfully remedied.
  + Supervise the training of relevant personnel on the new equipment. Issuance of the Commissioning Certificate will be subject to the following: The Contractor has delivered the operation and maintenance manuals, training of relevant personnel on the new equipment as well as all drawings and documents requested in the contract to the MoH.
  + Accompany the work performance tests after completion and analyze and evaluate the final performance tests with the approval of the MoH. Analyses, conclusions and recommendations will be compiled in the project completion report to be submitted to MoH.
  + Prepare a short technical report describing the testing and commissioning. All carried out tests together with their reviewed results should be included in the Consultant's monthly and quarterly reports.
  + Certify that works are executed as per approved design, drawings, standard specifications, technically sanctioned and within the provisions of contract agreement.
  + Submit the certified work record and drawings of works executed.
  + Issue a Certificate of Completion to the Contractor verifying the outstanding defects the Contractor shall rectify before operational acceptance.
  + Arrange the operational acceptance and handover of the completed works from the Contractor to the MoH upon satisfactory rectification of all the defects notified to the Contractor.

**Reporting Requirements for this Task**:

**Initial Inspection Reports**: The report should indicate the early findings on the Design Supply Installation Contractor’s contract and if any alterations needed, include the necessary calculations, details, the opportunities that the effects may be avoided or reduced, and time and cost implications.

**Monthly Progress Reports**: These will describe the physical and financial progress of the contract and address contractual and technical issues. They will provide information on (tentative list below, which may be amended):

* 1. A description of the physical progress with reference to the program (including progress charts and color dated photographs giving all information regarding the progress of the works);
  2. Explanations for differences between actual and forecast progress;
  3. A summary financial report including cash flow projections and budget expenditures;
  4. Status of payments and payment requests;
  5. Explanations for differences between actual and estimated cash flow, summary of claims and disputes;
  6. Significant milestones, obstacles, achievements, constraints on progress and problems encountered, and appropriately identified solutions;
  7. Clarifications on procedural issues;
  8. Variations and proposals for future changes in the timing and budgets of individual activities;
  9. A projection of activities for the coming month;
  10. Recommendations for further action and improvement in both the short and long term;
  11. Human resources, mechanical equipment and materials, test and quality control records, copies of test results and statistical evaluation of test results in tabular or graphical form. Measures taken in relation to poor results will be indicated;
  12. Local issues/stakeholder issues (including complaints from nearby communities and/or workers);
  13. A summary of site specific environmental and social issues (status of implementation of the relevant ESMP, update on OHS compliance, as well as an outline of environmental, social and OHS issues encountered);
  14. The report will include percentages of completed and planned items in the Contractor's contract, as well as actual and planned cash flows prepared in project planning tools (Primevera, Asta, etc.) accepted by the MoH as of the reporting period.

The report will be submitted to the MoH by the fifth day of the following month. The MoH will review any comments on the report and resubmit to the MoH within one week.

In addition, the Consultant will record images showing the progress on site on a weekly basis from delivery, installation, commissioning phases with dates and save them on USB stick in acceptable format and submit to MoH.

The Consultant will also prepare a tabular report summarizing the cumulative progress of the main work activities on a weekly basis. The report will be submitted to the MoH via electronic mail in an acceptable format by Monday of each week.

**Other reports upon request*.***

The MoH may request the Consultant to submit special reports on matters related to the execution of the contracts. The Consultant will prepare such requested report within a reasonable time. Consultant is obliged to provide any assistance to the MoH upon request in the preparation of reports on project implementation reports, financial reports, etc. to the bodies constituting the institutional framework for project implementation described in the introduction to this project assignment.

* Budget Reports: Reports showing how the budget allocated for the project has been spent and how well the budget planning has been followed.
* Expenditure and Cost Control Reports: Reports on the comparison of actual expenditures with projected costs and financial status assessment.
* Equipment Procurement and Installation Reports: Reports containing information on the purchase, delivery and installation of necessary equipment.
* Technical Design Reports: Reports containing details on the technical specifications of the equipment to be used in the facility, its layout and the architectural design of the facility.
* Occupational Safety Reports: Reports that include the implementation of occupational health and safety measures during the installation of the facility and the reporting of any safety violations.
* Documentation and Licensing Reports: Reports that include obtaining the necessary permits and documents showing the facility's compliance with legal regulations.
* Documentation Reports: Reports that provide documentation of the entire production process, including work orders, procedures, records and other documents.
* Quality Control Reports: Reports containing the results of tests conducted to assess the quality of the products produced. These reports determine product conformity to specifications and quality standards.
* Quality Assurance Reports: Report on quality assurance after the completion of supply and installation processes of technology platforms, including information on security, quality, performance and maintenance requirements of the platform supplied.
* Calibration Reports: Reports showing the regular calibration of the equipment used and the calibration results.
* Cleaning and Hygiene Reports: Reports assessing the cleanliness and hygiene status of production areas, including how cleaning procedures are implemented and the results.
* Production Reports: Reports containing details of each stage of the production process, including information such as production quantities, use of raw materials, process steps and production personnel.
* Test Reports: Reports containing the results of laboratory tests, including information such as test methods, sample preparation, test results and evaluations.
* Analytical Method Validation Reports: Reports that determine the accuracy and reliability of laboratory test methods.
* Equipment and Material Reports: Reports containing information on the calibration, maintenance and use of laboratory equipment.
* Laboratory Quality Control and Assurance Reports: Reports that include the laboratory's quality control and assurance procedures and how these procedures are implemented.
* Laboratory Logs: Detailed daily records of laboratory activities, including information such as work performed, materials used and results obtained.
* Personnel Training Reports: Reports containing the trainings and authorizations received by facility employees.
* Sustainability Reports: Reports evaluating the facility's environmental impacts and sustainability measures.

## Task 2: Supervision of corrective works to remedy defects arising in Small Works during the Defects Liability Period

* Commissioning of the completed blocks shall be performed by the Consultant to verify and document that the equipment and systems were designed, installed, tested and properly operated to meet the described requirements of the DSI contract.
* The Consultant will continue to be responsible for the supervision and control of the contracts and completion of the works for the small construction works during the Defects Liability Period as defined in the contracs. The level of inspections will be appropriate to the scale of work carried out. These control and supervision activities are to ensure that the works agreed to be carried out during the Defects Liability Period are carried out properly and completed, and that any defects in any part of the works are eliminated. If any defect is detected during this period, the Consultant will immediately investigate the cause, report to the MoH and take the necessary measures to eliminate the defect. A report of these investigations will be submitted to the MoH and this report will include all details of any defects, errors, accidents or malfunctions that occurred, and estimated repair costs and timelines for their completion.
* During the Defects Liability Period, the Consultant will provide needed technical personnel acceptable to the MoH. Therefore, the Consultant must consider assigning a minimum number of personnel consisting of technicians during the Defects Liability Period.
* Preparation and submission of as-built drawings, workshop drawings, operation and maintenance manuals for all equipment and facilities included in or related to the works will be checked and followed by the Consultant in a timely manner. As-built drawings, operation and maintenance manuals must be obtained from the Contractor during the issuance of the delivery certificate. When deemed necessary, MoH may request the Consultant to convert the approved manufacturing drawings into as-built drawings. The consultant will also prepare a report providing all information regarding the "as-built conditions", including (but not limited to) calculations, drawings, specifications, test reports and final cost analysis, and submit it to the MoH for approval.
* The Consultant, with their designated representative, will be present during all tests and inspections of machinery and equipment conducted at the Supplier's or Contractor's facilities, at the point of delivery and/or at the final destination of the goods or elsewhere.

**Reporting Requirements for this Task:**

Reports must include, but not be limited to, the following information:

* **Commissioning Reports:** After all items in the problem registration list are closed and the trainings are completed, a final commissioning report is prepared, which includes the documentation and results of the work done.

All kinds of machinery, equipment and systems used in the project, user manuals, operation and maintenance manuals, handbooks that contain system diagrams and should be hung in technical places, manufacturer catalogues, authorized service contact information, as-built projects, calculations, test reports, commissioning forms and minutes and other related documents will be submitted with the final commissioning report.

The report should consist of the following headings:

* + - * 1. Equipment and systems included for work
        2. Executive summary
        3. Issues log list
        4. Floor plans and/or system flowcharts
        5. Basic test checklists
        6. Pre-functional checklists
        7. Initial start-up forms
        8. Functional performance test forms
        9. Energy performance assessments
        10. Training documents
        11. System guides
        12. Other documents and images
        13. Annex

**Draft Project Completion Report**.

It will be delivered 4 weeks before the completion of the contract period. These will provide an overview of the project and a measure of success. They will include:

1. A summary of the information contained in the previous monthly reports;
2. An overall assessment of the project;
3. A description of the physical progress with reference to the Work Schedule;
4. Explanations for differences between actual and predicted progress;
5. A summary financial report including cash flow projections and budget expenditures;
6. Status of payments and payment requests;
7. Explanations for differences between actual and estimated cash flow in the summary of claims and disputes;
8. An assessment of the impact of the project on the number of people employed;
9. A report on problems encountered and how to overcome them,
10. Recommendations for missing work;
11. Report on compliance with ESMPs.

The Consultant will review and approve, in consultation with the MoH, the relevant completion reports with attached test results for specific sections of work submitted by the Contractor. These reports will address all Testing related to Completion and Post Completion Testing, including the results thereof. Approval of the completion reports will be a prerequisite for the issuance of any Commissioning Certificate and Post Completion Tests.

* **Final Completion Report**

It will be submitted 2 weeks after the completion of the contract period or after comments on the draft project completion report provided by the MoH. The content will be the same as in the draft completion report with the inclusion of comments/recommendations from the reviewing parties.

The report shall contain at least:

1. Draft Final Accounts
2. Approved as-built drawings (signed by the Contractor and Consultant)
3. Energy Performance Certificates
4. Data on the technical difficulties encountered and how they were solved
5. Evaluation on Contractor’s EHS performance
6. Copies of the requests for issuance of the Commissioning Certificate;
7. The approved Design list submitted by the Contractor showing all changes relating to the main design elements or works performed;
8. Quality assessment of materials and workmanship;
9. Data on technical difficulties encountered and how to resolve them;
10. Comments made on the designs,
11. List of Operating and Maintenance Instructions,
12. Final Report on Contractor's EHS performance (Code of Conduct, ESMP compliance, permits/licenses and other relevant project requirements.

The report will be delivered to the Employer upon completion of the works, including (but not limited to) all work records, calculations, drawings, specifications, test reports and final cost analysis, reproducible “as-built” drawings and instructions necessary for satisfactory operation and maintenance of the project.

The final report should be due on the completion of assignment. A physical presentation in power point format will be the part of Final Report.

* **Visual Presentation Materials:** Up to 500-1000 visual presentation visuals including posters, brochures, catalogues and leaflets will be prepared, printed and distributed by the consultant for the VPC project to give information and to raise awareness about the energy efficiency measures implemented in the building, and the benefits of these applications.

The graphic designs of the presentation visuals will be subject to the MoH approval before printing. All visual materials shall include the logo and the names of the MoH and the project, the template of which will be provided by the MoH. The posters will be presented especially in the areas/sections where innovative and green applications are implemented.

* **Defects Liability Period (DLP) quarterly reports:**

A report on Defects Liability Period inspections will be submitted to the MoH, including all details of any defects, malfunctions, accidents or malfunctions that occurred, along with estimated repair costs and timelines for their completion. Reports will be prepared quarterly.

* **DLP final report** containing full details of all work carried out during the period will be submitted when the Defects Liability Period ends. This report will be submitted at least 30 days prior to issuing the Defects Liability Certificate for the completed works.

## Task 3: Human Resource Planning, Recruitment Support and Training

# Provide support regarding services for the implementation of the approved Human Resources Plan.

# Provide support regarding recruitment services and determining the optimum salary ranges for each job position.

# Carry out the trainings of the selected personnel.

# Support the implementation of the pilot phase and provide an assessment that includes recommendations for improvements in the new HRM System.

# Support for the implementation of the approved training plan for the Vaccine Production Center,

# Provide services for the creation and implementation of personnel training programs for the training and authorization of the personnel to be employed at the facility,

# Provide trainings related with the entire process other than equipment trainings,

# Supervise the trainings to be provided by technology transfer partners,

# All the trainings will be certified with acceptable certificates,

# As a result of these trainings provided by the consultant, the relevant personnel should be competent enough to carry out commercial scale productions in the facility, and the training programs should be revised when necessary to ensure that the facility is operational with these personnel.

# Create a project library of all the documents, reports, maps, working papers, progress pictures and other reference material used and/or created during the period of the assignment. A list of documents proposed to be kept in the library shall be included in the report for acceptance by the MoH.

**Reporting Requirements for this Task**:

The reports must include, but not be limited to, the following information:

Human resources, recruitment and training activities in the subject period will be included in the Montly Progress Reports.

## Task 4: Execution and finalization of WHO Certification Procedures, GMP/GLP Certification and Approvals

# The process of obtaining the documents specified in the list above for Ankara Vaccine Production Center will continue from the beginning of the construction process, including the production and testing phases of the vaccines to be produced, the commissioning of all devices, pilot production and main production phases. All the processes in question will be carried out and finalized by obtaining approvals from TİTCK and WHO at each stage, including Biosafety Level licensing, GMP and GLP steps. The consultant will support the determination of these processes and the follow-up of the approval steps.

# Provide technical assistance to the MoH, including performing all the necessary tasks to be performed by the Contractor from start to finish until VPC (Vaccine Production Center) produces at least one vaccine which (i) receives authorization from Türkiye’s National Regulatory Authority, the Turkish Medicines and Medical Device Agency, and (ii) is subsequently submitted to WHO for Pre-Qualification,

# Technical assistance to the MoH, including performing all the necessary tasks to be performed by the Contractor from start to finish until the WHO Certification of the entire facility is approved,

# Provide technical assistance to the MoH until the approval process of WHO for the entire facility, VPC and the approval of PQL (Pre-qualification List) from WHO for one selected product are completed.

# Ensure that the necessary approvals are obtained for the required licensing processes, quality control standards and safety protocols as compliance with relevant regulations and local legal requirements crucial for the establishment of a vaccine manufacturing facility,

# Ensure that the 5 P’s of GMP are followed throughout the entire production process.

# Provide and evaluate the necessary trainings and product-specific trainings to ensure that all employees strictly comply with GMP/GLP production processes and regulations.

# Implement necessary control and internal audit plans for GMP/GLP to evaluate the performance, productivity, efficiency and adequacy to ensure sustainability.

* Supervise the necessary business plans of the products made to pass tests, comparisons and quality assurance.
* Supervise workflow plans complying with the standard methods for packaging, testing and allocation of sample products.
* Supervise GMP/GLP Processes Planning Programme and ensure that the programme is successfully implemented
* Supervise GMP/GLP Procedures Planning Programme and ensure that the programme is successfully implemented
* Supervise GMP/GLP Premises Planning Programme and ensure that the programme is successfully implemented
* Conduct GMP/GLP audits regularly
* Supervise Standard Operating Procedures (SOPs)

**Reporting Requirements for this Task:**

The reports must include, but not be limited to, the following information:

# The process of obtaining the documents specified above for Ankara Vaccine Production Center from the beginning of the construction process, including the production and testing phases of the vaccines to be produced, the commissioning of all devices, pilot production and main production phases regarding WHO, GMP and GLP procedures in the subject period will be included in the Montly Progress Reports.

## TIMELINE

The time-based task is expected to begin when the Design, Supply, Installation (DSI) contractors are on board, tentatively in the last quarter of 2026 for the contractor for R&D and Experimental Animal Production/Test Buildings and the first quarter of 2027 for the contractor for Vaccine Manufacturing Buildings, to be completed within a period of 36 months, depending on the completion of the contracts.

It must be noted by the Consultant that during the supervision periods, any program, report specifications and other documents submitted to the MoH for approval will be reviewed by the MoH and approved within 15 calendar days or returned for revision and/or resubmission.

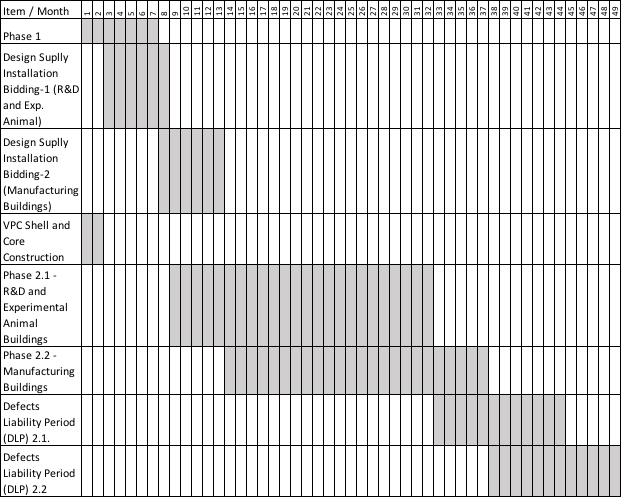
The Consultant will submit all the documents in a timely manner to complete the services on time without any delay. The timeline for completion of the Consultants' services for the various parts of the work indicated below will be presented to the MoH.

During the execution of the services, the MoH and the Consultant will review the Consultant's Work Plan and Personnel Schedule each month. If necessary, the Consultant will update these by requesting the MoH's approval.

The overall time frame for the starting of Phase 2 is the commencement of the Contractors’ assignments. The estimated duration for Phase 2 for contract management, supervision, monitoring, equipment procurement & installation, HR plan development, technology selection and transfer, other tasks and 12 months for Defects Liability Period is 36 months in total.

Hence, the Consultant must be aware that a Site Handover Date for the Contractor can be taken as a date the Consultant to start the supervision of works that emphasizes the payment start date for the consultant regarding Phase 2 (supervision and contract administration service).

Tentative Timeline



**Variations in Coverage**

* Starting date of the Contractor’s contract may vary due to contingencies. The Consultant will wait for the bid evaluation or other matters to be concluded before starting Phase 2 of the assignment and will not request any payment or compensation.
* Delivery requirements for the above outputs related to the ongoing phases of the consulting services must be considered by the Consultant as a guide to the scope and type of documentation that will be requested by the MoH in the performance of the services. Moreover, the Consultant will include in their fees the submission of all reports, drawings, documents, etc., which are specifically requested in this Terms of Reference or may be derived from them and the Contractors' contract. However, the MoH may change such requirements during the performance of the services.
* If additional reports or copies in addition to those indicated above or which may be derived from this Terms of Reference are required, these will be provided by the Consultant at the cost of preparation and reproduction of such documents, reports or drawings.
* After completion of the contract, the Consultant will deliver to the Client all original copies of services-related correspondence, documents, test results, drawings, etc. along with indexes in files and forms acceptable to the MoH.

1. **REPORTING REQUIREMENTS**

All Documents are required to be in Turkish and English. All reports must be submitted in hard copy (signed and stamped double copy) and electronic copy.

Reports for each task will be submitted to and approved by the MoH. The Consultant must obtain approval for each output before moving on to subsequent tasks. The table below summarizes the reports and includes an indicative timeline.

|  |  |  |  |
| --- | --- | --- | --- |
| **Task** | **Reports** | | **Submission Deadline** |
| 1 |  | Initial Inspection Reports | 4 weeks from the start of Phase 2 |
|  | Monthly Progress Reports | Together with the submission of the interim payment certificate for each month |
|  | Other reports upon request | No specific deadline |
| 2 | 2.1. | Commissioning Report | With the closure of all the itens in the problem registration list (issues log) |
| 2.2. | Draft Project Completion Report | 4 weeks before the completion of the contract |
| 2.3. | Final Completion Report | 2 months after the issuance of Certificate of Completion |
| 2.4. | Visual Presentation Materials |  |
| 2.5. | DLP Quarterly Reports | Quarterly during DLP |
| 2.6. | DLP Final Report | By the time of the expiration of the DLP |
| 3 | 3.1. | Human Resources, Recruitment and Training Reports | In accordance with approved work plan |
| 4 | 4.1. | WHO, GMP/GLP Reports | In accordance with approved work plan |
|  |  |  |  |

All documents and outputs must be prepared in both English and Turkish.

* Report Format : A4 or A3, preferably A3 size when appropriate including scaled down drawings.
* Drawing Format : A1 size (unless otherwise required or agreed upon)
* Drawing Scale : Must be agreed upon with MoH.

The Consultant will upload all outputs to the online platform addressed by the MoH and provide an electronic copy (an external hard disk) of all the above-mentioned outputs in addition to the printed copies. Metric weighing and measuring system will be used. Drawings will be submitted as per the format, labeling, batching and detailing as requested by the MoH.

As specified in the General Conditions of Contract, all drawings, reports, plans, specifications and other documents prepared under the scope of this Contract are the property of the MoH. Therefore, the Consultant will also submit all the originals of the drawings and other documents in the required format.

## 12. FACILITIES PROVIDED BY THE CONSULTANT

The Consultant will provide adequate, qualified and experienced personnel in order to ensure appropriate supervision of the contracts and engineering services both throughout the contract period and the Defects Liability Period, and to ensure that works are carried out in accordance with the latest regulations and rules. All costs for equipment, administrative and logistical support must be covered by the Consultant and included in the financial proposal.

* + All costs arising from the activities of its personnel during the contract period, including accommodation, per diem allowance, transportation, insurance, etc.
  + Logistics, equipment, office supplies, hardware and software to ensure monitoring is fully functional.
  + All communication costs, including fax, e-mail, phone, etc.
  + All costs incurred for the equipment, vehicles, services and logistical support, and incurred during preparation, copying, printing, etc. of documents and drafts which are required for the implementation of the contract.
  + Technical equipment at the monitoring site;
  + Other equipment, vehicles, services and logistic support required for the implementation of the contract.
  + Written and spoken English and Turkish are required throughout the project. If the Consultant requires translation services, the costs of this service will be covered by the Consultant and the Consultant will be responsible for the accuracy of the translation.
  + The Consultant is obliged to provide all other elements required for the work of the professional staff they assigned for the performance of this contract agreement, at their own expense.
  + The Consultant will be fully responsible for providing the central field office. The central office will be furnished and equipped by the Consultant. All operating expenses of the site offices, except water and electricity (to be provided by the Contractor) will be under the responsibility of the Consultant.

## 13. SUPPORT TO BE PROVIDED TO CONSULTANTS BY THE MoH

The MoH will assist the Consultant, where possible, in obtaining approvals and permits from Municipalities and other Government Authorities for the services to be performed.

Inputs (DSI signed contract, up-to-date contract drawings, latest bill of quantities, etc.) will be provided free of charge to the Consultant by MoH. After completion of the services, the Consultant will return all these drawings and documents received to the MoH.

## 14. TEAM COMPOSITION AND QUALIFICATION REQUIREMENTS FOR KEY PERSONNEL

## (TIME BASED)

The Consultant will provide an experienced supervision and contract management team with proven technical and managerial competence and experience in the supervision and management of contracts for hospital projects, vaccine production facilities, etc.

**Team Composition**

* The working language of the project is English and Turkish. All the team members assigned by the Consultant must possess proficiency in English language. Day-to-day communication language will be Turkish and English at the field level to ensure smooth communication among all participants, direct and indirect, of the Project.
* All key and support personnel will be mobilized immediately to assess the design and make any necessary adjustments before works start. In addition, necessary support personnel for administrative services will also be proposed (experts, officers, drivers, secretaries, etc.).
* The Team Leader will be required for inspections during the twelve (12) months Defects Liability Period, together with the relevant Costing and Planning, Electrical and Mechanical Engineers. The Supervision Team and the Team Leader will have the right to follow up, supervise and document the implementation of health and safety measures as per Law No. 6331.
* The Consultant's team will include at least the following qualified engineers and other professionals competent to perform the duties described in this Terms of Reference.

The Consultant will have Key Experts (KE) available, including but not limited to the following;

* K-1 / Team Leader (TL)
* K-2 / Project Manager (PM)
* K-3 / Design Architect
* K-4 / Mechanical Engineer
* K-5/ Electrical and Electronics Engineer
* K-6 / Environmental Expert
* K-7 / Social Expert
* K-8 / Cost and Planning Engineer
* K-9 / Regulatory Expert
* K-10 / Biosafety Expert
* K-11/ GMP ~~and GLP~~ Expert
* K-12 / Medical Device Specialist (MDS)
* K- 13 / Animal Experiment Specialist
* K-14 / Quality Assurance Specialist
* K-15 / Licensing Specialist
* K-16 / Calibration and Maintenance Specialist
* K-17 / Laboratory (GLP-Good Laboratory Practices)Expert
* K-18 / Human Resource Expert
* K-19/ Training Specialist
* K-20 / Business Development and Marketing Specialist
* K-21 / Energy Efficiency Expert
* K-22 / Process Engineer (Black & Clean Utilities Specialist)
* K-23 / Vaccine Production & Quality Expert
* K-24 / Vaccine Quality Control Specialist
* K-25 / Sterility Assurance Specialist

The Consultant will provide adequate personnel in terms of expertise and time allocation, as well as the necessary equipment to complete the activities required within the scope of work and ultimately achieve the project's objectives in terms of time, cost and quality.

The Project Manager and experts will collaborate with other consultants and attend meetings when requested by the MoH.

The Consultants team must at least have following experience and qualifications requirements:

**Team Leader (TL) (1)**

The Team Leader is responsible for the overall contract coordination and quality control of contract implementation. TL will ensure that the engagement of experts is agreed with the MoH and that they are engaged on time to deliver the project outputs. The expected role of the Team Leader is to guide the project from a strategy and policy perspective. This role will last until the plant is operational and GMP approval is obtained.

* Bachelor's degree in Pharmaceutical Sciences, Microbiology, Biotechnology, pharmaceutical engineering, or any other discipline relevant with the project.
* Master's degree in business management or project management.
* Proven expertise and experience in vaccine manufacturing strategy, vaccine portfolio planning, project planning and review of vaccine manufacturing project, design and review of architectural and engineering services for exterior and interior design for a vaccine manufacturing facility/project.
* Minimum 15 years of experience in consultancy services in complex projects in the sector for International Financial Institutions (IFI) funding, preferably the World Bank.
* Minimum 5 years of work experience in consultancy services for vaccine production.
* Minimum 2 completed projects in the field of health sector.
* Previous work experience in a relevant field in a public or private sector company in Türkiye is an asset.
* Knowledge of English language.

**Project Manager (PM) (1)**

The Project Manager is responsible for overall contract coordination and quality control of contract implementation, management of timelines, budget oversight and communication. The Project Manager coordinates all team members, will ensure that the assignment of Experts is agreed with the MoH and project deliverables are delivered on time.

The Project Manager is expected to provide operational management and coordination with all stakeholders. This will last until the plant is operational and GMP approval is obtained.

* Bachelor's degree in Pharmaceutical Sciences, Microbiology, Biotechnology, pharmaceutical engineering or any other discipline relevant with the project.
* Master's degree in business management or project management.
* Minimum 10 years of professional experience in biological/biotechnological active substance production and sterile finished product, pharmaceutical production facilities.
* Minimum 12 years of experience in consultancy services in complex projects in the sector for International Financial Institutions (IFI) funding, preferably the World Bank.
* Minimum 2 completed projects in the field of health sector.
* Good knowledge of design and technical documentation requirements of the projects tendered under the tendering procedures and rules of IFIs, preferably the World Bank.
* Have a good knowledge of the requirements of Turkish legislation regarding design, construction, engineering, environmental and social issues is an asset.
* Knowledge of English language.

**Design Architect (1)**

The Design Architect is expected to develop conceptual and basic architectural designs and layouts for the Vaccine Production Center.

* University degree in architecture.
* Master's degree in a relevant field will be an asset.
* Experience in developing architectural designs and layout plans for the vaccine facility.
* Minimum 10 years of professional experience
* Minimum 5 years of experience in similar works.
* Experience in the design processes of any pharmaceutical production facility from the very beginning.

**Mechanical Engineer (1)**

The Mechanical Engineer is expected to review the mechanical aspects.

* University degree in mechanical engineering.
* Experience in ventilation systems (HVAC) design, installation, qualification and maintenance processes.
* Master's degree in a relevant field will be an asset.
* Experience in supervising mechanical aspects, including conceptual and basic designs
* Minimum 10 years of professional experience
* Minimum 5 years of experience in similar works.

**Electrical & Electronics Engineer (1)**

The Electrical Engineer is expected to review the electrical and electronics aspects.

* University degree in electrical & electronics engineering
* Master's degree in a relevant field will be an asset.
* Experience in building management systems (BMS) design, installation, qualification and maintenance processes.
* Experience in supervising electrical/electronic aspects, including conceptual and basic designs
* Minimum 7 years of professional experience
* Minimum 5 years of experience in similar works.

**Environmental Specialist (1)**

The Environmental Specialist is expected to recommend and oversee environmental norms and compliances for the facility.

* University degree in environmental engineering.
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of professional experience.
* Experience in recommendation and supervision of environmental norms and compliance.
* Minimum 3 years of experience in similar works, especially working knowledge of the World Bank Environmental Framework.

**Social Specialist (1)**

The Social Specialist is expected to recommend and oversee social norms and compliances for the facility.

* University degree in Social Sciences.
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of professional experience.
* Experience in recommendation and supervision of social norms and compliance.
* Minimum 3 years of experience in similar works, especially working knowledge of the World Bank Social Framework.

**Cost and Planning Engineer (1)**

The Cost and Planning Engineer is expected to prepare the cost details and financial plans for the project. This task will last until the end of the first phase of the project.

* Bachelor's degree in commerce, economics, statistics, civil engineering
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 2 years of experience in similar works, especially in the development of comprehensive scope of works, bill of quantities, timelines and budgets.

**Regulatory Expert (1)**

The expert shall be responsible for understanding and implementing relevant regulations and legal requirements. The Regulatory Expert manages the facility's licensing processes and ensures compliance with legal requirements. Regulatory Expert is expected to audit and recommend GMP and GLP aspects for the facility. This task will last until GMP & GLP approval is obtained for the facility and laboratory respectively.

* Master's degree in pharmaceutical sciences, pharmaceutical engineering, regulatory affairs, biotechnology, microbiology, biochemistry and virology sciences, or any other discipline relevant with the project.
* Proven track record of successfully consulting on similar projects involving construction of vaccine production center or similar facilities.
* In-depth knowledge and understanding of vaccine manufacturing processes, regulatory compliance requirements specific to vaccine manufacturing plants, clean room designs, HVAC systems, process flow optimization, equipment layout and utilities required for vaccine production.
* Familiar with Good Manufacturing Practices (GMP), regulatory guidelines and quality control standards specific to vaccine production facilities.
* Expertise in facility design and layout for vaccine manufacturing plants.
* Well-versed in regulations set forth by regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other relevant authorities.
* Proven track record in the country is an asset.

**Biosafety Specialist (1)**

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences, pharmaceutical engineering
* Registered Biosafety Specialist (to an internationally recognized biosafety association)
* Certified Workplace Safety Specialist
* Minimum 5 years of experience as a biosafety consultant
* Minimum 10 years of experience at least in 3 labs as an ABSL-3/BSL-3/BSL-2 biosafety expert
* Experience in review and approval of ABSL-3 / BSL-3 / BSL-2 facility designs
* Experience in supervising constructions of ABSL-3 / BSL-3 / BSL-2 facilities
* Experience in commissioning biosafety facilities
* Field training experience in biosafety and animal biosafety

**GMP (Good Manufacturing Practices) Expert (1)**

* Bachelor's or Master's degree in medicine, veterinary medicine, pharmacy, biology or chemistry
* Certified training on ~~GLP,~~ GMP issues
* Experience in conducting facility inspections and providing training in terms of GLP and GMP
* Having at least 5 years of experience as a GLP and GMP consultant
* Experience in clean room facility design review and approval.
* Experience in supervising the construction of clean room facilities.

**Medical Device Specialist (1)**

* Bachelor's or Master's Degree in Pharmaceutical Sciences, Microbiology, Biotechnology Biomedical or pharmaceutical engineering with at least 10 years of experience in this field
* Minimum 10 years of experience in preparation of technical specifications and installation of laboratory devices
* Experience in conducting FAT and SAT, supervision of equipment installation, verification and commissioning.
* Minimum 5 years of experience in similar works.

**Animal Experiment Specialist (1)**

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences or Veterinary Sciences.
* Master's degree in a relevant field will be an asset.
* Relevant experience in animal experiments on vaccines
* Minimum 8 years of professional experience
* Minimum 3 years of experience in similar works, especially working knowledge of WHO (World Health Organization) certification and GLP.

**Quality Assurance Specialist (1)**

A person who ensures the implementation of GMP/GLP standards and oversees quality control processes. The quality assurance specialist conducts audits to ensure the compliance of the facility and takes corrective measures when necessary. This task will last until the end of the project.

* Bachelor's or Master's Degree in Microbiology, Biochemistry, Biotechnology, Pharmaceutical Sciences or Pharmaceutical Engineering or other relevant discipline related to the project
* Master's degree in a relevant field will be an asset.
* Minimum 5 years of experience in pharmaceutical industry quality management systems and quality risk management processes.
* Experience in recommendation and supervision of quality assurance elements for the facilities

**Licensing Specialist (1)**

The expected task of the Licensing Specialist is to supervise and recommend licensing activities for the facility. This task will last until the end of the project.

* Bachelor's or Master's Degree in Business Administration, Law, or Pharmaceutical Sciences.
* Master's degree in a relevant field will be an asset.
* Experience in recommendation and supervision of licensing activities.
* Minimum 5 years of professional experience.
* Minimum 3 years of experience in similar works.

**Calibration and Maintenance Specialist (1)**

Specialists who ensure that equipment is regularly calibrated and maintained. These people ensure that the equipment functions correctly and meets quality standards.

* Bachelor's or Master's Degree in Biomedical Engineer, Machinery Engineer
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 6 years of experience in similar works.

**Laboratory (GLP-Good Laboratory Practices) Expert (1)**

Experts responsible for conducting laboratory tests and analyzing the results in projects following GLP processes.

* Bachelor's or master's degree in veterinary, genetics, bioengineering, pharmaceuticals, biology, chemistry engineering or molecular biology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience in laboratories.
* Minimum 6 years of experience in similar works.

**Human Resources Expert (1)**

* Bachelor's or master's degree in business, phychology or sociology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 6 years of experience in similar works.

**Training Specialist (1)**

The person responsible for training and authorization of staff. The specialist ensures that employees are trained and informed in accordance with GMP/GLP standards.

* Bachelor's or master's degree in the fields of veterinary, genetics, bioengineering, pharmaceuticals, biology, chemistry engineering or molecular biology.
* Master's degree in a relevant field will be an asset.
* Minimum 10 years of professional experience.
* Minimum 6 years of experience in similar works.

**Business Development and Marketing Specialist (1)**

During the technology transfer process, business development and marketing experts may be needed for marketing and commercialization of the product or process. These people determine how the product or process will be marketed and develop marketing strategies.

* Master's degree in business administration, finance, economics, engineering, or a field specific to the industry being studied.
* Deep understanding of the industry’s dynamics, trends and regulations.
* Have a track record of successfully conducting feasibility studies for similar projects or industries.
* Proficiency in data analysis, market research, financial analysis and risk assessment.
* Experience in analysing financial data, developing financial projections, assessment of investment costs, calculatation of return on investment (ROI), and evaluation of the project’s financial feasibility.
* Similar experience in marketing and commercialization of vaccines,
* Proven track record in relevant projects in the region is an added advantage.

**Energy Efficiency Expert (1)**

* Master’s degree in science, engineering, economics, business administration or equivalent areas,
* Minimum 10 years of relevant experience in the energy sector.
* Direct experience in at least two of the following areas: energy efficiency, energy sector economics, energy sector policy and regulation, energy and climate policy, renewable energy, transmission and distribution infrastructure, utility financial analysis and/or utility reform, power pools and regional integration.
* Strong quantitative and analytical skills and ability to work independently are expected.
* Excellent interpersonal skills and ability to build strong partnerships with different stakeholders.

**Process Engineer (Black & Clean Utilities Specialist) (1)**

The Process Engineer will be responsible for designing, optimizing, and validating production processes in a vaccine manufacturing facility, with a strong focus on Black and Clean Utilities. This role includes overseeing HVAC, sterilization, process validation, and ensuring compliance with GMP, WHO, EMA, FDA, and TİTCK standards. The specialist will play a key role in maintaining cleanroom integrity, contamination control, and process efficiency in vaccine production.

* Bachelor’s degree in Mechanical Engineering, Chemical Engineering, Industrial Engineering, or a related field.
* Master’s degree in Process Engineering, Bioprocess Engineering, Pharmaceutical Engineering, or a relevant discipline is preferred.
* Minimum 10 years of professional experience in pharmaceutical, vaccine, or biopharmaceutical production processes.
* Minimum 5 years of experience in Black and Clean Utilities, HVAC, and cleanroom design and operation.
* Strong knowledge of HVAC, cleanroom validation, and airflow dynamics.
* Experience with sterilization processes (autoclave, VHP, dry heat, gamma irradiation).
* Understanding of GMP-compliant facility design and process engineering principles.
* Proficiency in process modeling, equipment validation, and energy efficiency in pharmaceutical manufacturing.

**Vaccine Production & Quality Expert (1)**

The Vaccine Production & Quality Expert is responsible for technical oversight of vaccine development, production, and quality control. This role involves ensuring compliance with biosafety standards, sterility assurance, and GMP-compliant manufacturing techniques. The expert will oversee vaccine formulation, purification, filling, and stability studies while ensuring adherence to WHO, EMA, FDA, and TİTCK quality standards.

* Bachelor’s degree in Pharmacy, Bioengineering, Biomedical Engineering, Chemical Engineering, Molecular Biology and Genetics, Microbiology, Biochemistry, or a related discipline.
* Master’s degree in Pharmaceutical Technology, Biotechnology, Bioprocess Engineering, Microbiology, Biochemistry, Virology, or a related discipline (preferred).
* Extensive experience in vaccine production, including upstream and downstream processing, formulation, adjuvants, and filling processes.
* Knowledge of bioprocess engineering, cell culture, fermentation, and purification techniques used in vaccine production.
* Expertise in GMP-compliant aseptic techniques, sterilization methods (autoclave, dry heat, gamma irradiation, vaporized hydrogen peroxide - VHP).
* Experience in sterility assurance, contamination control, and biosafety standards for vaccine manufacturing.
* Proficiency in analytical method validation for vaccines, including HPLC, ELISA, PCR, and potency assays.
* Knowledge of cleanroom classification (ISO 14644) and environmental monitoring in vaccine production facilities.
* Experience in vaccine R&D and technology transfer projects.

Vaccine Quality Control Specialist (1)

The Vaccine Quality Control Specialist is responsible for ensuring the quality, safety, and efficacy of vaccines through rigorous quality control (QC) testing and compliance with international regulatory standards. This role involves conducting microbiological and analytical testing, method validation, stability studies, and contamination controlwhile ensuring adherence to WHO, TİTCK, EMA, and FDA guidelines. The specialist will work closely with sterility assurance, quality assurance, and production teams to maintain the highest quality standards in vaccine manufacturing. The expert will also focus on antigen production, formulation, purification, and stability studies to ensure high-quality vaccine development.

* Bachelor’s or Master’s degree in Microbiology, Biochemistry, Biotechnology, Pharmacy, Chemistry, Chemical Engineering, or Molecular Biology.
* Certified training in GMP, GLP, and WHO prequalification processes (preferred).
* Minimum 10 years of experience in vaccine or biopharmaceutical quality control.
* Minimum 5 years of hands-on experience in QC laboratory testing, including microbiological and analytical methods.
* Expertise in sterility, endotoxin, mycoplasma, and potency assays.
* Experience in HPLC, ELISA, PCR, and other advanced analytical techniques.
* Knowledge of environmental monitoring, contamination control, and stability testing.
* Familiarity with WHO PQS (Prequalification of Vaccines), TİTCK, and international vaccine quality standardsaccording to WHO guidelines.
* Proficiency in QC method validation and analytical method transfer.
* Experience in data integrity, deviation management, and CAPA (Corrective and Preventive Actions).
* Knowledge of cleanroom classification, biosafety, and quality risk management.
* **Antigen production** processes, including **recombinant protein production, viral vector production, inactivated or live attenuated vaccine manufacturing.**
* **Upstream and downstream processes,** such as **bioreactor operation, cell culture techniques, filtration, and purification.**
* **Antigen stabilization and formulation** to ensure vaccine efficacy and longevity.

Sterility Assurance Specialist (1)

The Sterility Assurance Specialist is responsible for ensuring the sterility of vaccines and pharmaceutical products through cleanroom management, aseptic processing, and contamination control. This role involves implementing sterility testing, sterilization validation, risk assessments, and environmental monitoring in compliance with WHO, TİTCK, EMA, and FDA guidelines. The specialist will work closely with quality control and production teams to maintain sterility assurance at all manufacturing stages.

* Bachelor’s or Master’s degree in Microbiology, Biochemistry, Biotechnology, Pharmacy, Chemistry, or Chemical Engineering.
* Certified training in GMP, GLP, and WHO prequalification processes (preferred).
* Minimum 10 years of experience in pharmaceutical or vaccine production with a focus on sterility assurance.
* Minimum 5 years of hands-on experience in aseptic processing, cleanroom management, and contamination control.
* Expertise in environmental monitoring, bioburden testing, endotoxin testing, and sterility testing.
* Familiarity with WHO, TİTCK, EMA, and FDA sterility assurance guidelines.
* Experience in cleanroom classification (ISO 14644), airflow visualization studies, and HEPA filtration validation.
* Knowledge of aseptic techniques and sterilization methods (autoclave, dry heat, gamma irradiation, vaporized hydrogen peroxide - VHP).
* Proficiency in media fill validation, disinfectant qualification, and risk-based sterility assurance strategies.
* Experience in CAPA (Corrective and Preventive Actions), deviation management, and root cause analysis.

\* Experience in Similar Works includes the following:

- Develop detailed designs and technical specifications, consulting services for the construction of healthcare projects such as hospitals, vaccine production facilities etc. for the key staff within the scope of all duties.

- Understand the requirements for establishing a vaccine production facility, including but not limited to the following:

a. Platform technology and production process

b. Biosafety levels and containment

c. Up-to-date GMP and GLP requirements

d. WHO Pre-Qualification Process

It is an asset for all key staff.