IDB Inter-American Development Bank

**REQUEST FOR EXPRESSIONS OF INTEREST**
**CONSULTING SERVICES**

Selection # # RG-T3919-P001
Selection Method: Competitive selection
Country: Regional
*Sector:* Regional Integration Unit (INT) and the Social Protection and Health Division (SCL/SPH)
*Funding – TC #: RG-T3919*
*Project #: ATN/CF-18701-RG*
*TC name: Escalamiento de Capacidades de Inmunización de los países de PROSUR*
*Description of Services:*

*Link to TC document:* https://www.iadb.org/en/project/RG-T3919

The Inter-American Development Bank (IDB) is executing the above-mentioned operation. For this operation, the IDB intends to contract consulting services described in this Request for Expressions of Interest.
Expressions of interest must be delivered using the IDB Portal for Bank Executed Operations (http://beo-procurement.iadb.org/home) by: 13th of December at 5:00 P.M. (Washington D.C. Time).

The consulting services ("the Services") include:

1. Proposed new vaccine production facility pre-feasibility study.
    *a.* The Firm is to conduct a pre-feasibility study for the type of facility agreed upon in Phase 1. The study should identify enablers and barriers for the new facility to be able to operate in a sustainable manner.
    *b.* The Firm must then recommend potential solutions for these gaps, especially ones which can be effectively implemented by governments or through government support and evaluate the feasibility the proposed solutions can be implemented successfully[1]. A recommendation on where the facility should be located must also be made if a location wasn't already agreed as part of Phase 1.
    *c.* The Firm must deliver a high level production facility business case which covers the following: Estimated capital expense (CAPEX), operational expense (OPEX) and Cost of Goods (COGs) for the products to be made there, an explanation of the scope of the facility (capacity during pandemic and non-pandemic times, production steps and technologies to be employed), timeline for facility build and licensure and finally the economies of scale and internal operational considerations (facility utilization, product portfolio, etc) needed for the facility to be viable in both pandemic and non-pandemic times. A preliminary financial model including CAPEX, OPEX and COGs estimates should be created to detail the overall financial viability of the facility over the initial 5-10 years of operation.
    *d.* The Firm will participate in a series of meetings to keep the Steering Committee and Member States abreast of the findings of the pre-feasibility study as it is being conducted.
2. Co-develop, facilitate, and actively participate in workshops to define a strategic roadmap for implementing new vaccine manufacturing facility.
    *a.* A workshop will be held where the final recommended concept package for the new vaccine facility will be presented by the Firm to Member States for validation[2]. If the outcome of the pre-feasibility study is positive, the concept package will serve as the foundation of what will be used to engage potential financiers, technology transfer partners, facility design firms and other firms required for the project.

[1] Factors which could be used to gauge the feasibility a solution would work include but are not limited to: Firm's experience on other projects/case studies from similar situations, the degree to which it aligns with what Member states have already agreed to, ongoing discussions with Steering Committee members or Member States. The gap closure solutions will ultimately be pressure tested during Activity 9.
[2] This validation must also explicitly include at least preliminary approval of the incentives and support required for the facility from Member States or other organizations who must provide them.

*b.* The Firm will create a roadmap for the implementation of the approved facility concept package. The roadmap shall layout the steps required to progress from the end of the pre-feasibility study through to final facility project execution. It must also include a list of roles and responsibilities for the entities required to progress through this roadmap. A final workshop will be held for Member States to review and validate the roadmap.

3. Co-develop, facilitate, and actively participate in a public/private forum to socialize the results of pre-feasibility and discuss the roadmap
    *a.* Firm(s) shall present an overview of the roadmap and pre-feasibility and how they lead to the final recommendations which were approved by Member States.
    *b.* Forum attendees to provide feedback, pressure test the concepts and express willingness or ability to participate in such a cooperative agreement
    *c.* Forum attendees to include but are not limited to: representatives from Member States, the Bank, global health organizations (i.e., PAHO, WHO, CEPI, COVAX), local vaccine and pharmaceutical manufacturers and other actors in the local vaccine supply chain.

The services should be completed and accepted by the Bank on the third week of April 2022.

Firms who apply must have experience executing at least three projects with a value greater than $100,000 in the below areas. To demonstrate this experience, the Firm must provide a brief description of the relevant projects as well as 3 client references.

- Support and guidance to national governments on immunization, vaccine procurement or vaccine manufacturing policy; and/or
- Execution of vaccine manufacturing feasibility studies, including a financial model of the proposed facility, which assessed the various ecosystem factors detailed in the TOR below

The Firm must provide financial statements for the past three year which demonstrate the Firm's financial stability

Proposals from multiple Firms working in a Consortium or where a Firm will use sub-contractors must demonstrate that the various team members have worked together successfully on past projects.

The Firm must declare any potential vested interests or conflicts of interest with any ongoing vaccine manufacturing or related project in the LAC region

Eligible consulting firms will be selected in accordance with the procedures set out in the Inter-American Development Bank: *Policy for the Selection and Contracting of Consulting firms for Bank-executed Operational Work* - GN-2765-4. All eligible consulting firms, as defined in the Policy may express an interest. If the Consulting Firm is presented in a Consortium, it will designate one of them as a representative, and the latter will be responsible for the communications, the registration in the portal and for submitting the corresponding documents.

The IDB now invites eligible consulting firms to indicate their interest in providing the services described above in the draft summary of the intended Terms of Reference for the assignment. Interested consulting firms must provide information establishing that they are qualified to perform the Services (brochures, description of similar assignments, experience in similar conditions, availability of appropriate skills among staff, etc.). Eligible consulting firms may associate in a form of a Joint Venture or a sub-consultancy agreement to enhance their qualifications. Such association or Joint Venture shall appoint one of the firms as the representative.

Interested eligible consulting firms may obtain further information during office hours, 09:00 AM to 05:00 PM, (Washington D.C. Time) by sending an email to: Alejandra Radl (alejandrara@iadb.org) and a copy to Jaime Cardona (jaimecar@iadb.org) and Bill Savedoff (*wsavedoff@iadb.org)*

Inter-American Development Bank
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**TERMS OF REFERENCE**

*Consultancy to conduct a pre-feasibility study*

## 1. Background and Justification

***1.1.*** IDB's Regional Integration Unit (INT) and the Social Protection and Health Division (SCL/SPH) are seeking an international vaccine manufacturing expert to prepare a rapid vaccine supply diagnostic study to support a project aimed at generating capacities in the countries that integrate PROSUR[3] to produce vaccines for the attention of epidemiological events such as the COVID-19 pandemic.

***1.2.*** INT provides a wide-range of products to support the integration, trade and investment agenda of our region through: (i) the design, preparation and execution of an operational pipeline and portfolio of financial operations (loans, technical assistance, and operational inputs); (ii) support to strategic integration initiatives within the region and with external strategic partners in the Americas, Europe and Asia; (iii) support to the Public-Private development and integration agenda in the region (through initiatives such as Connect Americas, the Americas Business Dialogue and the organization of major international trade and investment fora); (iv) high-level policy dialogues and applied policy research on issues related to trade, investment and integration; and (v) expert technical assistance and capacity building.

***1.3.*** INT's Regional Integration Unit (RIU) is responsible for: (i) leading the Bank's work on strategic integration initiatives that require a multisector approach, enhancing synergies and ensuring the initiatives' progress and the involvement of the private sector; (ii) designing and implementing operations and technical assistance in the area of regional integration in collaboration with other Sectors and areas of the Bank; (iii) developing knowledge products in the area of regional integration; and (iv) strengthening the institutional capacity of relevant and multi-sector regional integration initiatives in Latin America and the Caribbean.

***1.4.*** The Social Sector (SCL) is a multidisciplinary team convinced that investing in people is the way to improve lives and overcome the development challenges in Latin America and the Caribbean (LAC). Jointly with the countries in the region, SCL formulates public policy solutions to reduce poverty and improve the delivery of education, work, social protection, and health services to citizens. The objective is to advance a more productive region, with equal opportunities for men and women, and greater inclusion of the most vulnerable groups.

***1.5.*** SPH is tasked with the preparation and supervision of IDB operations in borrowing member countries in the areas of social protection (safety nets and transfers and services for social inclusion which include early childhood development, youth programs, care services, among others), health (health capital investment strategies, health networks strengthening, health system financing, organization and performance, etc.), and nutrition.

[3] PROSUR is a mechanism and space for dialogue and cooperation of countries in South America, to advance towards a more effective integration.

***1.6.*** INT and SCL/SPH have been approached by countries that integrate PROSUR to work together on a project to generate capacities in the countries that integrate PROSUR to produce vaccines and other health technologies for the attention of epidemiological events. Colombia holds the pro tempore presidency of this mechanism, and is willing to devote resources from its Presidential Cooperation Agency – APC-, to be administered by the IDB, to create a strategic plan to enhance the region's capacities to produce vaccines. This consultancy will support the development of this project.

## 2. Objectives

- The objective of this consultancy is to develop a concept package for the construction or expansion of one or more vaccine production facilities which, if endorsed by Member States, will be used to engage potential financiers, technology transfer partners, facility design firms and other firms required to implement the project.

## 3. Scope of Services

1. Proposed new vaccine production facility pre-feasibility study.
    *a.* The Firm is to conduct a pre-feasibility study for the type of facility agreed upon in Phase 1. The study should identify enablers and barriers for the new facility to be able to operate in a sustainable manner. The assessment should include, but is not limited to:
        i. Key factors for internal production facility viability – Economies of scale to ensure competitive cost of goods, sustained demand during non-pandemic times to ensure the facility stays in a constate state of preparedness, means to ensure the facility can acquire the requisite human capital and know-how in its local workforce, a means to attract new products and technologies in order to build a portfolio of products for non-pandemic times and to ensure novel pandemic products are available for transfer to them during pandemic times, access to investment capital, a means to build a strong quality posture and proven track record for product launches and production outputs being met, etc.
        ii. Coherent Policy and Political will – offtake agreements or incentives needed, evaluation of immunization policy (i.e., target populations for recommended vaccines, public vs private immunization funding), how long will these agreements or incentives need to last and is there coherence at top levels of national and regional governments on this. This may also require a deeper dive than was provided during Activity 3 with regards to local vaccine market demand and procurement mechanisms.
        iii. Ownership structure – Ownership structure and governance which may be most beneficial for facility operation, especially during pandemic times when the need is highest and during non-pandemic times when funding may be tight.
        iv. Product Distribution – Are there any issues with the local distribution supply chains in the region which may preclude some vaccines or manufacturing locations from being used? For example, is there sufficient frozen cold chain to move mRNA vaccines around the region and provide sufficient access to everyone in need? If not, how will this be built, or do we need to consider products stable at higher temperatures?
        v. Innovation Landscape – potential sources of Tech Transfer for products to launch the facility, where will follow on products (Covid variants or other products post Covid) be developed, how to keep the facility's product pipeline full and the facility relevant and operationally ready, are there certain technology platforms or products which will lend themselves to be a more sustainable long-term investment. For example, are there potential non-pandemic uses for mRNA or viral vector facilities?

vi. Regional Trade – Deeper analysis of the gaps and potential solutions for procurement and regional trade policy reported during Phase 1. Also, are price preferences for local suppliers possible? What other market access incentives may be needed to entice innovators to localize production?

vii. Existing Physical Infrastructure – Are there existing brownfield pharma or vaccine facilities (human or veterinary) which would be well suited for this facility or would a greenfield be the best option given the choice of locations and local players?

viii. Finance – Sources of CAPEX and availability/stipulations, will this be regional, joint country or national based funding, what incentives are currently in place or need to be added, is there a private market for these products, what is the long-term financial sustainability of this project?

ix. NRA Strength – Current Maturity Level and experience with chosen technology of NRAs in potential locations, whether a level 3 or 4 (and possibly WHO PQ) is necessary and the potential time to achieve the desired NRA maturity level? How will this all affect the ease of approval for regional export (either PQ or similar standard required by pooled procurement mechanism of choice), speed of clinical trials and commercial registration? What is the local NRA or regional consensus on the level of clinical trials or bridging studies for various types of tech transfers?

x. Intellectual Property – any barriers or concerns there may be with regards to the technologies or partners which may be used in the project and if there are specific locations which are better suited from an IP perspective.

*b.* The Firm must then recommend potential solutions for these gaps, especially ones which can be effectively implemented by governments or through government support and evaluate the feasibility the proposed solutions can be implemented successfully[4]. A recommendation on where the facility should be located must also be made if a location wasn't already agreed as part of Phase 1.

*c.* The Firm must deliver a high level production facility business case which covers the following: Estimated capital expense (CAPEX), operational expense (OPEX) and Cost of Goods (COGs) for the products to be made there, an explanation of the scope of the facility (capacity during pandemic and non-pandemic times, production steps and technologies to be employed), timeline for facility build and licensure and finally the economies of scale and internal operational considerations (facility utilization, product portfolio, etc) needed for the facility to be viable in both pandemic and non-pandemic times. A preliminary financial model including CAPEX, OPEX and COGs estimates should be created to detail the overall financial viability of the facility over the initial 5-10 years of operation.

*d.* The Firm will participate in a series of meetings to keep the Steering Committee and Member States abreast of the findings of the pre-feasibility study as it is being conducted.

2. Co-develop, facilitate, and actively participate in workshops to define a strategic roadmap for implementing new vaccine manufacturing facility.

*a.* A workshop will be held where the final recommended concept package for the new vaccine facility will be presented by the Firm to Member States for validation[5]. If the outcome of the pre-feasibility study is positive, the concept package will serve as the foundation of what will be used to engage potential financiers, technology transfer partners, facility design firms and other firms required for the project. This concept package shall include:

i. A list of approved incentives and support that PROSUR Member States or other organizations will provide.

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[4] Factors which could be used to gauge the feasibility a solution would work include but are not limited to: Firm's experience on other projects/case studies from similar situations, the degree to which it aligns with what Member states have already agreed to, ongoing discussions with Steering Committee members or Member States. The gap closure solutions will ultimately be pressure tested during Activity 9.

[5] This validation must also explicitly include at least preliminary approval of the incentives and support required for the facility from Member States or other organizations who must provide them.

ii. A revised business case and other relevant scope items developed during the pre-feasibility study.

*b.* The Firm will create a roadmap for the implementation of the approved facility concept package. The roadmap shall layout the steps required to progress from the end of the pre-feasibility study through to final facility project execution. It must also include a list of roles and responsibilities for the entities required to progress through this roadmap. A final workshop will be held for Member States to review and validate the roadmap.

3. Co-develop, facilitate, and actively participate in a public/private forum to socialize the results of pre-feasibility and discuss the roadmap
    *a.* Firm(s) shall present an overview of the roadmap and pre-feasibility and how they lead to the final recommendations which were approved by Member States.
    *b.* Forum attendees to provide feedback, pressure test the concepts and express willingness or ability to participate in such a cooperative agreement
    *c.* Forum attendees to include but are not limited to: representatives from Member States, the Bank, global health organizations (i.e., PAHO, WHO, CEPI, COVAX), local vaccine and pharmaceutical manufacturers and other actors in the local vaccine supply chain.

## 4. Expected Outcome and Deliverables

Payment is contingent upon acceptance of final deliverables by the IDB. The selected firm should plan submission of draft deliverables into their work plan and timeline to meet expected timeframes. The selected firm is expected to submit the products from each deliverable in soft copy formats. Please see payment schedule below.

| **Deliverables** | **Timeline** | **Payment %** |
|---|---|---|
| • Pre-Feasibility Study Draft gap analysis complete on 10 main ecosystem areas (Activity 1A) | Month 2 | **20%** |
| • Pre-Feasibility Study Draft complete (Activities 1B, C and D) and submitted to Bank and Steering Committee for review and comment | Month 3 | **20%** |
| • Pre-Feasibility Concept package and Road Map completed following Workshops with Member States | Month 4 | **30%** |
| • Pre-Feasibility Concept Package and Road Map updated following Public Forum and submitted as a final product | Months 5 | **30%** |
| TOTAL | | **100%** |

## 5. Project Schedule and Milestones

Expected duration of the project is 5 months from signature of contract.

## 6. Reporting Requirements

Every report must be submitted to the Bank in a digital file in Spanish. If applicable, the report should include cover, main document, and all annexes. Zip files will not be accepted as final reports, due to Records Management Section regulations.

## 7. Acceptance Criteria

Upon submission, all deliverables will be reviewed by members of qualified staff from INT and SCL/SPH as well as external experts if deemed necessary. If the reviewers deem that the deliverables meet the requirements as stated in the TORs the product will be accepted.

**8. Other Requirements**

- Vaccine Manufacturing Technical Specialist
  - A minimum of 10 years working in the vaccine manufacturing industry ideally with experience at a multi-national vaccine production facility; experience working in LMICs or the LAC region is preferable
  - Must have a broad knowledge of the processes required to make vaccines from bulk drug substance through form/fill and packaging, preferably with experience executing facility construction and/or technology transfers projects
- Project Financial Modeler
  - A minimum of 10 years working with and building financial cost models for production facilities, preferably with some experience in the vaccine, pharmaceutical or healthcare industry
- Local Vaccine and Immunization Policy Expert
  - A graduate of a science or medical field with a minimum of 10 years working in the public health sector within the LAC region,
  - Must have direct experience working with national vaccines and immunization programs within the region, ideally with a good working knowledge of the various government and regional agencies involved in vaccine procurement and immunization policy
  - Must be resident in LAC and be fluent in English and either Spanish or Portuguese
- Legal and Trade Policy Specialist
  - A minimum of 10 years working in international trade law with direct experience conducting legal and regulatory due diligence of procurement and PPP mechanisms, preferably within the vaccine, pharmaceutical or healthcare industry
  - Ideally has experience structuring the legal aspects of PPPs such as: contracts, risk allocation, product intellectual property issues and technology transfer agreement
- Global Public Health and Vaccine Market Specialist
  - A minimum of 10 years working in the global public health sector and must have direct vaccines and immunization program experience
  - Must have broad knowledge of the global vaccines market landscape with respect to market and policy dynamics, key vaccine innovators and relevant global public health stakeholders
- Government Policy or PPP Specialist
  - A minimum of 10 years working in the PPP sector, ideally some experience in vaccine, pharmaceutical or healthcare related projects with experience in structuring PPP options
  - Should have a working knowledge of the legal and trade policy frameworks which may be relevant to PPPs with a regional remit

**9. Supervision and Reporting**

The work will be supervised Alejandra Radl who will provide comments and approve documents and reports, give any instructions for changes, as well as schedule periodic meetings for project assessment. It shall be Firm's responsibility for ensuring that such meetings are conducted, and such reports are submitted to the Bank.

**10. Schedule of Payments**

Payment terms will be based on project milestones or deliverables according to the schedule above in item "4".