



UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

GQSP Colombia/210814

Provision of a course on Quality Control Methods for Vaccines

1. Background

The United Nations Industrial Development Organization (UNIDO) is the specialized agency of the United Nations that promotes Inclusive and Sustainable Industrial Development (ISID) for poverty reduction, inclusive globalization and environmental sustainability. The mandate of UNIDO is to promote and accelerate inclusive and sustainable industrial development in developing countries and economies in transition. UNIDO's vision is a world where economic development is sustainable and economic progress is equitable.

One of the projects implemented by UNIDO is the Quality Programme for the Chemical Value Chain- GQSP Colombia funded by the Secretary of State for Economic Affairs of the Swiss Confederation (SECO), the Ministry of Commerce, Industry and Tourism of Colombia and Colombia Productiva.

The main objective of the project is to promote the integration of Colombia in the regional and multilateral trade systems, through the strengthening of the National Quality Subsystem within the framework of the priorities of ten (10) industrial groups that integrate the chemical value chain, and also to increase and improve the capacities of SMEs to meet technical requirements, international quality standards, private and sustainability standards, necessary for trade facilitation.

The project is being implemented over a four-year period and its interventions include the support to the National Institute of Food and Drugs Surveillance (Invima) to improve the processes conducted by the biologic products laboratory in compliance with international standards on quality control of vaccines. This purpose is covered by the product 1.3 of the GQSP Colombia logical framework:

<p>Product 1.3. The technical competencies of the entities responsible for Inspection, Surveillance and Control, such as INVIMA, the Superintendency of Industry and Commerce, the ICA, etc, are strengthened to improve the quality levels of the national chemical industry and facilitate compliance with national and international technical standards.</p>

To learn more about the project Global Quality and Standards Programme – GQSP Colombia, visit <https://gqspcolombia.org/>.

2. Scope of required service

The objective of the required service is the provision of a course to deepen the knowledge in quality control methodologies used by manufacturers of vaccines. This course will be offered to Invima's laboratories personnel.

- The contents of the course must include at least the following topics:
 1. Techniques and methodologies for quality control of vaccines,
 2. Experimental animals as biological reagents,
 3. Variability of the vaccines response in animals and by strains,
 4. Experimental design in animal experimentation,
 5. Methods of analysis in antigens characterization
 6. Immunological evaluation methods of antigens and antibodies
 7. Cellular evaluation methods of antigens and antibodies,
 8. Analytical methodologies validation for biological products with statistical analysis.
 9. Lethal Dose 50 (LD50) and Effective Dose 50 (ED50) in Biomodels for quality control of animal serum and/or vaccines.
- The course must be delivered on an online platform provided by the provider or agreed with UNIDO.
- The connectivity and quality of transmission through the technological platform will be the responsibility of the provider.
- The instructors/facilitators designated to deliver the course must demonstrate experience of at least 7 years in quality control of vaccines, verifiable through supporting documents.
- The provider must keep a record of attendance of all participants.
- A knowledge assessment at the end of the training is desirable but not mandatory.
- The provider must issue a certificate of approval to attendees who have completed the training program and the knowledge assessment. The certificates issued must include, in addition to the provider's logos, the UNIDO and GQSP logos. The use of the program's image must follow the guidelines of the GQSP Colombia once the contracting is official.
- The contractor will provide the necessary documentation and the memories of the course to all participants.
- The course will be developed in 60 hours. The distribution of the course hours can be agreed; however, it is preferred to schedule morning sessions.

- The course will be given to a limited number of participants previously selected by GQSP Colombia. The number of participants will be at least 20 people (Spanish speakers), with technical qualifications as bacteriologists, microbiologists, biologists, chemists, and pharmacists.
- The course must be taught in Spanish and the support material should be prepared in Spanish as well.
- Topic presentations, study cases and discussions should be included to facilitate the understanding of the academic content.
- The course content is expected to be delivered at intermediate-advanced level.
- The content of the course should consider that the Laboratory personnel will need to deepen knowledge for the evaluation of the summary protocols for vaccines manufacture, submitted by manufacturers. These protocols include quality control techniques for vaccines, as well as techniques for the evaluation of new products such as RNA vaccines and with viral vectors.

At the end of the training, the participants will fill out an evaluation of the event. The information collected will be an input for the provider to fill out the activity report or results report, according to the format provided by UNIDO. The report must be sent within the following 10 business days after the end of the training, via email to f.hernandezperez@unido.org y l.pinedavelandia@unido.org

The selection of the eligible proposal will comprehensively contemplate the **facilitator's** experience, the quality of the technical proposal and the comparative evaluation of the economic proposal.

3. Description and General Time Schedule

All activities/deliverables shall be finalized and all stated payment supporting documents shall be submitted to UNIDO no later than 31 December 2021. Estimated time frame for activities to be delivered is October – November 2021.

Following activities/deliverables are expected from the bidder:

Main Activities	Deliverables	Expected duration
Launch meeting Before the planned course, the provider meet UNIDO / GQSP technical team in order to clarify	Meeting report	1 hour

concerns and approve the detailed work schedule. It can be done through a video call.		
Training documentation Before the course, the provider must send UNIDO / GQSP team the academic material that will be used in the course program.	Training documentation	At least 5 working days before the training
Technical test Prior to the online training, the trainer makes an appointment with UNIDO/ GQSP team to test the technical processes.	Technical test	At least one working day before the course
Online course It should be delivered according to the planned and approved program and content.	Online course	60 hours
Final Report It should include a description of the activities developed, the result of knowledge assessment obtained by the attendees and recommendations.	Final report	Before 10 working days after course completion
Additional documents See numeral 2. Scope of required service	List of attendees Participants certificates Satisfaction Surveys	Before 10 working days after course completion

All request documents should be provided to the UNIDO Project Management Unit (PMU) in electronic copy, consisting of the following electronic files:

- PDF file
- Original work files (Word, Power point, Excel, etc.)

Requested reports should be provided in Spanish.

4. Language requirements

The course as well as all communication with UNIDO PMU, will be in Spanish.

5. Payment terms

Payment will be subject to compliance per the concept of UNIDO

Deliverable	Documents required for a payment to be processed	Payment
✓ Launch meeting report ✓ Training documentation ✓ Successful technical test	✓ Purchase Order countersigned ✓ Launch meeting report ✓ Training documentation ✓ Relevant invoice	50%
✓ Online course ✓ Participants certificates ✓ Final report	✓ Participants certificates ✓ Final report ✓ Relevant invoice	50%
Total		100%

Payments will be payable within 30 days upon receipt and acceptance of deliverable and invoice (electronic version) indicating the contract number and instalment requested.

Any suggestion from the bidder over the payment terms must be reviewed and accepted by the Project Management Unit (PMU).

6. Qualification Requirements

Following are qualification requirements for bidder's technical offer to be considered:

- **Corporate registration:** The bidder should provide a certified copy of their Certificate of Incorporation or other documents setting forth the legal basis of the company and therefore proving a legal capacity to enter into a contract. For Colombian companies: Commercial Registration and current legal representation (no more than 30 days) and RUT.
- **Technical Proposal:** Taking as a reference the main activities described in scope of the service, the bidder must clearly specify the methodology to be implemented including details or descriptions of each activity as well as execution dates.
- **Facilitator:** The bidder must present the facilitator assigned for the activity, attaching his/her resume.
- **Commercial proposal:** It must include a value for each activity to be carried out that includes all the expenses incurred to fulfill and carry out all the activities necessary for the presentation of the final deliverables such as travel expenses, when apply, and experts' fees.

7. Evaluation Criteria

Proposals will be evaluated according to the following criteria:

Evaluation Criteria	Description
Technical proposal	The bidder should submit a technical proposal in compliance with the Terms of Reference
Facilitator(s) experience	The instructors/facilitators designated to deliver the course must demonstrate experience of at least 7 years in the quality control of vaccines, verifiable through supporting documents
Commercial proposal	The bidder should submit a commercial proposal that includes the cost per activity and the total offer cost.

Evaluation of technical criteria, and therefore a decision whether an offer is considered technically compliant, will be done according to the compliance or non-compliance against the stated requirements in this TOR

8. Submission of offers

Bidder's offer should be submitted per e-mail addressed to info@ggspcolombia.org together with the documentation above, indicating in the subject of the email "Quality Control Methods for Vaccines, course proposal" by **22 September 2021 at 23:59 Colombian Time**.

- All questions about this bid should be sent to info@ggspcolombia.org no later than closure deadline.

UNIDO General Terms and Conditions of Contract (Annex A).

The contract shall be awarded to the qualified bidder whose Technical Proposal has been found substantively responsive and whose Commercial Proposal is the lowest cost to UNIDO.