UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

GQSP Colombia/ 210814

Provision of an online course on Good Laboratory Practices according to World Health Organization technical reports

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 a project 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 pharmaceutical and microbiological analysis laboratories in compliance good laboratory practice (GLP). This purpose is covered by the product 1.3 of the GQSP Colombia logical framework:

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.

2. Scope of required services

The objective of the required service is to contract a course of Good Laboratory Practice (GLP) according to the World Health Organization (WHO) Technical Report Series, 44th and 45th reports, regarding quality control and pharmaceutical microbiology national laboratories.

- The course must be delivered on an online platform provided by the contractor or agreed with UNIDO. This course will be offered to Invima´s laboratories personnel.
- The connectivity and quality of transmission through the technological platform will be the responsibility of the contractor.
- The instructor or facilitator designated to deliver the course must demonstrate experience of at least 10 years working on GLP based on WHO reports, verifiable through supporting documents.
- The contractor must keep a record of attendance of all participants.
- The contractor must issue a certificate of participation to attendees who have completed the training program. The certificates issued must include, in addition to the contractor'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 bidder must present a distribution of the sessions in the proposal and it can be agreed.
- The course will be given to at least 36 participants, Spanish speakers, previously selected by GQSP Colombia and Invima.
- The course must be taught 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 GLP.
- The contents of the course will be considered at intermediate-advanced level and must include at least the following topics:

  1. GLP based on the 44th WHO report

  - Organization and management
  - Quality management system
  - Documents control

- Records
- Data processing equipment
- Personnel
- Facilities and infrastructure
- Equipment, instruments and other devices
- Contracts
- Reagents
- Reference substances and reference materials
- Calibration, performance verification and qualification of equipment, instruments and other devices
- Traceability
- Entry of samples
- Analytical worksheet
- Validation of analytical procedures
- Essays
- Evaluation of the test results
- Analysis certificate
- Retained samples
- General rules

2. GLP applicable to microbiology laboratories, based on the 45th WHO report

- Personnel
- Environment
- Validation of test methods
- Equipment
- Reagents and culture media
- Reference materials and reference cultures
- Sampling
- Handling and identification of samples
- Quality assurance of results and performance quality control
- Test procedures
- Test reports
- Infrastructure and workflow
- Air system, area classification and air flow.

3. Tests Out of Specification (OOS)

- How to handle an out of specification result in microbiological and physicochemical tests
- Investigation of OOS results (obvious error, assignable cause)
- Proposal and resolution of Hypothesis Tests (Phase II of OOS)
- Non-compliant test work
- Re-analysis of the sample (Requirements and cases)

- The content must delve into technical annexes cited in the reports related to the air system and workflow in the laboratory and the master plan of validations (including generalities of software validation and its interrelation with Audit trail).
- With regard to the microbiology and biological products laboratory, it is expected to have few hours to delve into issues of uncertainty in general methodologies and vaccine potency/strength tests with practical exercises.
- The distribution of the content should be considered as follows: 1) module of generalities applicable to microbiological, physicochemical and biological analysis laboratories (approximately 10 hours); 2) specific module for topics related to the microbiology and biological laboratory (approximately 30 hours); and 3) module for topics related to the physicochemical analysis laboratory (approximately 20 hours).

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 contractor 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. Deliverables and General Time Schedule

All activities/deliverables shall be finalized and all stated payment supporting documents shall be submitted to UNIDO no later than 30 November 2021. Estimated time frame for activities to be delivered is September – Early October 2021.

Following activities/deliverables are expected from the bidder:

Main Activities	Deliverables	Expected duration
Launch meeting Before the planned course, the contractor meet UNIDO Project Management Unit (PMU) in order to clarify concerns and approve the detailed work schedule. It can be done through video call.	**Meeting report**	1 hour
Training documentation Before the course, the contractor must send UNIDO / GQSP team the academic material that will be used in the course program.	**Training presentations**	At least 5 working days before the training
Technical test Prior to the online course, 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 additional material to share with the attendees and participants' certificates.	**Final report** **Participants´ certificates**	Before 10 working days after course completion
Additional documents See numeral 2. Scope of required service	**List of attendees** **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 ✓ Delivery of participants' certifications ✓ Activity 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.

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/consultant:** 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:

Technical criteria:

Evaluation Criteria	Description
Technical proposal	The bidder should submit a technical proposal in compliance with the Terms of Reference, including a detailed methodology and the action plan.
Facilitator experience	The bidder should be able to evidence relevant experience of the designated facilitator of at least 10 years in GLP in Colombia and/or Latin America, according to WHO Technical Reports, providing his/her CVs and related supports
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 Terms of Reference.

Commercial criteria:

Bidders should note that only technically compliant offers/proposals should be further considered for commercial evaluation.

The financial offer should contain all costs involved to perform the required services to comply with the object of this Terms of Reference.

8. Submission of offers

Bidder´s offer should be submitted per e-mail addressed to info@gqspcolombia.org together with the documentation above, indicating in the subject of the email "Good Laboratory Practices course proposal" by **08September 2021 at 23:59 Colombian Time**.

All questions about this bid should be sent to info@gqspcolombia.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.