



TERMS OF REFERENCE

GQSP Colombia/ 210404

To contract an online Audit Trail Review course

1. Background

The United Nations Industrial Development Organization (UNIDO) is the specialized agency of the United Nations that promotes industrial development for poverty reduction, inclusive globalization and environmental sustainability. The mission of UNIDO, as described in the [Lima Declaration](#) adopted at the fifteenth session of the UNIDO General Conference in 2013, is to promote and accelerate [inclusive and sustainable industrial development](#) (ISID) in Member States. The relevance of ISID as an integrated approach to all three pillars of sustainable development is recognized by the 2030 Agenda for Sustainable Development and the related Sustainable Development Goals (SDGs), which will frame United Nations and country efforts towards sustainable development in the next fifteen years. [UNIDO's mandate is fully recognized in SDG-9](#), which calls to “Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation”. The relevance of ISID, however, applies in greater or lesser extent to all SDGs. Accordingly, the Organization’s programmatic focus is structured in four strategic priorities: [Creating shared prosperity](#); [Advancing economic competitiveness](#); [Safeguarding the environment](#); and [Strengthening knowledge and institutions](#).

Each of these programmatic fields of activity contains a number of individual programmes, which are implemented in a holistic manner to achieve effective outcomes and impacts through UNIDO’s four enabling functions: (i) technical cooperation; (ii) analytical and research functions and policy advisory services; (iii) normative functions and standards and quality-related activities; and (iv) convening and partnerships for knowledge transfer, networking and industrial cooperation. Such core functions are carried out in Departments/Offices in its Headquarters, Regional Offices and Hubs and Country Offices.

The Directorate of Digitalization, Technology and Agri-Business (DTA), headed by a Managing Director, coordinates and mainstreams the Fourth Industrial Revolution (4IR) in its technical cooperation, strategic, normative activities aiming at fostering the inclusive and sustainable development in the era of 4IR. The Directorate creates new and innovative technical cooperation deliverables in the areas of trade, investment, technology innovation and agro-



industry and agri-business. The Directorate comprises the Department of Digitalization, Technology and Innovation (DTI) and the Department of Agri-Business (AGR).

Responding to the growing demand for supporting inclusive and sustainable industrial development (ISID) in the era of the new industrial revolution, the Department of Digitalization, Technology and Innovation (DTA/DTI) leads the way in addressing opportunities, challenges and risks stemming from the fourth industrial revolution (4IR) and its contribution to sustainable socio-economic progress. The Department is responsible for the strategic coordination of 4IR-related matters with designated focal points in other technical Departments and organizational entities of UNIDO, as appropriate. In consultation with public and private partners, DTI designs and implements holistic interventions that are tailored to specific country needs. The Department's interventions actively identify and combine complementary services from across three Divisions, namely:

- Innovation and Digitalization Division (DTA/DTI/IDD)
- Investment and Technology Promotion Division (DTA/DTI/ITP)
- Quality Infrastructure and Smart Production Division (DTA/DTI/QIS)

The Quality Infrastructure and Smart Production Division (DTA/DTI/QIS) seeks to build national and regional quality infrastructure systems needed to provide internationally recognized services, including strengthening institutional capacities (i.e. metrology, standardization and accreditation); building conformity assessment capacities (testing, inspection, certification, calibration, etc.); supporting small and medium enterprises (SMEs) to take advantage of new technologies and standards for smart production and thus participate in global value chains; trade facilitation and promoting quality awareness with the public sector, economic operators and consumers.

Global Quality and Standards Programme - GQSP Colombia

Quality Program for the Chemical Chain

Within the framework of the Global Quality and Standards Programme – GQSP, signed between UNIDO and SECO, which objective is to strengthen the quality infrastructure in prioritized countries, and increase the capacity of compliance with requirements and quality standards of SMEs in strategic sectors; and in coordination with the Ministry of Commerce,



Industry and Tourism, UNIDO implements in Colombia, the Quality Program for the Chemical value Chain – GQSP Colombia.

Its general objective as a GQSP country project and aligned with the objective of GQSP Global, 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 with international standards on data integrity. 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. Objective

Contract a course on international regulations and methodology for applying Audit Trail Reviews of data generated during the manufacturing and quality control of pharmaceutical products. This course will be offered to Invima's laboratories personnel.

3. Scope and specifications

- The course must be delivered on an online platform provided by the contractor or agreed with UNIDO.
- 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 3 years teaching this type of course, verifiable through supporting documents.
- The contractor must keep a record of attendance of all participants and will have to carry out a knowledge assessment at the end of the training.
- The contractor 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 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 1 session of 8 hours. However, another distribution can be agreed.
- The course will be given to a limited number of participants previously selected by GQSP Colombia. The number of participants will be a maximum of 20 people (Spanish speakers).
- Offer the course in Spanish is considered an advantage. If an interpreter English – Spanish is required, he/she will not be count as part of the participants.
- Topic presentations, study cases and discussions should be included to facilitate the understanding of Audit Trail Reviews to conduct them effectively.
- The contents of the course must include at least the following topics:
 1. Regulatory requirements for audit trail review
 2. Guidance documents for audit trail review
 3. Audit trail content and methodologies
 4. Audit trial vs. System Log
 5. Monitoring GMP-relevant data
 6. Laboratory and QA examples of GMP relevant data
 7. Review of Audit Trail Entries
 8. Technical Controls to Review of Audit Trails.

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.

4. Description of activities and deliverables

In accordance with the description of numeral 3 Specifications of the required service, the proposal must consider the following activities and deliverables for the course (after the signing and legalization of the contract), for the fulfillment of the objective:

Main Activities	Outputs	Expected duration
Launch meeting Before the planned course, the contractor meet UNIDO / GQSP technical team 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 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	8 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 3 Specifications of the required service	List of attendees Satisfaction Surveys	Before 10 working days after course completion

5. Deliverables and payments

Payment will be subject to compliance per the concept of UNIDO

Deliverable	Payment
✓ Launch meeting report ✓ Training documentation ✓ Successful technical test	50%
✓ Online course ✓ Delivery of participants certifications ✓ Activity final report	50%
Total	100%

6. Minimum Requirements of the Proposal

A detailed proposal in line with the presented terms of reference is expected. The proposal must be submitted in detail with all relevant information that is considered important for an objective evaluation.

The proposal must contain at least:

Bidder cover letter: In which the proponent introduces the company, its services and any relevant information. Moreover, the bidder should mention that: “accepts that the presentation of the proposal implies understanding of the conditions and obligations established in this term of reference”



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.

Economic 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.

UNIDO, as an agency of the UN system, is granted full tax exemption

7. Evaluation Criteria

Offers will be evaluated based on compliance with the terms of reference and the following criteria.

Evaluation Criteria
Cover letter
Technical proposal
Facilitator resume
Economic proposal

8. Legal aspects

- **Deliverables:**

All deliverables must be sent to UNIDO Project Management Unit, who will review them prior to approval.

- **Payment terms:**

The payment of the services will be made according to the plan established in the contract, not less than 30 calendar days after each delivery approved by the Management Unit of the GQSP and after the project manager's approval.

- **The legal status of UNIDO:**

The terms of reference shall respect UNIDO's legal status as an intergovernmental organization of the United Nations system exempt from taxation. Nothing in this document



or relating to it shall be deemed to be a waiver, express or implied, of any of the privileges and immunities of UNIDO. Additional conditions may be expressed in the service terms of reference.

- **Compensation:**

The Terms of reference shall relieve UNIDO of any liability, claims, costs, and commitments arising from intellectual property or other disputes arising under this document or resulting from the Terms of reference's acts or omissions, its agents, or officials.

- **Confidentiality of information**

The terms of reference shall keep the UNIDO Global Quality and Standards Programme (GQSP) informed and shall consult on matters of common interest which, in its judgment, will benefit the performance of the terms of reference. All information that UNIDO submits to the Terms of reference or obtained as a result of the work with the beneficiary of the service is considered confidential unless indicated otherwise. The Terms of reference shall implement the necessary provisions to safeguard the confidentiality and restrictiveness of the information, documents, and queries that are made in the development of the terms of reference and the presentation of the offer.

- **UNIDO General Terms and Conditions**

The bidder chosen must comply with the UNIDO general terms and conditions for services (Annex A).

IMPORTANT:

1. It is not recommended to deviate from the Terms of Reference.
2. However, any additional alternative must be explicitly agreed between UNIDO and the contractor company.
3. Any inquiry about the present Terms of Reference must be sent to info@gqspcolombia.org before process deadline.
4. The technical and economic proposal must be sent to info@gqspcolombia.org together with the documentation above, indicating in the subject of the email "Audit Trail course proposal". Deadline for submitting the proposal and requested documentation: **April 23rd 2021**