

## UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

# TERMS OF REFERENCE FOR PERSONNEL UNDER INDIVIDUAL SERVICE AGREEMENT (ISA)

Title:	National Regulatory Affairs Consultant (NRAC)		
Main Duty Station and Location:	UNIDO Office. Bogota, Colombia		
Mission/s to:	As required		
Start of Contract (EOD):	o1 September 2020		
End of Contract (COB):	30 December 2020		
Number of working days	40 working days (WAE)		
Project:	180283-Quality Programme for the Chemical Value Chain		

### **ORGANIZATIONAL CONTEXT**

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 mandate of UNIDO is to promote and accelerate inclusive and sustainable industrial development in developing countries and economies in transition.

The Programme Development and Technical Cooperation (PTC) of UNIDO is responsible for providing technical cooperation services on technological and economic issues and is organized in the following departments: Department of Partnerships and Results Monitoring, Department of Agri-Business Development, Department of Trade, Investment and Innovation, Department of Energy and Department of Environment. Furthermore, PTC has a close cooperation with other field based Centers and Offices, such as the Investment and Technology Promotion Offices, forming the extended field network of UNIDO.

The Department of Trade, Investment and Innovation (TII) supports countries in their efforts to develop through trade, investment and innovation the potential of the manufacturing sector to drive socio-economic progress. The Department is responsible for assisting countries to strengthen competitiveness in global markets through capacity building in quality, environmental sustainability, and social accountability requirements in accordance with international management system standards and private sector requirements. It supports the establishment

of linkages between producers/processors in developing countries and local, regional and global value chains (retailer, manufacturers) by developing capacities in the area of product quality.

## **PROJECT CONTEXT**

In order to consolidate UNIDO/SECO interventions on trade standards compliance within one tool, adding the benefit of a global component facilitating synergies and enhancing coherence among the interventions, UNIDO and SECO have developed a coherent programmatic approach: the Global Quality and Standards Programme (GQSP). The GQSP supports selected countries to align the demand for and supply of quality services required to prove and verify the quality of products. It will have two components (1) Global Knowledge Management (C1) and (2) Country Projects.

The project "Quality Programme for the Chemical Value Chain" has been developed to be considered under component 2 and its overall objective is to foster Colombia's integration into the regional and multilateral trading systems, through the strengthening of the National Quality Subsystem (SICAL) within the framework of the priorities of the 10 industrial groups that compose the Chemical Value Chain and the increase and improvement of MSME's capacities to comply with technical requirements, international quality, private and sustainability standards required for trade facilitation. The project includes three complementary outcomes that are aligned to the Global Quality and Standards Programme (GQSP), to be implemented over a period of four years:

Outcome 1: The sustainability and technical competence of the National Quality Subsystem SICAL are improved in the relevant areas to strategic sectors of the Chemical Value Chain to improve its competitiveness and favorize its access to new markets.

Outcome 2: The capacity of the MSMEs of the Chemical Value Chain to comply with technical regulations, international quality, private and sustainability standards is enhanced.

Outcome 3: The awareness for quality is enhanced for the improvement of quality and competitiveness.

### **FUNCTIONAL RESPONSIBILITIES**

The results of the consultancy of the National Regulatory Affairs Consultant (NRAC) will cover mainly, but not limited to outcome 1 and outcome 3, in particular those activities related to the enhancing of technical competences of the entities responsible for Inspection, Surveillance and Control such as INVIMA; to support national entities to improve its legal and regulatory framework according to the best international practices and to support the development of a national catalogue of qualifications to close the gaps between supply and demand of competences in quality-related topics in the Chemical Value Chain.

The NRAC will conduct his/her activities under the supervision of UNIDO's PTC/TII/SQI Project Manager, and under the coordination of the Project Management Unit (PMU), led by the National Technical Coordinator (NTC) and the National Quality Specialist (NQS). In addition, the NRAC should collaborate with other consultants to ensure integrated and coherent activities contemplated in the production of other related outputs.

Main duties	Expecte d duration	Location	Expected results
Provide substantive advice on questions related to the strengthening of national institutions (with regulatory/surveillance functions linked to the pharmaceutical and chemical sectors), formulation of public policies related to the establishment of technical regulations and the improvement of Inspection, Surveillance and Control activities.	Entire duration	UNIDO Country Office. Bogotá, Colombia	Advice provided Substantive working documents prepared. Aid memoires
Advice and support the execution of detailed work plans aimed at the strengthening of technical capacities of national institutions in charge of regulation / surveillance functions (related to pharmaceutical and chemical			Work plans established, updated, approved and Monitored
sectors), under the guidance of the PMU and in close coordination with relevant institutional Stakeholders.			Progress reports approved
Advice and support the execution of work plans to develop a national catalogue of qualifications to close the gaps between supply and demand of competences in quality-related topics in the Chemical Value Chain, under the guidance of the			Work plans established, updated, approved and Monitored
PMU and in close coordination with relevant institutional Stakeholders.			Progress reports approved
Establish and maintain relations and exchange of information with local authorities and other partners under the guidance of the PMU.			Effective relationships ensured between actors
Organize the execution of technical working groups, technical events, trainings and other related activities			Attendance lists and documents (presentation, photos, training material, acts, aid the memoire)

Provide technical assistance for the formulation of technical documents (e.g. guides, standards, articles, reports).

Support the implementation of the training program aimed at the strengthening of technical capacities of national institutions

Collaborate in the preparation and execution of training programs aimed at enhancing the technical competence and know-how of the national institutions, enterprises and related stakeholders.

Identify resources and requirements for the implementation of the technical assistance programmes and training programs (experts, logistic needs, etc.).

Identify in detail the nature of international and national expertise required in consultation with relevant national counterparts and under the guidance of PMU

In consultation with the NTC, support the preparation of technical specifications for the purchasing of equipment and services, if deem necessary.

Assist the preparation and execution of technical study tours, working groups, awareness events and other related activities.

Support the PMU in the day-to- day operations and monitoring of project activities.

Ad-hoc requests: Any other assignments related to a timely and effective implementation of the project as requested by the TL/PM.

Technical documents, acts, aide-memoires drafted and approved

Detailed activity reports approved

Training plan, training curricula, lists of participants, evaluation prepared.

Detailed budgets and plans prepared and approved

Profiles of necessary expertise identified, draft job descriptions prepared.

Specifications documents and terms of reference as required

Plans, progress reports submitted and approved, list of participants/photos collected and saved for future purposes.

Reports of the monitoring and strategic activities of the Quality Programme for the Chemical Value Chain

## MINIMUM ORGANIZATIONAL REQUIREMENTS

#### Education

• Bachelor's Degree in Chemistry or Life Sciences (preferably Pharmaceutical Chemist). Advanced university degree in Sciences, Economy, Management or Administration with solid knowledge in regulatory affairs at pharmaceutical and chemical industries and national authority's relationship.

## Experience:

- At least five years of practical experience in institutions or private sector companies
  working in regulatory affairs at pharmaceutical and chemical industries. Experience
  working in national authorities will be added advantage.
- Strong grasp of the policymaking process at national and regional levels
- Strong planning, strategizing, managing, monitoring, scheduling skills.
- Excellent strategic, networking skills to build effective relationships
- Administrative and computerized abilities are required and preferably in an international environment.

## Languages

- Fluency in written and spoken Spanish and English is required.
- Fluency or working knowledge of another official UN language will be considered an asset.

## **REQUIRED COMPETENCIES**

### Corporate Competencies:

- Promotes the vision, mission and strategic goals of UNIDO;
- Displays cultural, gender, religion, race, nationality, and age sensitivity and adaptability.

### **Functional Competencies:**

- (1) Technical knowledge:
  - Demonstrates a thorough understanding of the issues and challenges related to the NQI;
  - Exhibits a good knowledge of institutional development and capacity building issues.

## (2) Development and Operational Effectiveness:

- Ability to lead and contribute to strategic planning, change processes, results-based management, work planning, and reporting;
- Ability to formulate and manage budgets, oversight of implementation, monitoring and evaluation of development projects;
- Ability to apply development theory to the specific country context to identify creative, practical approaches to overcome challenging situations;
- Ability to implement new systems and effect behavioral and attitudinal change.

## (3) Knowledge and Information Management and Learning:

- Facilitates knowledge and information sharing and learning culture;
- Actively works towards continuing personal learning and development in one or more practice areas, acts on learning plan and applies newly acquired skills.

## (4) Management and Leadership:

- Builds strong relationships with stakeholders and clients, focuses on impact and results for clients, and respond positively to feedback;
- Ability to establish effective working relations in a multicultural team environment;
- Excellent interpersonal skills;
- Consistently approaches work with energy and a positive, constructive attitude;
- Demonstrates strong oral and written communication skills;
- Demonstrates capacity to communicate effectively; resource management; capacity to plan and organize programmes effectively;
- Demonstrates resourcefulness, initiative and mature judgment;
- Demonstrates openness to change and ability to manage complexities;

## Core values:

- 1. Integrity
- 2. Professionalism
- 3. Respect for diversity

## Core competencies:

- 1. Results orientation and accountability
- 2. Planning and organizing
- 3. Communication and trust
- 4. Team orientation
- 5. Client orientation
- 6. Organizational development and innovation