West African Health Organization (WAHO)

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Project for the Development of the Pharmaceutical Industry in the ECOWAS Region

CALL FOR EXPRESSION OF INTEREST
(CONSULTANCY FIRM)

Service: Consulting Firm to Mentor National Medicine Regulatory Authorities and their Pharmaceutical Quality Control Laboratories on quality management and ISO 9001 Certification.

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1. The outbreak of the Ebola virus disease in 2014 and COVID-19 pandemic in 2020 reinforced the urgency for ECOWAS member states to strengthen their pharmaceutical industry, improve the business environment to boost local production of essential medicines as well as reduce its dependency on global value-chains for medical supplies and build resilience in the sector. The Project of Development of the Pharmaceutical Industry (DPI) Industry is a regional undertaking conceived to support ECOWAS pharmaceutical institutions, including the Medicines Regulatory Authorities (MRAs), quality control laboratories, and regional pharmaceutical training institutions. This project is supported by the African Development Bank and aim to strengthen the pharmaceutical sector to boost local production of safe, quality, and affordable medicines and vaccines in the ECOWAS region to meet the healthcare services and needs of the population.

2. An effective Quality Management System (QMS) enables National Medicine Regulatory Authorities (NMRAs) to standardize their procedures, boosting efficiency, transparency, and documentation. The benefits extend beyond faster market entry for new products to include safeguarding public health. By ensuring access to high-quality, regulated medicines, a robust system protects populations from the dangers of unregulated supplies. Furthermore, the existence of certified quality control laboratories to support regulatory functions also impact positively on the capacity of a NMRAs to provide effective oversight and restrict the circulation of substandard and falsified products. So, securing ISO certification requires expert guidance; therefore, a consulting firm is required **to mentor National Medicine Regulatory Authorities and their Pharmaceutical Quality Control Laboratories on quality management and ISO 9001 Certification.**

3. The consulting firm will be responsible for coaching targeted National Medicine Regulatory Authorities and their respective pharmaceutical quality control laboratories to develop, implement, and improve their QMSs, based on the principles of applicable ISO requirements and WHO guidance on implementing quality management systems for national regulatory authorities and Good Practice for pharmaceutical quality control laboratories. The consulting firm will work closely with NMRAs and national quality control laboratories, under the general supervision of the DPI Project Coordinator, Director of the Department of Public Health and Research (DSPR) and the

Director of the Department of Health Planning and Information (DPIS). The consulting Firm will perform the following tasks:

- Conduct a preliminary assessment of the level of implementation of the QMS using the results of the WHO self-assessment (when available) and submit report.
- Validate the prioritization of QMS requirements, timelines, responsibilities, and authorities with targeted institution staff, through collection of input and feedback to promote ownership of QMS implementation.
- Consolidate the feedback and input into an activity/ action plan, as a roadmap for QMS implementation for the and submit plan.
- Provide all required training on requirements and other related processes to help the organization in implementing QMS requirements and/or obtaining ISO 9001certification.
- Assist in the development of all mandatory procedures as required by WHO guidelines.
- Offer close guidance in the preparation and review of final documents prior to the application for certification.
- Guide the targeted institution team in applying for ISO 9001 certification.

4. The assignment will be implemented over a period of 120 days starting from the signing of the contracts and will require approximately **120 man-days**. The consulting firm will work with 8 NMRAs and their respective quality control Laboratory (1. Benin 2- Cabo Verde 3- Côte d'Ivoire 4- Guinea 5- Liberia 6- Sierra Leone 7- The Gambia and 8-Togo). The West African Health Organization (WAHO) invites consultancy firm to submit their applications to provide the services described above. Interested and qualified consultants/agency must provide information on their capacity and experience demonstrating that they are qualified for the assignment. The consultant/agency **firm must meet the following profile:**

- Have completed at least two similar assignments/experiences in the last ten (10) years in providing technical assistance in ISO 9001 QMS certification.
- Ensure the provision of consultancy services in the 3-official language of ECOWAS member states.
- Extensive and proven combination of skills and expertise in the field of ISO certification, with expertise related to 9001certification gained through previous experience of similar work in or outside the ECOWAS region.

5. The expressions of interest or applications must include the following documents:

- A letter of interest addressed to the Director General of the West African Health Organization (WAHO).
- A presentation of the firm (date of creation, country of origin, geographical address, organization, etc.) accompanied by proof of its legal existence (copy of the commercial register and/or statutes).
- A table presenting references for similar missions/experience (assistance in developing a QMS roadmap towards ISO certification, including ISO 9001, highlighting the following minimum information for each mission: (i) the purpose and content of the assignment, (ii)

the name of the project, (iii) source of funding (iv) the name, address and contact details of the client commissioning the assignment, (v) the country in which the assignment was carried out, (vi) the year of completion, including the start and end dates of the assignment, (vii) the contract amount, (viii) the list of key experts who carried out the assignment, as well as any relevant information about the assignment carried out.;

- Certificates of satisfactory performance or certificates attesting to the successful completion of services.
- For consultants working in a consortium: A consortium agreement relating to the subject matter of the assignment, duly drawn up and signed by each member of the consortium and designating the lead member of the consortium authorized to act on behalf of and for the account of the consortium.
- Presentation and organization of the permanent staff, with details of the current position held in the company's organization chart (this does not include the key personnel required in the ToR).

6. The consultancy firm will be selected based on the quality and cost-based selection method (SBQC) in accordance with the Procurement Operations Manual of the African Development Bank.

7. The eligibility criteria, shortlisting and selection procedure will be in accordance with the Procurement Framework for Operations Financed by the Bank Group, October 2015 edition, which is available on the Bank's website at: http://www.afdb.org.

8. The detailed selection criteria are as follow:

- Experience in technical assistance to states/institutions in developing roadmaps for ISO certification in general over the last 10 years: 30 points.
- Capacity to ensure the provision of consultancy services in the 3-official language of ECOWAS member states: 40 points.
- Experience in technical assistance to states/institutions in developing roadmaps for ISO 9001 QMS certification in the ECOWAS region over the last 10 years: 20 points.
- Presentation of experienced permanent staff with a view to fulfilling the mission, with details of their current position within the company :10 points.
- In the event of a tie, preference will be given to the consultant with more experience in technical assistance to states/institutions in developing roadmaps for ISO 9001 QMS certification.

9. Information, deadline, and address for submission of applications

- Interested and qualified consultancy firms may also obtain further information on the reference documents from the email addresses below, during working hours from Monday to Friday from 09:00 to 17:00 at the following addresses:
- This notice will be published on the ECOWAS website, the WAHO website https://data.wahooas.org/tenders/tenders/list, and by the WAHO focal points in each of the 12 countries (websites of the ministries in charge of health).
- Interested parties may access and download the terms of reference and the notice of expression of interest from the ECOWAS and WAHO websites at the following address: https://data.wahooas.org/tenders/tenders/list
- Interested and qualified consultancy firms are invited to express their interest by submitting their files electronically to the following addresses: https://data.wahooas.org/tenders/tenders/list
- The deadline for receipt of expressions of interest is **January 09, 2026**, at **12:00 GMT**.
- The client will not be responsible for any costs or expenses incurred by the consultant in connection with the preparation or submission of the EOI.

Dr Melchior Athanase J. C. AÏSSI
Director General

Project of the Development of the Pharmaceutical Industry in the ECOWAS Region

Recruitment of a Consulting Firm to Mentoring National National Medicine Regulatory Authorities and Pharmaceutical Quality Control Laboratories on quality management and ISO 9001 Cerfication

TERMS OF REFERENCE

December 2025

I. BACKGROUND

A robust health ecosystem depends on an effective regulatory system to ensure public access to safe, effective, and high-quality medical products. Such a system must also ensure that the services provided consistently meet legal and regulatory requirements and promote public confidence. An effective Quality Management System (QMS) enables National Medicine Regulatory Authorities (NMRAs) to standardize their procedures, boosting efficiency, transparency, and documentation. The benefits extend beyond faster market entry for new products to include safeguarding public health. By ensuring access to high-quality, regulated medicines, a operative system protects populations from the dangers of unregulated supplies. Furthermore, the existence of certified quality control laboratories to support regulatory functions also impact positively on the capacity of a NMRAs to provide effective oversight and restrict the circulation of substandard and falsified products.

In the Economic Community of West African States (ECOWAS), the need to strengthen regulatory capacity of NMRAs and the quality of infrastructures to achieve international standards was recognized by the Regional Pharmaceutical Plan adopted in 2014, and successive initiatives have been undertaken to support its implementation. However, despite considerable progress, most of the countries in the region still face challenges in building an integrated and well-functioning regulatory system.

The Project of the Development of the Pharmaceutical Industry (DPI) in the ECOWAS, designed by the African Development Bank, aims to assist ECOWAS pharmaceutical institutions with an overall goal to improve access to quality, safe, efficacious, and affordable medicines. As a part of the initiative, one of the key components of this project is to provide capcity building and advisory services for the ECOWAS pharmaceutical sector. Therefore, strengthen regional NMRAs and quality control laboratories with quality management systems to achieve international standards, i.e. ISO 9001will help to strenght regulatory functions.

The implementation of QMS as an integral part of regulatory processes should be supported with adequate resources and designed to be simple enough to remain manageable with the current resources, while being efficient and consistent. So, to ensure that the expected results are achieved, it is essential to recruit a consulting firm to coach ECOWAS member states QMS roadmaps towards ISO certifications.

II. SCOPE OF WORK

The consulting firm will be responsible for coaching targeted National Medicine Regulatory Authorities and their respective pharmaceutical quality control laboratories to develop, implement, and improve their QMSs, based on the principles of ISO requirements and WHO guidance on implementing quality management systems for national regulatory authorities and Good Practice for pharmaceutical quality control laboratories.

The consulting firm will work closely with NMRAs and their quality control laboratories, under the general supervision of the DPI Project Coordinator, Director of the Department of Public Health and Research (DSPR) and the Director of the Department of Health Planning and Information (DPIS).

III. MAIN DUTIES AND RESPONSIBILITIES

The consulting Firm will perform the following tasks:

- Conduct a preliminary assessment of the level of implementation of the QMS using the results of the WHO self-assessment (when available) and submit report
- Validate the prioritization of QMS requirements, timelines, responsibilities, and authorities with targeted institution staff, through collection of input and feedback to promote ownership of QMS implementation.
- Consolidate the feedback and input into an activity/ action plan, as a roadmap for QMS implementation for the and submit plan.
- Provide all required training on requirements and other related processes to help the organization in implementing QMS requirements and/or obtaining ISO 9001certification.
- Assist in the development of all mandatory procedures as required by WHO guidelines.
- Offer close guidance in the preparation and review of final documents prior to the application for certification.
- Guide the targeted institution team in applying for ISO 9001 certification.

IV. QUALIFICATIONS, EXPERIENCE, AND SKILLS

The consulting firm must have:

- Minimum of ten (10) years of experience in providing technical assistance in ISO 9001 certification.
- Extensive and proven combination of skill and expertise in the field of ISO certification, with expertise related to 9001certification gained through previous experience of similar work in or outside the ECOWAS region.
- Ensure the provision of consultancy services in the 3-official language of ECOWAS member states.

- The ability to deploy a team with a minimum of four (4) experts consisting of one (1) QMS lead consultant and two (2) associate QMS consultant and one (1) Pharmaceutical specialiast. The team members are expected to fulfil the following qualifications and experience:

Lead QMS Consultant:

- Master's Degree relevant to business management, public administration, engineering and/or other related fields.
- At least ten (10) years of experience of ISO 9001 QMS conducted to private and/or government institutions.
- Certified ISO 9001 Lead Auditor.
- Have participated in at least one ISO certification mission
- Work experience in a multicultural environment.
- Good computer skills (MS Office applications, project procurement management tools, logistics management tools) and ability to use information technology as a tool and resource.
- Team spirit, leadership, and initiative.
- Good organizational skills, high sense of integrity, and good interpersonal skills.
- Good problem-solving skills.
- Proficiency in at least two of the official languages of ECOWAS (English, French, or Portuguese) is required.

Associate QMS consultants:

- Master's Degree relevant to business management, public administration, engineering and/or other related fields
- At least eight (8) years of QMS audit experience as a team member or any other roles in audit in private and government institutions and a training certificate on conducting audit on ISO 9001.
- Have participated in at least one ISO certification mission
- Work experience in a multicultural environment.
- Good computer skills (MS Office applications, project procurement management tools, logistics management tools) and ability to use information technology as a tool and resource.
- Team spirit, leadership, and initiative.
- Good organizational skills, high sense of integrity, and good interpersonal skills.
- Good problem-solving skills.
- Proficiency in at least two of the official languages of ECOWAS (English, French, or Portuguese) is required.

Pharmaceutical Specialist:

- Master degree in Pharmacy, Pharmaceutical Sciences, Chemistry, or a related field.

- At least eight (8) years of experience working in an official Medicine Quality Control Laboratory or similar.
- Deep understanding of the ECOWAS medicines regulatory landscape, WHO Global Benchmarking Tool (GBT).
- Deep knowledge of WHO guidance on implementing quality management systems for national regulatory authorities and Good Practice for pharmaceutical quality control laboratories.
- Work experience in a multicultural environment.
- Good computer skills (MS Office applications, project procurement management tools, logistics management tools) and ability to use information technology as a tool and resource.
- Team spirit, leadership, and initiative.
- Good organizational skills, high sense of integrity, and good interpersonal skills.
- Good problem-solving skills.
- Proficiency in at least two of the official languages of ECOWAS (English, French, or Portuguese) is required.

V. PROJECT DURATION AND LOCATION

The assignment will be implemented over a period of 150 days starting from the signing of the contract and will require approximately **240 man-days.**

The consulting firm will work with the following institutions:

Country	**NMRAs and their Quality Control Laboratory**	**Only NMRAs**	**Only Quality Control Laboratory**
Benin	X	X	
Cabo Verde			
Côte d'Ivoire	X		
Guinea	X		
Liberia			X
Sierra Leone			X
The Gambia			X
Togo	X		

VI. DELIVERABLE AND PAYEMENTS METHODS

The selected consulting firm will receive payments upon certification of satisfactory completion of tasks, according to the following schedule:

Payment tranche	Deliverables	Portion
1st tranche	Preliminary reports on the assessment and Plan of activities/actions for the implementation of the QMS roadmap accepted by WAHO/ECOWAS Commission.	30%
2nd tranche	1) Training Reports on requirements and other related processes to help the organization in implementing QMS requirements and/or obtaining ISO 9001certification. 2) Operational Toolkit: Including Model Guidelines, SOPs, templates, and other necessary tools	40%
3rd tranche	Full report on the implementation of the Activity/Action Plan and the Draft application for ISO 9001 certification accepted by WAHO/ECOWAS Commission.	30%
Total Contract Price (Inclusive of all taxes and fees)		**100%**

VII. EVALUATION AND SELECTION CRITERIA

The procurement method to be used is Quality and Cost Based Selection.

The eligibility criteria, shortlisting and selection procedure will be in accordance with the Procurement Framework for Operations Financed by the Bank Group, October 2015 edition, which is available on the Bank's website at: http://www.afdb.org