

Term of Reference

Regulatory Strengthening Expert

Position title: Regulatory strengthening expert

Mission country: RWANDA/Kigali

Duration: 45 days

Sector: Strengthening the Rwanda Food and Drugs authority trough the Twinning Project

Expertise France is the French public international cooperation agency. It designs and implements projects which aim to contribute to the balanced development of partner countries, in line with the Sustainable Development Goals (SDGs) of the 2030 Agenda and the priorities of France's external action. Its mission is to support the capacity building of partner countries in the definition and implementation of public policies adapted to the needs of the population, contributing to the achievement of the Sustainable Development Goals (SDGs). Expertise France operates within the framework of public contracts, financed by French bilateral aid or through international tenders. The agency offers a wide range of interventions, based on multi-stakeholder partnerships, in areas such as economic and financial governance, social protection and employment, health, sustainable development and issues of stability, safety and security.

1. Project Description:

In an effort to support the Rwanda Food and Drugs Authority to improve its regulatory functions related to medicinal products including vaccines, a Consortium of European countries set up a Twinning Project for Rwanda. In this regard, Expertise France is coordinating the implementation of this EU Funded Twinning project aimed at strengthening the Rwanda Food and Drugs Authority (Rwanda FDA) in its regulatory functions related to medicinal products including vaccines. This twinning project involving several regulatory agencies from EU Member States aims to support the Rwanda Food and Drugs Authority to improve the enabling environment for regulation of medicinal products and vaccines in the country. To achieve this overall objective, the project has three components:

1. Improving legal framework and regulatory functions linked to medicinal products
2. Strengthening of market surveillance and control function - vigilance & laboratory testing functions
3. Support the establishment of the official batch release function for vaccines

2. Description of the mission :

As REGULATORY STRENGHTENING EXPERT within the Rwanda FDA Twinning project team and under the supervision of the Resident Twinning Advisor, the **objectives expected are:**

Activity 1.0 "Immersive work to provide tailored support for the RFDA to improve the legal framework and regulatory functions related to medicines"

Activity 2.0 "Immersive work to provide tailored support for the RFDA to strengthen the market surveillance and control function

And the **expected tasks are the following:**

- To assist the RFDA in defining its needs
- To better understand the work implemented on a day-to-day basis by the RFDA in its different assigned tasks ;
- To identify what support the twinning can bring to reinforce the capacities of the RFDA ;
- To correlate the analyses of the needs made by the European experts during their presence in Rwanda through the setting up of workshops with the analyses that could be made by the expert.
- To help define the ToRs of the missions of the regulatory experts of the different European regulatory agencies involved in the project
- To facilitate the work between the international experts and the local experts.

3. Qualifications and competences:

Required qualifications

- Master's degree in Pharmaceutical Sciences, Doctor in medicine, Biochemistry and Science
- A PhD in the field relating to regulatory affairs for pharmaceuticals is an asset

Required experience

- At least 10 years of relevant experience in a regulatory agency in pharmaceutical regulatory affairs (ie Drug regulatory affairs, market control, market authorization, vigilance, inspection, regional and international cooperation...)
- Direct experience with products assessment procedures and of WHO global benchmarking tool and/or progression of regulatory authorities towards achieving maturity levels 3 and 4;
- An international experience (i.e. in the international development sector and outside your country of origin), especially in Africa is an asset.

Required skills and knowledge

- Good knowledge of all regulatory functions
- Strong knowledge of the current agenda on regulatory harmonization in Africa and the support provided by the European Commission to AUDA NEPAD, WHO and EMA and the support provided by the European partners such as Expertise France, GIZ and Enabel
- Good knowledge of pro-active multi-actor partnership building
- Excellent organizational skills;
- Adaptability and flexibility with priority setting capacities;
- Excellent oral and written communication skills;
- You are fluent in spoken and written French and English

