# 051 – Job title: International consultant on regulatory and pharmaceutical systems strengthening.

1. **Background**

WHO is providing support to the continuous capacity building of Viet Nam’s National Regulatory Authority in the areas of regulatory strengthening; clinical trials; quality assurance of medical products (vaccines, medicines, diagnostics and other health technologies) and policy and legislation. In December 2020, Viet Nam’s National Regulatory Authority (NRA) achieved maturity level 3 for regulating vaccines. The NRA has established an institutional development plan for improving NRA functions across its agencies and every two years the NRA is expected to conduct its self-assessment using the WHO Global Benchmarking Tool. For the past decade, the Viet Nam WHO country office has supported Viet Nam’s NRA to ensure the quality, safety, and efficacy of vaccines, and more recently, COVID-19 vaccines. With the COVID-19 pandemic still ongoing, COVID-19 vaccines are one of the most important tools in COVID-19 prevention and response. Since the COVID-19 outbreak, several institutes in Viet Nam have started to conduct COVID-19 vaccine research and development.

The Ministry of Health has requested WHO to continue to support the capacity building of Viet Nam’s NRA to further progress on its institutional development plan, next assessment using the WHO Global Benchmarking Tool, and regulation of COVID-19 vaccines, including clinical trial design of domestic COVID-19 vaccines, vaccine effectiveness, and adverse events following immunization (AEFI) monitoring.

The short-term international consultant would support the country office to provide specialized technical expertise for the NRA as it undergoes the next round of WHO Global Benchmarking and to support the over-all work in the area of regulations and pharmaceuticals.

2. **Planned timelines**

   - **Start date:** 05 December 2022 (subject to confirmation)
   - **End date:** 03 November 2023

3. **Work to be performed**

**Method(s) to carry out the activity**

Under the direct supervision of the UHC Team Coordinator, and collaboration of Vaccine Preventable Diseases and Immunization (VDI) officer as a team, the incumbent will carry out the given activities.
Under the direct supervision of the UHC Team Coordinator, Dr Socorro Escalante at Escalantes@who.int; and collaboration of Vaccine Preventable Diseases and Immunization (VDI) officer as a team, the incumbent will carry out the given activities.

- Specific responsibilities include, but are not limited to, the following:
  - Technical support to the National Regulatory Authority in progressing its institutional development plan
  - Coordination and facilitation of support to the NRA in the next assessment using the WHO Global Benchmarking Tool
  - Technical support to strengthen COVID-19 vaccine regulation, including COVID-19 vaccine domestic production and clinical trial design
  - Coordination of NRA counterparts, such as DAV, ASTT, NIDQC, and NICVB, and partners,
  - Assist technical officer in coordinating technical support and capacity building to mRNA technology transfer related activities
  - Perform other related duties as needed.

**Output/s**

**Output 1:** Updated NRA institutional development plan and next assessment using the WHO Global Benchmarking Tool

- **Deliverable 1.1:** Summary report on progress of institutional development plan (28 February 2023)
- **Deliverable 1.2:** Technical report on WHO Global Benchmarking Tool assessment (30 August 2023)

**Output 2:** COVID-19 vaccine research and development roadmap with focus on clinical trial design and vaccine effectiveness

- **Deliverable 2.1:** Technical report on COVID-19 vaccine domestic production (30 December 2022)
- **Deliverable 2.2:** Technical report on mRNA technology transfer capacity building (30 October 2023)

Note: Due to COVID-19, the work and deliverables are subject to change. The incumbent needs to be flexible to adjust to any unforeseen adjustments that might occur during the implementation.

**Output 3:** Review of legislative and regulatory instruments and policies

- **Deliverable 3.1.** Technical report on the review of the pharmaceutical law (30 April 2023)
- **Deliverable 3.2.** Technical report on the development of Law on Medical Equipment (30 June 2023)
4. **Specific requirements**

a. **Qualifications required:**

   - **Education:**
     - Essential: Minimum first University degree in medicine, pharmacy or public health from a recognized university and a postgraduate degree in pharmacy, public health
     - Desirable: Degree in regulatory science

b. **Experience required:**

   - Essential: A minimum of seven years of experience in medicines, medicines regulations and pharmaceutical systems in national, regional and international organizations. Expertise to support development of laws, regulations and policies.
   - Desirables: Actual experience working with regulatory authorities or providing support to national regulatory authorities as an expert. Relevant work experience in WHO or the UN system would be an asset and in the field of vaccines and medicines clinical trial, and production.

c. **Skills / Technical skills and knowledge:**

   - Strong analytical, planning and operational skills
   - Knowledge and skills in literature review and searching technical publications
   - Proven ability to synthesize complex information to show good judgement and to generate approaches
   - Excellent written communication skills, including proven ability to write clear and concise documents, including reports, submissions and briefing documents
   - Proficiency with MS Office Suite, with excellent MS Word, Excel and PowerPoint skills

d. **Language requirements:**

   - **Essential:** Expert knowledge of English.

e. **Competencies**

   - Excellent interpersonal and communication skills
   - Demonstrated ability to work as part of a team or independently
   - Ensuring the effective use of resources
   - Builds and promotes partnerships

5. **Place of assignment**
The consultant is expected to perform her/his work at WHO Viet Nam Country Office in Hanoi, Viet Nam

6. Medical clearance
The selected Consultant will be expected to provide a medical certificate of fitness for work.

7. Travel
   • Not specific

8. Budget
Please take note of the following when submitting application:
- The contractor will be responsible for paying taxes, if any

Those who are interested can contact our focal person with contact detail at the end of the announcement before/by 15 November 2022 and should be addressed to:

Administrative Officer
World Health Organization
UN Building, 304 Kim Ma Street,
Hanoi, Viet Nam

OR

wpvnmaplicants@who.int
For further information on this TOR, please contact:
wpvnmwr@who.int