﻿﻿﻿**﻿Expression of Interest for**

**Consultant for Translation and Localization of the Regulations**

Date of Publication: December 20, 2024

**Background:**

The Promoting the Quality of Medicines Plus (PQM+) program, funded by the U.S. Agency for International Development (USAID), aims to strengthen medical product quality assurance systems in low- and middle-income countries (LMICs). PQM+ provides technical assistance to build the capacity of medicines regulatory authorities and quality assurance systems in these countries, ensuring access to quality-assured essential medical products.

In line with the recommendations of the WHO Global Benchmarking Tool (GBT) assessment, the Department of Drug Administration (DDA) in Nepal has drafted a revised Drugs Act. Currently drug bill is circulated among various ministries for their suggestions and MoHP is preparing to submit the draft bill for parliamentary proceedings after incorporating the suggestions from various stakeholders. Based on the current drug bill PQM+ will support DDA in developing three key regulations among the identified ones as per draft drug bill. This support will help establishment of robust regulatory frameworks aligned with international standards and WHO GBT assessment mandates, thereby strengthening the regulatory oversight of medicines in Nepal and ensuring the availability of safe, effective, and quality-assured pharmaceutical products.

PQM+ program is seeking for a consultant to support on translation and localization of the priority regulations for National Medicines Regulatory Authority of Nepal.

**Scope of Work:**

The consultant will support in translating and localization of priority regulations into Nepali, specifically the legal aspect to Nepal’s context, as well as facilitating stakeholder consultations to draft the regulations for Inspection (GxP), Registration, and Post-Marketing Surveillance, ensuring alignment with prescribed formats.

* Legal consultant will translate, review and revise the regulation to the recommended format to finalize the draft regulations.
* Organize and facilitate meetings with DDA officials and other stakeholders to discuss the draft regulations.
* Document outcomes of each consultation session, providing clear summaries and feedback for regulation refinement.
* Localization of the regulations for Nepal’s context, adhering to the recommended format and incorporating legal best practices.
* Revise drafts based on feedback gathered from DDA officials/ stakeholder consultations.
* Prepare final drafts of the three regulations, incorporating DDA officials/ stakeholder input and feedback from consultation meetings.
* Submit completed drafts to DDA and provide support for submission to the Ministry of Health and Population.

**Deliverables:**

1.        Final drafts (Nepali translated) of the three regulations:

            Regulations for Inspection (GxP),

            Regulation of Registration,

            Regulation for Post-Marketing Surveillance

2.        Meeting minutes/feedback from DDA officials/ stakeholder consultations

**Expected Level of Effort (LOE)**

15 days

**Basic Qualifications:**

* Bachelor's degree in law and other related subjects
* More than 10 years of experiences in developing/drafting/amending law regulations, strategy for different programs.
* Proven experience in English to Nepali translation.
* Strong interpersonal, communication, and facilitation skills, with a high level of coordination with government and development partners.
* Fluency in Nepali and English with excellent command over Nepali language for legal documentation.
* Ability to demonstrate highest degree of ethics and integrity
* Experience of working in USAID funded program will be preferred

**Application Process**

Eligible consultant/s or firms may submit an Expression of Interest based on the above basic requirements including their consultancy fees per day (8 hour per day basis), CV, proof of relevance experience, at least 2 references and a copy of PAN/VAT registration certificate. Application should indicate the subject as “**Consultant to translate and adapt the regulations**” and submit to **usp.nepal@usp.org** by/before **January 7, 2025 (5:00 PM)**.

Only shortlisted applicants will be contacted for further process.