Template for Short-term Opportunities

Stellis CVs of interested applicants must be sent to: Samvel Azatyan, Team Lead, Regulatory Convergence and Networks (azatyans@who.int)

1. Division/Dept/Unit	2. Supervisor
MHP/RPQ/REG/RCN/FPI	Samvel Azatyan

3. Purpose of short-term opportunity

Under the direct supervision of the Team Lead, Regulatory Convergence and Networks (RCN), the incumbent is required to revise and update the WHO Global Model Regulatory Framework (GMRF) for medical devices including in vitro diagnostic medical devices (Model).

4. Background

The regulation of medical devices including in vitro diagnostics is critical in assuring their quality and performance. In May 2014 the World Health Assembly (WHA) adopted a Resolution regarding regulatory systems for medical products (WHA 67.20). The Resolution underscored the importance of effective regulatory systems as an essential component of health system strengthening and contribution to public health. WHO decided to develop guidance to support Member States that have yet to develop and implement regulatory controls relating to medical devices.

The GMRF was published in 2017 in English and was translated into French and Russian. Since then, the GMRF served as a reference document in introducing regulatory framework for medical devices including IVDs, a background document in WHO workshops on medical devices and is considered a standard in the development of the Global Benchmarking Tool (GBT) when adding medical devices as a product group to GBT Rev VI.

The field of medical devices is rapidly changing. Technologies are advancing in their nature and complexity. In addition, new suppliers are entering the field, often without much relevant experience or qualifications, and often with little local regulatory oversight. Jurisdictions are adapting their laws and regulations to better and timely regulate medical devices in order to protect and promote public health. They have often also had to quickly develop greater regulatory capacity by which to implement those regulations. The current pandemic clearly demonstrates the importance of safe, reliable, and appropriate quality medical devices including IVDs. It has also highlighted the importance of integrity in the supply chains, domestic and international, of medical devices (and related personal protective equipment). The need for reliable, appropriate, and accessible in vitro diagnostic medical devices has also been demonstrated. Experience in the use of the Model teaches that countries would benefit from an updated and in some aspects more detailed guidance and therefore the Model needs to be updated to address some of the developments in area of medical devices.

5. Contract dates	6. Contract type & Grade or Remuneration
3 April to 3 September 2022	Consultancy Contract – Pay Band C – USD 10 000 – USD 12 500 per month.

7. Deliverables or Functions – depending on contract type

Output 1: Plan and organize discussions of both external and internal partners in the revision of the GMRF.

Activity 1.1: Organize all consultative meetings i.e. Internal meetings with WHO Steering group, meetings with external experts.

Activity 1.2: Consult Regional Harmonization Initiatives such as IMDRF, AHWP, AMDF, ISO, IEC.

Activity 1.3: Prepare and organize public consultations on the final text of the revised and updated version of the GMRF with RECs, Industry association and other relevant stakeholders.

Activity 1.4 Prepare and submit a monthly report.

Output 2: Technical editing, design and finalize text of the GMRF.

Activity 2.1: Provide guidance to the technical editor.

Activity 2.2 Present the final draft to the WHO Steering Group for endorsement.

Activity 2.3. Guide on final design of the module.

Activity 2.4 Finalized text of GMRF

Activity 2.5 Prepare and submit a monthly report.

Output 3: Submit final revised /updated GMRF.

Activity 3.1 Prepare for submission to the Expert Committee (if applicable).

Activity 3.2 Submit final text of the revised and updated GMRF for approval.

Activity 3.3 Prepare and submit a monthly progress report.

Output 4: Create repository of responsible NRAs.

Activity 4.1 Prepare a list of NRAs including contact persons for medical devices for WHO member states.

Activity 4.2 Submit the list to WHO.

Activity 4.3 Prepare and submit monthly report

Output 5 Regulatory support for WHO member states in Asia.

Activity 5.1 Provide support upon request on regulatory framework on medical devices to national regulatory authorities in SEARO, WPRO and EMRO.

Activity 5.2 Prepare and provide the final report

8. Qualifications, experience, skills and languages

Identify the educational qualifications and expertise needed for the terms of reference outlined above.

Educational Qualifications

An advanced University degree or equivalent in pharmacy, biology, BSc in medical Laboratory technology or related fields.

Experience

- Over 10 years professional experience in regulating medical devices.
- An extensive knowledge on medical devices including In vitro diagnostics and their regulation.

Skills/Knowledge

- Excellent ability to communicate and work in diverse settings. Advanced computer literacy and knowledge of regulatory IT systems and databases.
- Good professional drafting and communication skills.

Languages and level required

Expert knowledge of English is essential. Ability to work in other UN languages would be an asset.

9. Location

Please specify where the staff / non-staff will work:

Off site: Home based

10. Travel *(If travel is involved, a medical certificate of fitness for work will be required.)*

The consultant will not travel during the duration of his contract.

11. Remuneration and budget *(travel costs excluded)*

For consultant contract: Pay Band C – USD 10 000 – USD 12 500 per month.

Date: 14 February 2022