Terms of Reference for Agreement of Performance of Work (APW) for Medical Device Prequalification Assessment: 2026_RFQ_PQT_AMD_001

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1. Purpose of APW

To contribute to the review of manufacturer's technical documentation for eligible medical devices which have been submitted for WHO's prequalification assessment and any other technical reviews in the scope of WHO's Prequalification Assessment of Medical Devices team's work.

2. Background

WHO prequalification aims to ensure that essential health products meet global standards of quality, safety and performance, in order to optimize use of health resources and improve health outcomes. Starting in 2026, WHO's Prequalification Assessment of Medical Devices team will open a new procedure for the assessment of medical devices, which will involve a comprehensive quality assessment of medical devices eligible for prequalification assessment through a standardized procedure aimed at determining whether the product meets WHO prequalification requirements.

This expansion of the team's scope will be a phased approach and include the centralizing of prequalification assessment, previously conducted in collaboration with the United Nations Population Fund to within the WHO Prequalification Unit. It will also complement the team's existing prequalification assessment activities for in vitro diagnostic medical devices.

A critical component of the assessment process relates to a technical review of the product dossier. To undertake this activity, external experts, with demonstrated technical expertise, are utilized to conduct the product dossier review. In addition, external experts are also engaged in the review following a structured process for reviewing changes to prequalified products, ensuring continued compliance with the WHO requirements.

With this expansion in scope, the Prequalification Unit is creating a new pool of medical device experts to support the Assessment of Medical Devices team with tasks related to the product dossier component of the prequalification assessment. Experts must understand the regulatory requirements for the dossier review, including the respective standards and internationally accepted guidance documents, major regulatory harmonization initiatives, and the associated guidance. The expert should have experience reviewing medical device product dossiers and have a comprehensive knowledge of medical devices, including an understanding of the challenges related to their use in resource-limited settings.

The Assessment of Medical Devices team will pilot the procedure with the assessment of (1) computer aided detection software for tuberculosis screening, (2) male latex condoms, female condoms and copper-bearing intrauterine devices and (3) male circumcision devices. Due to the new technical areas incorporated into the body of work conducted by the team, subject matter experts are needed in the fields of medical device technical assessments, regulation, and medical device software and artificial intelligence (AI).

3. Planned timelines

Start date: 01/08/2026 **End date: 01/07/2027**

Total duration: Pre-agreed number of days over 11 month period. The number of working days per month will be determined according to the needs of the team and the experts' availability.

4. Requirements – Work to be performed

Deliverable 1: Conduct a review of technical documentation submitted for prequalification assessment of medical devices. The completed reports are expected to be provided within the agreed timelines (usually four weeks from date of receipt of documents).

Deliverable 2: Conduct a review of technical documentation related to software and AI components of medical devices. The completed reports are expected to be provided within the agreed timelines (usually four weeks from date of receipt of documents).

Deliverable 3: Conduct a review of technical documentation submitted for change requests to prequalified medical devices. The completed reports are expected to be provided within the agreed timelines (usually four weeks from date of receipt of documents).

5. Requirements – Planning

Output – upon signature of contract and commencement of the work, the expert is expected to provide the completed report within the agreed timelines for each deliverable.

6. Inputs

The technical unit will provide the link to the documents upon signature of the contract and details of the review expectations by email/telephone call in advance of the contract.

7. Characteristics of the Provider

Mandatory:

- Proven experience in the field of medical device regulatory affairs, quality assurance, development and/or manufacturing of medical devices (at least 10 years relevant experience).
- Solid and demonstrated experience of regulatory requirements (FDA, EU MDR, ISO standards and other global regulatory requirements and quality standards), dossier submission and life cycle management for medical devices.
- Ability to comprehend principles of engineering, physiology, and medical device use.

Desirable:

- In-depth expertise in regulatory requirements/quality assurance of medical devices for at least one of the product categories below:
    - computer aided detection software for tuberculosis screening (CAD-TB); or
    - contraceptive devices (male and female condoms and/or IUDs) or;
    - male circumcision devices or;
    - development of software/AI and hardware medical devices.
- Working experience in different geographical regions, including resource-limited settings.

Skills and staffing: The selected contractor is expected to dedicate the following human resources to the project:

- Sufficient capacity and knowledge is required to cover the following areas of expertise:
    - At least 10 years of professional experience in the field of medical devices, including experience with regulatory submissions, conformity assessment, or product dossier evaluation, including assessment of safety, performance, risk management, clinical evidence, and manufacturing information.
- WHO pays utmost attention to the level of qualification and experience of the individuals involved, and to continuity in the services. The profiles (no individual names required) of the personnel proposed for these services should be included in the technical proposal.
    - Essential: Minimum an advanced university degree in science, engineering, or related biomedical/medical/scientific field.
    - Desirable: PhD degree in engineering or science.

Languages and level required : Advanced knowledge of English

Other: Provider must comply with the confidentiality and conflict of interest rules of WHO.

8. Place of assignment

Travel is not required. The work will be conducted offsite.