Consultant for Medical Device Prequalification Assessment: Vacancy notice for roster of consultants

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1. **Purpose of consultancy**

To contribute to the review of manufacturer's technical documentation for medical devices within the scope of 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 utilised 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. **Deliverables**

- Deliverable 1: Conduct a review of technical documentation submitted for prequalification assessment of medical devices within agreed timelines (usually 4 weeks from date of receipt of documents).
- Deliverable 2: Conduct a review of technical documentation related to software and AI components of medical devices within agreed timelines (usually 4 weeks from date of receipt of documents).
- Deliverable 3: Conduct a review of technical documentation submitted for change requests to prequalified medical devices within agreed timelines (usually 4 weeks from date of receipt of documents).

4. Qualifications, experience, skills and languages

Educational Qualifications:
Essential: Minimum an advanced university degree in science, engineering, or related biomedical/medical/scientific field.

Desirable: PhD degree in engineering or science.

Experience
Essential:

- At least 10 years of relevant experience in medical device regulatory affairs, quality assurance, development and/or manufacturing of medical devices.
- 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/Knowledge:
Extensive knowledge in the field of regulatory submissions, conformity assessment, or product dossier evaluation, and application of regulatory standards. Ability to conduct independent reviews including the assessment of safety, performance, risk management, clinical evidence, and manufacturing information for medical devices. Technical writing skills.

Languages and level required (Basic/Intermediate/Advanced):
Expert knowledge of English

Location: Home based, work to be conducted remotely.
Travel – travel may be needed, will cover travel-related costs.

5. Remuneration and budget (travel costs are excluded):

a. Remuneration: *Payband level - Remuneration currency - Payband range*
Bands B (350 USD/ day) or C (500 USD/ day), depending on the assigned tasks.

Number of working days per month to be determined according to the needs of the team and the experts' availability.

b. Living expenses (A living expense is payable to on-site consultants who are internationally recruited): **not applicable – home-based consultancy**

c. Expected duration of contract: **11 months with a pre-agreed number of days.**

Additional Information:

- This vacancy notice may be used to identify candidates for other similar consultancies at the same level.
- **Interested candidate is requested to create a PHF on WHO careers:** Candidates are required to create a PHF on WHO careers https://careers.who.int/careersection/ex/jobsearch.ftl?ftlcompclass=LoginComponent **Please refer to the attached "Annex 1_Stellis instructions for candidates"**
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- Only candidates under serious consideration will be contacted.
- A written test may be used as a form of screening.
- If your candidature is retained for interview, you will be required to provide, in advance, a scanned copy of the degree(s)/diploma(s)/certificate(s) required for this position. WHO only considers higher educational qualifications obtained from an institution accredited/recognized in the World Higher Education Database (WHED), a list updated by the International Association of Universities (IAU)/United Nations Educational, Scientific and Cultural Organization (UNESCO). The list can be accessed through the link: http://www.whed.net/. Some professional certificates may not appear in the WHED and will require individual review.
- For information on WHO's operations please visit: http://www.who.int.
- WHO is committed to workforce diversity.
- WHO has a smoke-free environment and does not recruit smokers or users of any form of tobacco.
- Applications from women and from nationals of non and underrepresented Member States are particularly encouraged.
- WHO prides itself on a workforce that adheres to the highest ethical and professional standards and that is committed to put the WHO Values Charter into practice.
- WHO has zero tolerance towards sexual exploitation and abuse (SEA), sexual harassment and other types of abusive conduct (i.e., discrimination, abuse of authority and harassment). All members of the WHO workforce have a role to play in promoting a safe and respectful workplace and should report to WHO any actual or suspected cases of SEA, sexual harassment and other types of abusive conduct. To ensure that individuals with a substantiated history of SEA, sexual harassment or other types of abusive conduct are not hired by the Organization, WHO will conduct a background verification of final candidates.
- Consultants shall perform the work as independent contractors in a personal capacity, and not as a representative of any entity or authority. The execution of the work under a consultant contract does not create an employer/employee relationship between WHO and the Consultant.
- WHO shall have no responsibility whatsoever for any taxes, duties, social security contributions or other contributions payable by the Consultant. The Consultant shall be solely responsible for withholding and paying any taxes, duties, social security contributions and any other contributions which are applicable to the Consultant in in each location/jurisdiction in which the work hereunder is performed, and the Consultant shall not be entitled to any reimbursement thereof by WHO.
- Consultants working in Switzerland must register with the applicable Swiss cantonal tax authorities and social security authorities, within the prescribed timeframes (Guidelines issued by the Swiss Mission are available at: https://www.eda.admin.ch/missions/mission-onu-

geneve/en/home/manual-regime-privileges-and-immunities/introduction/Manuel-personnes-sans-privileges-et-immunites-carte-H/Non%20fonctionnaires%20et%20stagiaires.html

For roster VNs:

- The purpose of this vacancy is to develop a list of qualified candidates for inclusion in this advertised roster. All applicants will be notified in writing of the outcome of their application (whether successful or unsuccessful) upon conclusion of the selection process. Successful candidates will be placed on the roster and subsequently may be selected for consultancy assignments falling in this area of work or for similar requirements/tasks/deliverables. Inclusion in the Roster does not guarantee selection to a consultant contract. There is no commitment on either side.