World Health Organization

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In reply please refer to: P5-447-3/JG/EB/1

Your reference:

Mr Teimuraz Pirvelashvili
Acting Head of Agency
State Regulatory Agency for Medical Activities
144, Ak Tsereteli Ave,
Tbilisi, 0119
Géorgie

10 July 2019

Dear Mr Pirvelashvili,

WHO Prequalification Team – Inspection Services
Request for nomination of an inspector for rotation position at WHO HQ Geneva, Switzerland

Please accept this letter as a formal request to nominate and release an inspector to join the World Health Organization Prequalification Team (WHO-PQT) for a period of four months. This initiative is specifically designed for GMP inspectors from emerging countries to enable them to spend time in Geneva to assist PQT and develop an understanding of how PQT does its inspections. This is part of the continuous efforts of WHO at strengthening National Medicines Regulatory Authorities (NMRAs). This rotation represents a great opportunity for the candidate, the NMRA and the region for capacity development, especially hands on experience on Good Manufacturing Procedures (GMP) Inspections and the working procedures of WHO-PQT.

The position is time limited with no possibility of extension, so that several inspectors can benefit from this initiative each year. WHO will prioritize nominations from:

- NMRAs in regions pursuing harmonization of their regulatory activities,
- NMRAs which have an urgent need and commitment for capacity building, and
- inspectors from countries with some local pharmaceutical production.

In order for the individual, the country and the region to benefit from the rotational position, we recommend that the nominated person:

1. Shall be a person already appointed as an inspector in the NMRA and have sound knowledge of regulatory affairs.
2. Should have appropriate qualifications and basic experience in inspection.
3. Should have good knowledge of WHO GMP, GCP, GLP and related norms and standards as appropriate for the intended inspection.
4. Should have a good command of English and be able to follow the inspection in English. Other language, like French may be considered.
5. Should have excellent communication and interpersonal skills, with the ability to work in a multicultural team and maintain effective working relationships with recognized experts and stakeholders.

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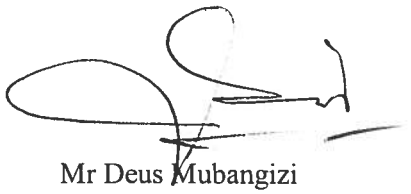
6. Should have unquestionable integrity and good conduct.
7. Should have no conflict of interest and shall sign a confidentiality agreement.
8. Should be willing and able to travel in foreign countries.
9. Should be able and in position to share the acquired skills with colleague inspectors in the NMRA and/or region.

Please send us the name of the inspector and CV no later than 1 September 2019 so that arrangements can be made to start during latter part of 2019. I would appreciate your assistance in promptly sending the nomination and letter of release for the nominated inspector.

Looking forward to hearing from you.

Yours sincerely,



Mr Deus Mubangizi
Coordinator, Prequalification Team
Regulation of Medicines and other Health Technologies