Medicines Control Authority of Zimbabwe

Regional Centre of Regulatory Excellence

Fellowship in regulatory science for African Medicine Reviewers/Assessors

Background
The Medicines Control Authority of Zimbabwe (MCAZ) Regional Centre of Regulatory Excellence (ReCORE) in partnership with the European and Developing Countries Clinical Trials Partnership (EDCTP) is offering a 2-year fellowship in regulatory science to 8 – 10 assessors working in African medicines regulatory authorities (MRA). Fellows will be admitted in two groups, the first in 2019 and the second group in 2020. The MCAZ is a leading regulator on the African continent and has trained regulators from all over the continent for many years.

The fellowship will involve completion of short courses through block release training at the MCAZ / University of Zimbabwe (UZ), completion of the summer course and winter mini-conference at the Utrecht-WHO Collaborating Centre for Pharmaceutical Policy and Regulation in the Netherlands, practical work assignments, case studies, specific hours of practice (dossier assessments) over the fellowship period and **a capstone project**. The capstone project should be in the area of specialisation selected by the fellow and address a specific problem, issue or research question in regulatory science. Funding will be provided for 8 fellows and 2 additional fellows will be accepted provided they can fund themselves. The approximate cost of the fellowship is US$28 950 for the entire fellowship period.

The purpose of the fellowship is to support the development of institutional and personnel capacities of medicines assessors to enable improved regulatory activities directly related to registration of new medicinal products. We offer a systematic competence-based training program with formal courses based on a defined curriculum for the capacity development of medicines assessors from Zimbabwe and other countries in the Southern African Development Community (SADC).

What do we offer?

- Part time fellowship in regulatory science; duration of 2-3 years depending on available time and individual effort; the fellowship should result in 1-2 papers suitable for publication;
- You will be taught how to assess dossiers, basic data analysis skills, epidemiology & biostatistics and how to write academic research papers;
- Supervision during course work, assignments and capstone project by experienced regulators and acknowledged researchers in the field of drug regulation
- A stimulating research environment including regular basic and advanced courses and other meetings (e.g. Pharmaceutical Policy Analysis summer course, WHO CC Winter meeting)
- Financial support for travelling and courses for funded fellows;
- Funding to take the Regulatory Affairs Certification (RAC) exam offered by the Regulators Affairs Professional Society (RAPS) for funded fellows;

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This project is part of the EDCTP2 programme supported by the European Union

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Candidate Profile

To be eligible for a fellowship, a candidate should:

- Hold a Bachelor of Pharmacy degree, Pharmaceutical Sciences degree or equivalent; A master degree is an added advantage
- Have at least three (3) years of work experience as a quality or clinical (BE) assessor in an MRA;
- Be able to use their work experience, data and policy issues as a topic for their capstone project;
- Be able to spend a minimum 8 working hours a week working on the fellowship;
- Be willing to think out-of-the-box and enjoy a multi-disciplinary approach to research questions;
- Be a 'learner' who proactively shares knowledge and welcomes feedback;
- Have good communication skills in English, both written and oral;

Features of the fellowship

- 1 - 2 original papers, at least 1 should be published / accepted in a peer reviewed journal;
- An example of a typical and more detailed workplan is annexed;

Further requirements and terms of reference

- Candidates should commit to visit the MCAZ/UZ at least once a year for block release training and to visit Utrecht University twice during the fellowship at the time of the pharmaceutical policy analysis summer course and during the WHO CC Winter meeting;
- Candidates may be required to undertake examinations online annually;
- Candidates should provide a commitment statement from their employer that their employer supports the application;
- Experienced fellows may be asked to contribute to the supervision and facilitation of basic courses;
- The number of positions is limited to 4 funded fellows and 1 self-funded fellow per year for 2 consecutive years. Initial assessment of candidates will be done on the basis of work experience, academic background, research theme and writing skills;
- The first group of fellows will be admitted in **January 2019**;
- Applicants will receive an acknowledgement within 1 week after their application and a decision letter within 1 month after the application deadline.

Application

To apply for the fellowship, please send a recent CV, two written references, an employer commitment statement, a writing sample of a recent paper or report and a personal statement which includes a proposal of a topic for your capstone project before **25 November 2018** to Mrs Tariro Makamure-Sithole, Project Coordinator, Medicines Control Authority of Zimbabwe, 106 Baines Avenue, Harare, Zimbabwe (tmakamure@mcaz.co.zw)

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Annex: Example of typical workplan

Year 1:

- Initial assessment of skills, capabilities and deficiencies;
- Undertake basic and advanced courses;
- Agree on topic of interest for capstone project;
- Attend Utrecht summer school;
- Prepare a research protocol for the project;
- Assess a specified number of dossiers

Year 2-3:

- Undertake basic and advanced courses;
- Undertake research activities encompassing quantitative, qualitative, and policy analysis methods resulting in a paper(s) of publishable standards;
- The research project should be accompanied by a literature review and annotated bibliography.
- Attend WHO CC Winter meeting.
- Finalise paper(s) for publication in journals and thesis;
- Write introduction, discussion and conclusion linking the body of work into a coherent whole.
- Take Regulatory Affairs Certification (RAC) examination

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