Food and Drug Administration
Department of Health
Filinvest Civic Drive, Alabang, Muntinlupa City

NOTICE OF VACANCY (Plantilla Position)

Center for Drug Regulation and Research

Number of Vacancy	Item Number	Position Title	Salary Grade	Basic Monthly Salary	Civil Service Commission (CSC) Minimum Qualification Standard
Licensing and Registration Division					
1	OSEC-DOHB-MDSP2-3-2000	Medical Specialist II	23	Php 80,003	**Education:** Doctor of Medicine with a Certificate as Fellow of the relevant specialty society and/or Diploma of the relevant specialty board **Experience:** Two (2) years of responsible experience as Medical Specialist I or other related experiences **Training:** 4 hours of relevant training **Eligibility:** RA 1080 (Physician)
Product Research and Standards Development Division					
1	OSEC-DOHB-MDSP2-30-2021	Medical Specialist II	23	Php 80,003	**Education:** Doctor of Medicine with a Certificate as Fellow of the relevant specialty society and/or Diploma of the relevant specialty board **Experience:** Two (2) years of responsible experience as Medical Specialist I or other related experiences **Training:** 4 hours of relevant training **Eligibility:** RA 1080 (Physician)

End User's Preference:

Education: Doctor of Medicine *from an accredited medical school who finished residency training and specialization

Experience: 5 years of relevant experience
* in a specialized field of medicine in an institution accredited for training in the chosen specialty with background in Pharmacology, Pharmacotherapy, Toxicology, Epidemiology, PV/AEFI Causality Assessment, preclinical and clinical researches related to drug development

Training: 32 hours of relevant training

*Pharmacology, Pharmacotherapy, Toxicology, Epidemiology, PV/AEFI Causality Assessment, Protocol Development and Evaluation, Clinical Research, GCP
*Preferably undergone postgraduate training program in a local or international academic institution of merit
*Preferably a member / fellow / diplomate of good standing and certified accordingly by the appropriate specialty society

Eligibility: RA 1080

Job Description:

1. Review and recommend for approval of clinical trials including amendments, pre-clinical and clinical study reports for new drug application, rationale of fixed-dose combinations, product classification and re-classification (e.g. Rx to OTC, initial, MR), Import Permit (Clinical Trials and One-time Importation), Compassionate Special Permit and New Dosage Form/Strength/Presentation/ etc. of pharmaceutical products.
2. Review and provide recommendations on the Nonclinical (Part III) and Clinical (Part IV) Documents of ASEAN Common Technical Dossier (ACTD) submissions.
3. Review and provide recommendations on the following: a. Risk Management Plan (RMP) b. Periodic Safety Update Reports (PSUR) c. Post Marketing Surveillance (PMS) Protocol
4. Conduct researches or literature review and/or peer review on drug product safety and efficacy
5. Conduct researches or literature review and/or peer review on drug product safety and efficacy
6. Develop policies, guidelines and operational procedures related to the product registration and/or conduct of clinical trials under the Center's jurisdiction
7. Initiate development of systems and approaches on product registration and evaluation of clinical studies including interpretation of results.
8. Provide technical assistance related to drug product registration and conduct of clinical studies, with interpretation of data or results to stakeholders
9. Establish inter/intra collaboration in the registration of new drug products and in approval and monitoring of clinical studies for FDA purposes.
10. Provide technical supervision to staff.
11. Perform other related functions as maybe assigned.

All qualified next-in-rank personnel shall be automatically considered candidates for promotion. For all interested FDA regular employees including the qualified next-in-rank candidates, they are required to submit item numbers 1, 2, 3, 5, 6, and 7 listed hereunder, to the FDA-Human Resource Development Division (HRDD). Failure to do so shall be deemed a waiver of their right to be included as candidates for the positions applied for. Further, please be advised that those employees with at least Very Satisfactory (VS) rating in the last two (2) Performance Rating periods shall be considered for promotion.

Other interested applicants shall submit the following documents to Food and Drug Administration – Human Resource Development Division for initial documentary review and evaluation:

1. Application Letter with the specific position applied for addressed to FDA Director General (Please indicate Item Number);
2. Four (4) sets of duly accomplished Personal Data Sheet (CS Form 212) with Work Experience Sheet (downloadable at www. csc.gov.ph);
3. Qualification Profile (Annex 1) in 1 copy (downloadable at www.fda.gov.ph/about/careers)

4. Civil Service (CS) Eligibility/ Board Rating & valid Professional Regulation Commission (PRC) ID;
5. Diploma in any relevant Master's/ Bachelor's Degree and Transcript of Records;
6. Performance Rating for the last two (2) rating periods (for government employees);
7. Certificates of trainings attended, if any (in case of managerial/ supervisory trainings for the last 5 years); and
8. Latest Appointment and Service Record/Certificate of Employment. (FDA Job Order Personnel need not submit this document)

Note:

- **Applicants are advised to secure certified true copies/ authenticated copies of documents specified in item numbers 4, 5, and 6 the soonest time, in case of appointment to the position applied for.**
- **Applicants are limited to apply up to <u>two (2) vacant positions</u> only.**

**Online submission of applications are now accepted. (www.fda.gov.ph/about/careers)*

Date of Posting: 19 JUN 2023
Deadline of Submission: 29 JUN 2023

Prepared by:	Approved by:
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