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

NOTICE OF VACANCY (Plantilla Position)

Center for Drug Regulation and Research
Product Research and Standards Development Division

Number of Vacancy	Item Number	Position Title	Salary Grade	Basic Monthly Salary	Civil Service Commission (CSC) Minimum Qualification Standard
1	OSEC-DOHB-MDSP2-510018-2015	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. Develop policies, guidelines and operational procedures related to the product registration and/or conduct of clinical trials under the Center's jurisdiction
6. Initiate development of systems and approaches on product registration and evaluation of clinical studies including interpretation of results.
7. Provide technical assistance related to drug product registration and conduct of clinical studies, with interpretation of data or results to stakeholders
8. Establish inter/intra collaboration in the registration of new drug products and in approval and monitoring of clinical studies for FDA purposes.
9. Provide technical supervision to staff.
10. 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 addressed to FDA Director General with the specific position applied for, Center/Office and Division assignment and Item Number;
2. Four (4) sets of duly accomplished and **notarized** Personal Data Sheet (CS Form 212) with attached Work Experience Sheet (Attachment to CS Form No. 212) (downloadable at www. csc.gov.ph);
3. Any Proof of Eligibility (Report of Rating/License/Certificate of Eligibility/Eligibility Card (photocopy, scanned copy, or site/screen capture of the eligibility using the Civil Service Eligibility Verification System [CSEVS], Professional Regulation Commission's [PRC]'s Licensure Examination and Registration Information System [LERIS], or Supreme Court of the Philippines [SC] Lawyer's List or other sites as may be applicable);
4. Copy of valid NBI Clearance
5. Photocopy of Diploma in any relevant Bachelor's Degree/Masters of Law/Bachelors Degree of Law and Transcript of Records (TOR);
6. Latest Performance Rating available (applicable for government employees only);
7. Certificates of trainings attended
8. Latest copy of Appointment Paper, Service Record and Certificate of Employment. (FDA employees and Contract of Service (COS) personnel are not required to submit this document)

Note:

1. **Applicants may also hand in or send through courier their application at Food and Drug Administration - Human Resource Development Division, Filinvest Corporate City, Civic Drive, Alabang Muntinlupa City;**

2. **Applicants are advised to secure certified true copies/ authenticated copies of documents specified in item numbers 5 and 6 the soonest time, in case of appointment to the position applied for;**
3. **Applicants are only limited to apply for up to two (2) vacancies in Contract of Service Positions and Plantilla Positions respectively; and**
4. **Applications with incomplete documents shall not be entertained.**

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

Date of Posting: 01 AUG 2023
Deadline of Submission: 11 AUG 2023

Prepared by:	Approved by:
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