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

NOTICE OF VACANCY (Plantilla Position)

Center for Drug Regulation and Research

Licensing and Registration Division

Number of Vacancy	Item Number	Position Title	Salary Grade	Basic Monthly Salary	Civil Service Commission (CSC) Minimum Qualification Standard
1	OSEC-DOHB-MDSP2-3-2000	Medical Specialist II	23	Php 78,455	**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 with a Certificate as Fellow of the relevant specialty society and/or Diploma of the relevant specialty board - a graduate of an accredited medical school who finished residency and training specialization
*Preferably Oncologist, Pharmacologist, Specialization in Infectious Disease, Cardiologist, Masters in Public Health, Masters in Statistics or Biostatistics, MS in Clinical Epidemiology

Experience: **Two (2) years** of responsible experience as Medical Specialist I or other related experiences
*Preferably with specialization in field of medicine in an accredited training in the chosen specialty with background in Pharmacology, Pharmacotherapy, Toxicology, Epidemiology, Pharmacovigilance (PV), Adverse Events Following Immunization (AEFI), Causality Assessment, Preclinical and clinical researches related to drug development.

Training: **Four (4) hours** relevant training
Preferably in:

- Pharmacology, Pharmacotherapy, Toxicology, Epidemiology, PV/AEFI Causality Assessment, Protocol Development and Evaluation, Clinical Research, Good Clinical Practice
- Undergone postgraduate training program in a local or International Academic Institution of Merit
- Member/fellow/diplomate of good standing and certified accordingly by the appropriate specialty society

Eligibility: RA 1080 (Physician)

Job Description:
(Licensing and Registration Division (LRD) – Registration Section)

1. Review safety and efficacy documents, e.g. Part III (Non-Clinical) and Parts IV (Clinical) of the ASEAN Common Technical Dossier (ACTD) and recommend the approval or disapproval of registration applications pharmaceutical drug products including vaccines and biologicals.
2. Based on the review made on the safety and efficacy of the drug dossier, recommend the appropriate product classification

3. Conduct research, literature review and/or initiate peer review on drug product safety and efficacy,
4. Recommend product re-classification (e.g. Rx to OTC or OTC to RX) based on literature review and review of safety alerts/ advisories especially from WHO and other National Regulatory Agencies (NRAs) such as USFDA, EMA and PMDA,
5. Develop, implement, review, repeal and /or update policies, guidelines, systems and operational procedures related to the drug product registration specifically on evaluation of safety and efficacy,
6. Provide technical assistance related to drug product registration and conduct of clinical studies, with interpretation of data or results to CDRR staff and all stakeholders.
7. Establish inter/ intra collaboration in the registration of new drug products and in approval and monitoring of clinical studies for FDA purposes.
8. Provide technical supervision to staff.
9. Participate in Good Clinical Practice (GCP) inspection of clinical trials site, review of findings, recommendation and report writing only when needed; and
10. Perform other related functions as may be 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 (Please indicate Item Number);
2. Four (4) sets of duly accomplished Personal Data Sheet (CS Form 212) (downloadable at www.csc.gov.ph);
3. Qualification Profile (Annex 1) (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:

1. **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.**
2. **Applicants are limited to apply up to two (2) vacant positions only.**

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

Date of Posting: 31 AUG 2022
Deadline of Submission: 10 SEP 2022

Prepared by:	Approved by:
JULIE L. ALVARA, RN, MBA CAO, Human Resource Development Division	**ATTY. RONALD R. DE VEYRA, MBA, CESO II** Deputy Director General, Internal Management