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					
2	OSEC-DOHB-FDRO3-27-2000 OSEC-DOHB-FDRO3-35-2021	Food-Drug Regulation Officer III	18	Php 46,725	**Education:** Bachelor's degree relevant to the job **Experience:** 2 years of relevant experience **Training:** 8 hours of relevant training **Eligibility:** Career Service (CS) Professional/ Second Level Eligibility
Product Research and Standards Development Division					
1	OSEC-DOHB-FDRO3-25-2000	Food-Drug Regulation Officer III	18	Php 46,725	**Education:** Bachelor's degree relevant to the job **Experience:** 2 years of relevant experience **Training:** 8 hours of relevant training **Eligibility:** Career Service (CS) Professional/ Second Level Eligibility

End User's Preference:

Education: Bachelor's Degree relevant to the job * Pharmacy, Nursing, Veterinary Medicine, Life Sciences (refer to list provided)
· Graduates of Pharmacy are preferred in the Registration Section
· Graduates of Veterinary Medicine, BS Pharmacy, Biology and other Life Science courses are preferred in the Veterinary Unit.
· Graduates of Pharmacy, BS Biology, BS Microbiology, BS Biotechnology, BS Molecular Biology and other Life Science courses are preferred in the Vaccines and Biotechnological Product Unit
· Graduates of Pharmacy or Clinical Pharmacy and Nursing are preferred in the Drug Safety/ Pharmacovigilance Unit and the Clinical Trial Unit.
· Graduates of Pharmacy and other Bachelor's Degree may be considered in the Licensing Section.

Experience: 2 years of relevant experience

*For LRD: experience in evaluation of applications for licensing and registration; experience in inspection
*For PRSDD: experience in policy making; clinical research, PMS or compliance monitoring or inspection

Training: 16 hours of relevant training
* For LRD: Drug registration requirements: Labelling, API & FPP Assessment, Stability, BA/BE, Manufacturing Process Validation, Analytical Method Validation, Variation; GMP; GDSP; GL
*For PRSDD: Policy-making; Research; GCP; Protocol Development and Evaluation; Drug Safety; PV/AEFI; Counterfeit monitoring

Eligibility: RA 1080 or Career Service (Professional) 2nd Level Eligibility
*For LRD: Pharmacist (RA 1080) · Veterinarian (RA 1080)

Job Description:

Licensing Division

1. Evaluate and process application for license-to-operate.
2. Provide technical assistance regarding license-to-operate to staff and stakeholders.
3. Participate in the development of policies, guidelines and operational procedures in licensing drug establishments.
4. Participate in the development of systems related to licensing of drug establishments.
5. Participate in strengthening of intra/inter collaboration related to accreditation/licensing and monitoring of drug establishments.
6. Perform other related functions as may be assigned

Registration Division

1. Review and process applications related to product registration.
2. Participate in the development of systems on product registration
3. Participate in the development of policies, guidelines and operational procedures on registration of products under CDRR jurisdiction.
4. Provide technical assistance related to product registration to staff and stakeholders
5. Participate in strengthening of inter/intra collaboration in the product registration.
6. Perform other related functions as may be assigned

Product Research and Standards Development Division

1. Evaluate and process product verification, and/or complaints, and/or product recall, adverse events, adverse drug reactions and adverse events following immunization including conduct of investigation and submission to UMC.
2. Recommend and coordinate with other concerned units further necessary regulatory actions, as appropriate.
3. Review and process applications under clinical trial unit such as but not limited to clinical trial protocol, informed consents, clinical trial protocol amendments, clearance of monitored release drugs, new drug, new indication, new dosage form/strength, FDC rationale, classification and reclassification, Compassionate Special Permit, and Import Permit.
4. Manages the Clinical Trial Registry/ database.
5. Provide technical assistance regarding post marketing surveillance activities and/or product safety and/or CTU-related applications to stakeholders.
6. Conduct research related to health and/or regulatory issues and/or recent advances and development in regulatory practices and/or literature or peer review to support initial recommendations for CTU-related applications

7. Participate in the development of policies, guidelines and operational procedures in scientific product evaluation, conduct of clinical trials, licensing of establishments and post marketing activities.
8. Participate in the development of systems related to product registration, clinical trials, licensing of establishments and post marketing activities such as pharmacovigilance.
9. Participate in strengthening of intra/inter collaboration related to monitoring of drug products and drug establishments, pharmacovigilance and CTU-related operations.
10. Provide technical supervision to staff.
11. 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 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:
JULIE L. ALVARA, RN, MBA CAO, Human Resource Development Division	**ATTY. RONALD R. DE VEYRA, MBA, CESO II** Deputy Director General, Internal Management