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

NOTICE OF VACANCY
HIRING OF CONTRACT OF SERVICE PERSONNEL

POSITION: (1) Medical Specialist I
PAY RATE: SG-21 (Php 45, 203/month)
OFFICE: Center for Drug Regulation and Research

QUALIFICATION STANDARD	
Education	Doctor of Medicine
Experience	1 year of relevant experience
Training	4 hours of relevant training
Eligibility	R.A 1080

End user's preference:
Education: Preferably Doctor of Medicine
Eligibility: Preferably R.A 1080

Job Description:
Licensing and Registration Division

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. Review and recommend GCP inspection findings and report;
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 may be assigned.

Applicants are advised to submit the following to the Human Resource Development Division, FDA Alabang Muntinlupa City.

1. Application Letter;
2. Duly Accomplished Personal Data Sheet (CS Form 212) (Downloadable @ fda website-Careers area);
3. Certified True Copy of Eligibility;
4. Certified True Copy of Diploma and Transcript of Record;
5. Certificate of Attendance to training/s, if any;
6. NBI Clearance;
7. Certificate of Employment/Service Record

Noted by:	Approved by:
JULIE L. ALVARA, RN, MBA CAO, Human Resource Development Division	**DR. SAMUEL A. ZACATE** Director General

Date of Posting: 05 OCT 2023
Deadline of Submission: 12 OCT 2023