HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Scientific Officer, Pharmacovigilance - HPM

ROLE SUMMARY

Reporting to the Pharmacovigilance Surveillance Assessor, the Scientific Officer post is located within the Human Products Monitoring (HPM) department working in the area of evaluation of pharmacovigilance data and contributing to Blood, Tissue & Cell and Organ (BTO) vigilance related activities, as necessary.

The role of the Scientific Officer is to contribute to the safety monitoring of medicines and BTO vigilance activities, to ensure HPRA obligations and requirements with regard to reporting are met in an appropriate and timely manner, to appropriately review, evaluate, follow up, collate and present adverse reaction data, to provide input and support for responses to technical and other queries, to support team organisation and activities to achieve required levels of performance and to respond effectively to changes in the internal and external environment.

The Scientific Officer is responsible for contribution to and development of the quality management system for the Pharmacovigilance (PV) section, liaising with the team as necessary. In this regard, the Scientific Officer works closely with colleagues in the PV team and as needed with colleagues, particularly in the wider HPM department, Compliance, Human Products Authorisation and Registration (HPAR), IT and Customer Service.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Working closely with the Pharmacovigilance Surveillance Assessor and other members of the team to ensure timely, effective and appropriate processing and evaluation of adverse reaction data, including follow up of individual case safety reports (ICSRs)
  - Working with colleagues to facilitate changes to safety reporting requirements arising from revisions to clinical trials legislation
  - Liaising with and providing technical information, advice and guidance on PV matters to HPRA and other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public
  - Working with colleagues to ensure that the strategic and operational goals of the PV section are achieved
  - Attending and contributing to meetings, as necessary

- Operational Objectives
  - Supporting the Pharmacovigilance Surveillance Assessor and other team colleagues
  - Preparing and compiling PV data for review and drafting reports, including as required:
    - HPRA database searches
    - EudraVigilance/WHO database searches

    - Literature and other searches, as needed
    - Requests for company database searches
  - Contributing to the review, evaluation and follow up of individual and cumulative safety data
  - Contributing to the review and analysis of adverse reaction reporting trends
  - Assisting in the implementation and maintenance of quality management in the PV section, including identifying potential problems and providing solutions in a timely manner
  - Highlighting any company/sponsor compliance concerns with PV obligations and liaising with team colleagues, particularly the Pharmacovigilance Compliance group to ensure follow up to address any issues identified
  - In the absence of more senior technical staff, reviewing incoming PV data to identify any urgent/emerging safety issues requiring immediate action and liaising with colleagues to progress these, as necessary

- Technical Objectives
  - Database/IT:
    - Coding, classification and evaluation of adverse event/reaction data
    - Maintaining records of in-house and archived adverse event/reaction data
    - Electronic reporting of adverse reactions to EudraVigilance
    - Collating data to contribute to responses to requests for information from HPRA, including for the EU network, WHO, Marketing Authorisation Holders (MAHs), healthcare professionals and patients/consumers
  - Pharmacovigilance Compliance:
    - Assisting in monitoring company/sponsor compliance with PV reporting requirements and obligations
    - Ensuring accurate and consistent use of nomenclatures and coding standards/requirements
    - Ensuring appropriate maintenance and management of adverse reaction data (paper and electronic records)
    - Any other areas or processes, which may come within the scope of the PV section
  - Quality Control:
    - Working with colleagues to contribute to the maintenance and update of the quality system for PV
    - Keeping current with HPRA key quality management activities as they impact on the PV section
    - Participating in audits as required and to the development of corrective and preventative actions, as necessary
  - Other:
    - Query handling
    - Contributing to preparation, review and evaluation of cumulative PV data, as necessary
    - Providing presentations to both internal and external stakeholders, as required

- Quality and Knowledge Management
  - Assisting with the effective implementation of the HPRA quality management system within the HPM department

- Assisting the Management team to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the PV section
- Assisting the Management team to ensure that available information and knowledge across the HPRA is effectively used by the PV section
- Assisting the Management team to ensure that PV section procedures remain consistent with relevant developments in National, European and International regulations, legislation and guidelines

- Performance Management
  - Highlighting issues identified (e.g. with reporting, procedures, compliance monitoring) to the Pharmacovigilance Surveillance Assessor and contributing to the development of measures to resolve them
  - Reporting regularly on progress against specified objectives, goals and targets
  - Participating in the performance management process

- Communications/Customer Service
  - Participating at regular internal team, section and department/organisational meetings

- General
  - Liaising with and providing support to other areas of the PV section, as required
  - Performing such other duties as the HPRA may reasonably require

QUALIFICATIONS AND EXPERIENCE

- To be considered for his post, candidates must:
  - Have a third level degree in a relevant scientific or related discipline
  - Relevant experience in pharmaceutical/clinical quality assurance, pharmacovigilance, compliance, clinical data management, or other related areas.
  - Experience with pharmacovigilance and adverse reaction reporting/monitoring activities
  - Previous experience with electronic reporting systems, clinical data management or clinical research would also be an advantage
  - Knowledge of relevant European and National legislation, guidelines and reporting requirements
  - Excellent communication skills with the proven ability to deliver appropriate information to the right people using a range of written, verbal and presentation skills
  - Excellent data analysis skills
  - Proven ability to work effectively as part of a multi-disciplinary team
  - Demonstrated initiative and problem solving capabilities
  - Proven ability to work unsupervised
  - Highly motivated and with the ability to manage deadlines

- In addition, the following would be considered an advantage;
  - Post graduate qualification in a relevant scientific or related discipline
  - Experience in scientific report writing
  - Experience coding with the Medical Dictionary for Regulatory Activities (MedDRA)

REMUNERATION

Salary: €37,180per annum (*new entrants - incremental scale).

SUPERANNUATION

The new Single Public Service Pension Scheme ("Single Scheme") commenced with effect from 1 January 2013. All new entrants to pensionable public service employment on or after 1 January 2013 are, in general, members of the Single Scheme.

LOCATION

The successful candidate will be working in the HPRA offices a minimum, of two days per week and can avail of working remotely up to a maximum of three days per week subject to the terms of the policy. The specific days each week when you work at each location will be determined by your manager. The HPRA reserves the right to cease, vary or change the office/home location split during or after the review period. Notwithstanding any applicable hybrid working arrangement, you may be required to work at any specified location as may be reasonably required by the HPRA from time to time.

HOURS OF DUTY

The hours of duty are fixed by the HPRA from time to time. The current arrangements are Monday-Friday (minimum 35 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

DURATION OF POST

This post is for the duration of one year due to maternity leave

HEALTH

A candidate must be fully competent and capable of undertaking the duties attached to the position and be in a state of health such as would indicate a reasonable prospect of ability to render regular and efficient service.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 22 days per annum.

DUTIES OF POST

The duties set out in the role profile (above) are indicative of responsibilities related to this role. As with all posts, the nature of HPRA business is evolving and flexibility is required in order to adapt to changing business needs.

CONFIDENTIALITY AND CONFLICT OF INTEREST

Employees are prohibited from having any personal or financial interest in any industry that the HPRA regulates from the date of appointment with the HPRA. All HPRA employees are required to declare any matter that could affect their impartiality or that could reasonably be perceived as affecting their impartiality. All new entrants are required to complete a declaration of interests prior to commencing employment in the HPRA. The HPRA's Conflicts of Interest Policy provides guidance on the types of interests to be declared. Any interests declared will be evaluated and any potential conflicts will be addressed in line with that policy.

The HPRA deals with highly confidential matters including identifiable details pertaining to healthcare professionals, patients and commercially sensitive information. Employees are prohibited from disclosing any information in relation to the business of any person obtained in his/her capacity as an officer of the HPRA.

DATA PROTECTION

The General Data Protection Regulation and Data Protection Acts 1988-2018 apply to the processing of personal data and the HPRA is committed to complying with its legal obligations in this regard. For information on how we process your information during recruitment, please see our privacy notice.

REFERENCES

The names and addresses of two referees to whom the applicant is well known but not related must be provided. Reference may be made to current and former employers without further notification of the applicant. Applicants having any reservations on this matter should so state at time of application.

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

CLOSING DATE

The closing date for applications for this post is **Wednesday, 15th February 2023**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation/complete a practical test - details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place on Thursday, 23rd February 2023

The HPRA will make reasonable accommodations for a person with a disability during the recruitment process.

COLLECTIVE AGREEMENT: REDUNDANCY PAYMENTS TO PUBLIC SERVANTS

The Department of Public Expenditure and Reform introduced, with effect from 1st June 2012, a Collective Agreement which had been reached between the Department of Public Expenditure and Reform and the Public Services Committee of the ICTU in relation to ex-gratia Redundancy Payments to Public Servants. It is a condition of the Collective Agreement that persons availing of the agreement will not be eligible for re-employment in the public service by any public service body (as defined by the Financial Emergency Measures in the Public Interest Acts 2009 – 2011) for a period of 2 years from termination of the employment. Thereafter the consent of the Minister for Public Expenditure and Reform will be required prior to re-employment. People who availed of this scheme and who may be successful in this competition will have to prove their eligibility (expiry of period of non-eligibility) and the Minister's consent will have to be secured prior to employment by any public service body.

DECLARATION

Applicants will be required to declare whether they have previously availed of a public service scheme of incentivised early retirement and/or the collective agreement outlined above. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Public Service employment and/or where they have received a payment-in-lieu in respect of service in any Public Service employment.

* Candidates should note that entry will be at the minimum of the scale and the rate of remuneration may be adjusted from time to time in line with Government pay policy.

EQUAL OPPORTUNITIES

The HPRA is an equal opportunity employer. The HPRA will not discriminate against an employee or prospective employee in relation to the nine discriminatory grounds as per the Employment Equality Acts, 1998-2015