HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Pharmacovigilance Surveillance Assessor, Pharmacovigilance – Human Products Monitoring

ROLE SUMMARY

Reporting to the Pharmacovigilance Manager, the Pharmacovigilance Surveillance Assessor will work within the Human Products Monitoring (HPM) department in relation to safety monitoring and pharmacovigilance activities.

The role of the Pharmacovigilance Surveillance Assessor is to lead the technical team responsible for the review and evaluation of national, Individual Case Safety Reports (ICSRs) within the Pharmacovigilance section; to ensure HPRA obligations and requirements with regard to reporting are met in an appropriate and timely manner; to provide technical support and guidance in the review and evaluation of ICSRs; to appropriately collate, evaluate and present national data; to provide input and support for follow up of ICSRs, responses to technical and other queries; to support team organisation and activities to efficiently and effectively manage the workload and achieve required levels of performance; and to respond effectively to changes in the internal and external environment.

The Pharmacovigilance Surveillance Assessor will also work closely with other members of the Pharmacovigilance and Vigilance Assessment sections and the overall HPM department, as well as other HPRA departments, particularly the Human Products Authorisation and Registration (HPAR) and Compliance departments.

The following key activities are indicative of the range of duties to be undertaken by the Pharmacovigilance Surveillance Assessor:

- Leading and supervising the technical team dealing with adverse reaction and event reporting in line with the goals and objectives of the Pharmacovigilance section and the HPM department
- Acting as a subject matter expert with regard to case processing and associated regulatory and scientific guidance
- Providing technical support in the review, evaluation and follow up of national, Individual Case Safety Reports (ICSRs)
- Monitoring trends in national reporting of ICSRs
- Highlighting ICSRs and national reporting experience, with overviews of cumulative data, as appropriate
- Collating, evaluating and presenting summary overviews of national reporting data
- Managing and monitoring HPRA compliance with ICSR reporting standards and timelines
- Actively managing the ICSR workload, through case allocation and follow up, development/enhancement of processes to facilitate throughput and proactive preparation for case processing and management in the context of report surges arising from stimulated reporting activities.

- Encouraging and facilitating adverse reaction reporting by healthcare professionals and patients/consumers
- Contributing to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines
- Contributing to the scientific review and evaluation of aggregated pharmacovigilance data, including product specific and class related reviews of medicinal products
- Liaising with and providing technical information, advice and guidance on pharmacovigilance matters to HPRA and other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public
- Supporting external compliance monitoring with pharmacovigilance obligations
- Participating at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation and opinions
- Representing the HPRA, as required

KEY RESPONSIBILITIES

- Strategic Objectives
  - Supporting the Management team in the day to day operation and on-going development of the Pharmacovigilance section
  - Working with the Management team in the preparation of work objectives for the Pharmacovigilance section
  - Working with the Management team to prioritise work objectives and to ensure that the strategic and operational goals of the Pharmacovigilance section are achieved
  - Providing support and direction to colleagues and others within the Pharmacovigilance section and the HPM department

- Technical/Operational Objectives
  - Overseeing and participating in the following key activities within the technical team:
    - Recording, coding, classification and follow-up of ICSRs
    - Electronic reporting of ICSRs, as required
    - Preparation, review and evaluation of pharmacovigilance data
    - Evaluation and trend analysis of national ICSRs
    - Proactive market monitoring and data gathering
    - Monitoring HPRA compliance with ICSR reporting requirements
    - Maintaining records of in-house and archived ICSRs (manual & electronic)
  - Contributing to the monitoring of medicinal products through the evaluation of ICSRs/national trend analysis and the review of aggregated pharmacovigilance data
  - Compiling national data to support assessments in the context of product specific and class related safety reviews
  - Promoting and facilitating adverse reaction reporting and coordinating initiatives to enhance and develop existing reporting options
  - Supporting and contributing to activities to facilitate exchange of national adverse reaction data with other state authorities
  - Compiling and providing information including national adverse reaction data, advice and guidance to HPRA colleagues, to support responses to e.g. parliamentary queries and ministerial representations, freedom of information requests, legal, customer service and media queries, in accordance with the applicable timelines

- Contributing to the provision of data and responses to facilitate responses to the European Medicines Agency (EMA) and other regulatory colleagues, pharmaceutical companies, WHO and associated organisations, relevant national and international bodies, healthcare professionals and members of the public
- Compiling data and information for monthly departmental reports, the Pharmacovigilance section of the annual report for the HPM department and the HPRA Annual Report
- Attending and contributing to relevant internal and external meetings
- Preparing and maintaining appropriate records of such meetings and activities, including minute taking and report preparation, when required
- Ensuring knowledge of state-of-the-art technologies and methodologies through ongoing professional education and review of the published literature
- Contributing to the monitoring of company compliance with pharmacovigilance obligations
- Contributing, as needed to the enforcement of regulations governing medicinal products

- 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 Pharmacovigilance Section
  - Assisting the Management team to ensure that available information and knowledge across the HPRA is effectively used by the Pharmacovigilance section
  - Proactively ensuring pharmacovigilance processes under the remit of the PV assessor remain consistent with relevant developments in National, European and International regulations, legislation and guidelines

- Performance Management
  - Coordinating the allocation of work and resources within the team
  - Working to promote and support effective performance within the team and the Pharmacovigilance section
  - Providing performance feedback, coaching and mentoring support to team members
  - Participating in the HPRA performance development programme (PDP)
  - Taking measures to identify and resolve issues impacting performance within the team and in the Pharmacovigilance section
  - Reporting regularly on progress against specified goals/targets and objectives

- Communications/Customer Service
  - Participating at regular internal team, section and department/organisational meetings
  - Attending meetings, conferences and training courses and representing the HPRA as appropriate
  - Executing professional duties in a manner that contributes to the efficiency and effectiveness of the HPRA
  - Providing technical information, advice, and guidance to regulatory authorities, healthcare professionals and other relevant stakeholders

- General
  - Perform such other duties as the HPRA may reasonably require

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, the ideal candidate will have:
  - A primary degree in a clinical or relevant life-science discipline e.g. clinical pharmacology
  - A minimum of two years' experience in pharmacovigilance and the evaluation of the safety of medicinal products in the pharmaceutical industry, government authority, academic or clinical setting
  - Experience with electronic reporting systems, coding standards and requirements, database searching and report analysis skills
  - Detailed knowledge of relevant medicines legislation and guidance
  - Excellent data analysis skills
  - A proven track record of working within multidisciplinary teams
  - Proven ability demonstrating excellent interpersonal, communication, report-writing and presentation skills
  - Proven ability to meet deadlines
  - Direct experience working with stakeholders/customers
  - Demonstrated initiative and team working capabilities
  - A demonstrated ability to think critically and independently

- In addition to this the ideal candidate will also have one or more of the following;
  - Post-graduate qualifications/training in pharmacovigilance, pharmacoepidemiology or other closely related scientific discipline
  - Knowledge and experience in clinical data management and evaluation
  - Experience of people/project management

REMUNERATION

Salary: €67, 890 per 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 is a two-year contract post.

ANNUAL LEAVE

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

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.

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 Assessment 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 Assessment.

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.

REFERENCES

The names and addresses of two referees to whom the applicant is well known but not related must be submitted with the application. 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.

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.

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

CLOSING DATE

The closing date for applications for this post is **Sunday,19th February 2023.**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation, or undergo a practical assessment - details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place on the week beginning **27th February 2023.**

Note: The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

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 opportunities employer. We are committed to equal employment opportunity regardless of gender, civil status, family status, sexual orientation, religion, age, disability, race or membership of the travelling community. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process and can be notified in the course of the interview correspondence.