HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Vigilance Assessor, Vigilance Assessment - Human Products Monitoring

ROLE SUMMARY

The Vigilance Assessor will work as part of a dynamic multi-disciplinary team within the Human Products Monitoring (HPM) Department of the HPRA. They will be responsible for monitoring the benefit-risk profile and for assessing risk management planning activities of medicinal products in Ireland and in the European Union in the post-marketing setting.
The Vigilance Assessor will be closely involved contributing to and leading safety assessments conducted by the HPRA both nationally and as part of the European network and will actively support the HPRA's contribution to the European Medicines Agency's Pharmacovigilance Risk Assessment Committee.

The key activities of the role will involve:

-Scientific evaluation of cumulative and emerging data on the risks of medicinal products from various post marketing sources including clinical studies, pharmacovigilance databases and scientific literature to facilitate the timely detection and assessment of any safety concerns.

-Consideration of the impact of such evaluations on proactive risk management planning for the medicinal product, as well as the need for, design and evaluation of post-authorisation safety studies to further evaluate the safety and benefit-risk profile of a medicine and support regulatory decision-making.

-Regulatory communication of such risks to healthcare professionals and patients in order to ensure the safe and rational use of medicines on the Irish market.

The position may be suitable for an individual with a pharmacy, life sciences or public health-related background with relevant clinical experience together with experience in conducting literature reviews, data analysis and critical appraisal to support clinical decision-making. Candidates should have a demonstrated ability for technical scientific report writing. Preference will be given to candidates with research experience, in particular in the area of pharmacoepidemiology or similar discipline.

KEY RESPONSIBILITIES

- Technical/Operational Objectives
  - Monitoring the safety of authorised medicinal products (pharmacovigilance) by reviewing periodic safety update reports (PSURs) and aggregated adverse reactions report data, data from clinical studies and by evaluating the published literature.

- Signal detection activities using available databases and with integration of quantitative and qualitative approaches for signal management in accordance with EU guidance
- Evaluation of signals from a range of data sources including the published literature and epidemiological studies
- Contributing to the assessment of data in the context of ongoing risk management and safety reviews (including referrals)
- Providing assessment of post authorisation safety study draft protocols and amendments
- Assessment of regulatory tools for minimising risks of medicinal products and working with relevant stakeholders to evaluate the effectiveness of implemented measures
- Contribution to transparency and risk communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines
- Liaison with, and advice to, applicants and professional colleagues in order to facilitate the assessment process
- Ensuring knowledge of state-of-the-art technologies through ongoing professional education and review of the published literature
- To perform such other duties as the HPRA may reasonably require

- Communications/Customer Service
  - Provision of technical information, advice, and guidance to regulatory authorities' healthcare professionals and other relevant stakeholders
  - Representing the HPRA as appropriate on national and international bodies at meetings and symposia at home and abroad
  - Participation at all levels (HPRA, national and international) in the formulation and preparation of regulatory policies, guidelines, legislation and opinions

- Strategic Objectives
  - Supporting the Management team in the running and ongoing development of the Vigilance Assessment section and in prioritising work objectives to ensure that strategic and operational goals of the section are achieved.
  - Providing support and direction to colleagues and others within the Vigilance Assessment section and the Human Products Monitoring department

- Quality Management
  - Assisting with the effective implementation of the HPRA quality management system with the Human Products Monitoring department
  - Assisting the Management team to ensure that Vigilance Assessment procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidelines
  - 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 Vigilance Assessment section
  - Assisting the Management team to ensure that available information and knowledge across the HPRA is effectively used by the Vigilance Assessment section

- Performance Management
  - Working to promote effective performance within the Human Products Monitoring department

- Participating in the performance development programme (PDP)
- Taking measures to identify and resolve issues impacting performance in the Vigilance Assessment section
- Reporting regularly on progress against specified goals/targets and objectives

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must:
  - Have a degree in pharmacy or other closely related scientific discipline.
  - Have at least 2 years relevant experience (acquired after the qualification required above)
  - Have a PhD, or other relevant post graduate qualification, preferably in the area of pharmacoepidemiology epidemiology, medical statistics, or other closely related scientific discipline.
  - Have experience in conducting literature reviews, data analysis and critical appraisal including the evaluation of observational research and have demonstrated an ability for technical scientific report writing, presentation and communication, including as part of research conducted in the academic, clinical or industrial field of medicine.
  - Have experience in the use of medicinal products in the clinical setting with a preference given to candidates who have experience in direct interaction with healthcare professionals and patients as part of provision of care or support
  - Have an understanding of the principles of benefit-risk evaluation and risk management planning for medicinal products
  - Be self-directed and have demonstrated an ability to use initiative and work independently to tight deadlines
  - Have strong analytical skills with a demonstrated ability to problem solve
  - Have excellent interpersonal skills with ability to work within multi-disciplinary teams
  - Display flexibility in an agile work environment
  - Experience with effective knowledge sharing and presentation skills

- In addition to this the ideal candidate will also have one or more of the following;
  - Experience in working in the field of pharmacoepidemiology and/ or pharmacoepidemiological research
  - Have experience of evaluation of the safety profile and risk management planning for medicinal products

REMUNERATION

Salary: €70,287-€81,508 per annum (incremental scale).
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.

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.

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 in line with the Hours of work and attendance policy after a period of six months.

DURATION OF POST

This is a 3-year contract post.

Note: The issuing of a 3 year contract is standard HPRA practice prior to moving to permanency for long term roles, such as this..

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.

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.

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.

The appointee will be required to demonstrate flexibility and anticipate that the role, activities and responsibilities may change in line with business needs and organisational development.

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 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.

CLOSING DATE

The closing date for applications for this post is **Sunday, 21st April 2024.**

INTERVIEWS

Applicants attending for interview may be required to complete a scenario-based practical or presentation - details will be notified to applicants who are shortlisted. It is anticipated that these will take place week beginning **29th April 2024.**

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.

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.