HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Vigilance Assessor (Acting), Vigilance Assessment – Human Products Monitoring

ROLE SUMMARY

The Vigilance Assessor will work within the Human Products Monitoring (HPM) department in relation to vigilance of post-marketing and pharmacovigilance activities.

The role of the Vigilance Assessor is the post marketing evaluation and regulation of the benefits and risks of medicinal products in Ireland and the European Union, to provide technical support to the Director of Human Products Monitoring in order to facilitate the effective safety monitoring of medicinal products.

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

- 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
- Assessment of Pharmacovigilance Plans including post-authorisation safety study protocols and amendments to protocols
- Interpretation of data from post-authorisation studies and clinical trials
- Assessment of Risk Minimisation Plans 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
- Assessment of Periodic Safety Update Reports (PSURs)
- Technical liaison with the HPRA colleagues, applicants, regulatory authorities and other relevant bodies, healthcare professionals and the community
- Provision of technical information, advice, and guidance to the HPRA colleagues, relevant bodies and individuals
    - Representing the HPRA on national and international bodies
    - Participation at all levels (HPRA, national and international) in the formulation and preparation of regulatory policies, guidelines, legislation and opinions

KEY RESPONSIBILITIES

- Strategic Objectives
    - Supporting the Management team in the running and ongoing development of the Vigilance Assessment section
    - Working with the Management team in the preparation of work objectives for the Vigilance Assessment section

- Working with the Management team to prioritise work objectives and to ensure that the strategic and operational goals of the Vigilance Assessment section are achieved
- Providing support and direction to colleagues and others within the Vigilance Assessment section and the Human Products Monitoring department

- 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 studies and by evaluating the published literature in relation to clinical experience, and by assisting with the evaluation of Individual Case Safety Reports (ICSR's) and quality defect reports as necessary
  - Providing assessment of post authorisation safety study draft protocols and amendments
  - Providing assessment and interpretation of data generated as a result of clinical trials or post-authorisation studies in order to guide decision-making
  - Contributing to the assessment of data in the context of ongoing risk management and safety reviews (including referrals)
  - Liaison with, and advice to, applicants and professional colleagues in order to facilitate the assessment process
  - Providing technical information, advice and guidance to organisations, (such as the Department of Health (DoH), the Irish Blood Transfusion Service (IBTS), the Food Safety Authority of Ireland (FSAI), industry representative bodies etc.), to healthcare professionals and lay persons
  - Ensuring knowledge of state-of-the-art technologies through ongoing professional education and review of the published literature
  - Providing advice and professional expertise to the HPRA's inspectors in the performance of their duties
  - Participation in the enforcement of regulations governing medicinal products
  - To perform such other duties as the HPRA may reasonably require

- 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 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
  - 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

- 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

- Communications/Customer Service
  - Participation in regular Human Products Monitoring department meetings and HPRA meetings
  - Attendance at meetings and symposia at home and abroad and representing the HPRA as appropriate
  - Execute professional duties in such a manner so as to contribute to the efficiency and effectiveness of the HPRA
  - Provision of 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, candidates must:
  - Have a primary degree in pharmacy or other closely related scientific discipline
  - Have at least 4 years relevant experience (acquired after the qualification required above)
  - Have comprehensive knowledge and experience of clinical pharmacology
  - Have comprehensive knowledge and experience in the use of medicinal products in the clinical setting
  - Have performed or published research in the academic, clinical or industrial field of medicine
  - Have experience or a good understanding of pharmacovigilance and risk management
  - Have a sound understanding of the interpretation of pharmacoepidemiological data and ability to apply this to clinical decision-making and risk minimisation
  - Have excellent interpersonal skills
  - Be of good character

- 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 or be currently undertaking a postgraduate qualification in pharmacoepidemiology, medical statistics or other closely related scientific discipline
  - Excellent data analysis skills including the use of statistical packages

REMUNERATION

Salary: €64,614 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.

HOURS OF DUTY

The hours of duty are fixed by the HPRA from time to time. The current arrangements are Monday-Friday (minimum 37 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

DURATION OF POST

This is for the duration of maternity leave

LOCATION

This role is being offered as part of our hybrid working model. The successful candidate can avail of working remotely for two days per week, and working three days per week in the HPRA offices, based in Kevin O'Malley house, Earlsfort Terrace, Dublin 2. The specific days each week when you work at each location will be determined by your manager. The introduction of the hybrid model will be subject to review at the end of 2022.
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.

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.

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.

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, 22nd May 2022**

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. Please note these interviews will be conducted via Microsoft Teamsand it is anticipated that these will take place on Tuesday, 31st May 2022.

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 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.

* 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.