HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Vigilance Assessment Manager, Human Products Monitoring (HPM)

ROLE SUMMARY

Reporting to the Director of Human Products Monitoring, the role of the Vigilance Assessment (VA) Manager is to lead a team within the vigilance assessment section, responsible for post-market surveillance activities of human medicines that have been authorised or licensed for use in Ireland.

Post-market surveillance activities employ a range of tools to monitor the safety of medicines, and which include the assessment of reports of suspected adverse events, conducting periodic safety reviews and signal management activities, evaluating new and emerging data from a variety of data streams as well as risk management planning for medicinal products and risk communication in co-operation with pharmacovigilance professionals in Europe and internationally.

The VA section of the HPM department is comprised of two teams, each with a VA Manager, responsible for management and technical leadership. The VA Manager, will report to the Director of Human Products Monitoring, and will direct, support and lead the team to achieve required levels of performance. The VA Managers will work together to ensure seamless integration of activities, and achievement of shared objectives and goals, and together will develop the sections activities and capabilities, through fostering a culture of scientific development, responding effectively to changes in the internal and external environment.

The VA Manager provides leadership, motivation, encouragement and effective management for all staff and ensures development and maintenance of a positive working environment. The VA Manager will be required to work with the management team and Director to develop processes, systems and resource capabilities within the Department to meet our regulatory responsibilities and undertake our activities efficiently and effectively.

The VA Manager is a member of the HPM management team, responsible for managing the overall performance of the VA section in partnership with the (other) VA Manager. This will be achieved by defining objectives, setting targets, coordinating activities, agreeing priorities, providing technical advice, maintaining effective communication lines and ensuring that the required standards, policies and practices are in place. The VA Manager is responsible for ensuring the delivery of service which meets best international practice both for scientific robustness and customer service, and for leading on implementation of any relevant reform measures or change initiatives, in line with HPRA organisational strategy.

Working with other colleagues in the department's management team the VA Manager ensures: appropriate levels of communication, integrated planning of resources, achievement of joint objectives and contributing to the development of an overall strategy for the department. The VA Manager also maintains effective working relationships with other HPRA departments/sections, in particular with staff of Human Products Authorisation and Registration (HPAR), in relation to areas of post marketing safety, and staff in Compliance, on matters including effective recall of defective

products from the market.

The VA Manager will be required to lead staff through significant change and development initiatives and make effective contributions to development of systems, processes, resources and capabilities to ensure effective and timely implementation of new legislation and Good Vigilance Practices (GVPs).

THE VA SECTION OF HPM ARE RESPONSIBLE FOR THE FOLLOWING;

- Managing the national contribution to the Pharmacovigilance Risk Assessment Committee (PRAC), including working with colleagues cross-organisationally to ensure coordination and integration of approach between PRAC and representatives/delegates to all EMA Committees and Working Parties
- Assessment of Periodic Safety Update Reports (PSUR), Risk Management Plans (RMP), Post Marketing Commitments (PMCs), Post-Authorisation Safety Studies (PASS), referral procedures, PRAC-led variations and risk minimisation plans
- Performing signal management and evaluation of new and emerging data from a variety of data streams
- Ensuring robust scientific decisions underpin the advice, recommendations, conclusions as well as any actions arising from post-market surveillance activities
- Taking the initiative in human medicines clinical risk management activities, including proactive monitoring of public health issues in the areas of pharmacovigilance risk management (such as Pharmacoepidemiology research and intelligence and the performance of product class reviews)
- Working together with the HPM management team, and colleagues across the organisation, in particular HPAR and Compliance, to identify a communication approach with regards to vigilance issues of public health relevance
- Providing assessment support to the pharmacovigilance section of HPM as may be required in relation to national safety monitoring and communications
- Contributing subject matter expertise to relevant cross-organisational activities and supporting a cohesive and integrated approach to the HPRA's regulation of human medicines, working with colleagues across the organisation including HPAR, Compliance and others to achieve this.
- Representing HPRA nationally, and at European and international level, as required.
- Other duties as may be required with regard to the post marketing regulation of human medicines.

KEY RESPONSIBILITIES OF THE ROLE

- Strategic Management
  - Supporting the Director of HPM in the management and ongoing development of the department, which may encompass identification of strategic objectives for VA and related areas, as well as implementation of reform measures and change initiatives to support the organisation's approach to oversight of regulatory activities for human medicines.
  - Working with colleagues in the HPM management team to prioritise objectives and to ensure that the strategic and operational goals of the Department are achieved.
  - In partnership with the VA Manager, developing strategic and operational plans for the VA section that deliver a patient focussed and risk centred system of regulation, focussed on

proactive and preventative measures and that is consistent with those of the Department and the wider HPRA.
  - Managing and developing staff, including through change and development initiatives and providing a supportive environment to enable a motivated, impactful and adaptable team.
  - Provide technical leadership in relation to handling of vigilance issues of public health relevance and in supporting strategic risk management and communication.
  - Working with colleagues in the HPM department to ensure effective and timely implementation of new legislation and guidance relevant to the department activities and to ensure relevant systems, processes and resources are in place to undertake these activities.
  - Supporting the formulation and preparation of national/international regulatory policies, guidelines and legislation as deemed appropriate.
  - Ensuring strategic contribution and participation in external, European and international initiatives.
  - Working together with the HPM management team, and cross organisationally, to develop the approach to engagement and communication with the public and other stakeholders to maximise the effectiveness, relevance and value of this engagement.
  - Working together with the HPM management team, to provide input into PRAC Rapporteurship biddings, in line with departmental strategic objectives

- Operational Management
  - Managing and supervising a VA team, working in collaboration with the (other) VA Manager to achieve strategic and operational goals.
  - Plan and organise work tasks within the section to ensure efficient delivery of work.
  - Working with the Director of HPM and other section managers to plan and organise efficient delivery of the departments activities, and integration of relevant cross-organisational activities.
  - Coordinating the allocation of work and resources within the VA section, in partnership with the (other) VA Manager.
  - Promoting effective and efficient use of resources with a focus on value, impact and relevance of outcomes.
  - Ensuring activities and follow up actions are conducted in accordance with appropriate legislation and administrative procedure.
  - Promote optimisation of assessment activities to ensure they are proportionate, appropriate, targeted and effectively prioritised (risk based approach).
  - Providing technical and management leadership, support and direction to the VA section.
  - Promoting a positive, open, professional working environment.
  - Preparing management reports as required and maintaining appropriate records of meetings and activities.
  - Contribution to business planning activities including service plans etc.
  - Contribution to the preparation of strategic, developmental and operational planning documents.
  - Attending and contributing to HPRA management team meetings, as appropriate.
  - Attending and contributing to meetings of the Advisory Committee for Human medicines as appropriate.
  - Attending and participating in European and international meetings as appropriate and at preparatory and follow up meetings within HPRA.
  - Representing the HPRA at meetings and working groups, as appropriate.

- Technical Management
  - Provide technical leadership and supervision of a VA team, ensuring robust scientific decisions underpin the advice, recommendations, conclusions and any actions arising from assessment of;
    - PSURs
    - RMPs
    - Referrals and EU wide reviews
    - Post Authorisation Safety Studies (PASS) Protocols and Post-Marketing Commitments (PMC), interim reports and final results
    - Union procedures
    - Signals
    - Risk minimisation plans
    - New and emerging data from a variety of data streams
    - Other areas or processes which may come within the scope of the section.
  - Reviewing assessment reports and documents, as appropriate.
  - Supporting PRAC delegates and assessors in the preparation for plenary presentations to the PRAC, and coordinating the liaison between the HPRA's CHMP and CMDh delegates, and representatives from the HPM and HPAR Management teams, on the outcomes/ recommendations of the PRAC, including any implementation timeframes agreed by the PRAC that need to be factored into operational and resource plans.
  - Contributing to the implementation of the agreed PRAC recommendations and outcomes, as appropriate, and liaising with colleagues in HPM, HPAR and Compliance departments to disseminate PRAC-related communications and information in a timely and effective manner.
  - Ensuring proportionate and timely action is taken to safeguard public health, in response to vigilance issues, including determining the communication approach for those of public health relevance.
  - Oversee and lead human medicines clinical risk management activities, including proactive monitoring of public health issues in the areas of pharmacovigilance risk management (including for example, Pharmacoepidemiology research and intelligence and the performance of product class reviews).
  - Managing knowledge within the VA team, ensuring state-of-the art assessment through ongoing professional education and review of relevant published material.
  - Coordinating the provision of advice and expertise and VA input into PV related compliance issues, as appropriate.
  - Providing vigilance advice and expertise to HPM department, as well as HPRA colleagues in relation to human medicines vigilance issues.
  - Attending and contributing to HPRA meetings, as appropriate.
  - In consultation with colleagues in HPM and HPAR as appropriate; providing advice and technical expertise to external stakeholders including; the Department of Health, other healthcare product related agencies, industry and patient representative bodies, healthcare professionals and members of the public, as may be required
  - Ensuring appropriate representation at relevant European, international and national committees/ working groups, including communication, follow up and implementation on any relevant issues that may arise.
  - Supporting interactions with Market Authorisation Holders on product related issues in conjunction with the relevant vigilance assessor(s)

- Ensuring appropriate liaison with pharmaceutical industry in relation to the provision of guidance and assessment outcomes.

- Quality and Knowledge Management
  - Ensuring that the procedures and policies of the HPRA Quality Management System are deployed and adhered to within the team.
  - Ensuring that appropriate Standard Operating Procedures (SOPs) and technical guidelines for the section are implemented, updated, adapted and communicated on an ongoing basis within the team.
  - Participating and managing the involvement of the section in any internal audits including the identification and implementation of any required corrective actions.
  - Working together with the HPM management team, ensuring that the section remains up to date with relevant developments in National, European or International regulations and legislation.
  - Ensuring that available information and knowledge across the HPRA is effectively used by the vigilance assessment section.
  - Working with the other members of the department, as appropriate, to ensure that relevant and appropriate information is being disseminated to stakeholders (internal HPRA, industry, healthcare professionals, the public, patient organisations etc.).
  - Contributing to the development of the knowledge network across the HPRA.

- Performance Management
  - Working with the Director of HPM and the (other) VA Manager to:
    - Deliver performance targets for the section and individual staff.
    - Leading, co-ordinating and participating in the performance management process within the VA section
    - Communication of objectives, tasks and KPI's to the VA team.
    - Taking measures to identify and resolve issues impacting performance.
    - Recognising good performance and promoting a culture of performance improvement within the Vigilance assessment section.

- Team Development/People Management
  - Working with HR & Change, the Director of HPM and other colleagues as required in managing the VA section.
  - Working with HR & Change, the Director of HPM and other colleagues as required to develop the team's capabilities and expertise.
  - Ensuring effective communication within the VA section and to the HPM management team and Director.
  - Providing a supportive environment to enable a motivated, high impact and adaptable team that engages actively and openly.
  - Planning for and identification of future skills gaps/training needs within the Vigilance assessment section.
  - Liaising with HR and Change in providing front line management of staff (e.g. recruitment, managing attendance, probation, performance management etc.)
  - Managing and guiding staff through organisational change and development initiatives.
  - Overseeing the development of staff, including the development, with HR, of individual training plans, and maintenance of training records and documentation.
  - Ensuring the provision of high quality induction and ongoing training for staff, including on the job training.

- Ensuring the provision of adequate technical, non-technical and continuous professional development for the Vigilance assessment section, as appropriate.
- Providing performance feedback, coaching and mentoring support to the management team and staff in the Vigilance assessment section, as required.

- Communications/Customer Service
  - Promoting a strong customer service focus taking account of broad stakeholder needs (internal and external) and in particular patients, healthcare professionals, economic operators across the sector, Department of Health, other public agencies and industry representative bodies.
  - Working with colleagues in the HPM department to develop and implement a communications strategy which aligns to the HPRA's corporate communications strategy and meets the needs of all HPRA stakeholders.
  - Acting as an advocate in representing the views of the section to the wider HPRA organisation.
  - In consultation with the Director of HPM and the management team, providing relevant regulatory information, advice and guidance to industry, regulatory authorities, healthcare professionals and other relevant stakeholders.
  - Ensuring responses to queries and in line with the HPRA service charter.

- General
  - Performing such other duties as the HPRA may reasonably require.
  - As with the other section managers in the HPM department, deputising in the absence, on business or leave, for the Director of HPM.
  - Availability to travel for European and international meetings will be a requirement in this role.

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A relevant degree in any one of the following areas: medicine, pharmacy, pharmacology or another relevant life sciences discipline
  - A relevant postgraduate qualification
  - A minimum of 5 years relevant clinical, pharmacovigilance or regulatory experience in the evaluation of medicines in a regulatory authority, government authority, pharmaceutical company, academic or clinical situation
  - Minimum of three years' relevant experience in the management of a multi-disciplinary team(s)
  - Familiarity with the relevant EU and national legislation relating to medicines, including good vigilance practice(s)
  - A strong personal work ethos and a proven ability to manage high work throughputs and manage deadlines
  - An ability to adapt to changing conditions and display ability to generate effective and pragmatic solutions to new situations and problems, both strategic and operational
  - Be a self-starter, capable of excellent communication, negotiation and decision making
  - Excellent interpersonal, organisational and communication skills
  - Experience of working collaboratively with cross-organisational teams in a solution focussed manner

- In addition, one or more of the following would be considered an advantage:
    - Experience in biostatistics, pharmacoepidemiology and pharmacovigilance;
    - Prior experience of EU assessment procedures for pharmacovigilance;
    - Relevant experience as a national representative at EU or international level;
    - Experience in the implementation of EU pharmacovigilance guidelines and legislation;
    - Experience in risk management and communication procedures.
    - Experience of regular high-level representation of organisational/national positions at National/European level

REMUNERATION

Salary: €85 - €95k (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 a three year fixed term contract.

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 25 days per annum.

DUTIES OF POST

The duties set out in the role profile (above) are indicative of responsibilities related to this role. The Manager will have to demonstrate flexibility and anticipate that the role, activities and responsibilities will change as the HPM department develops and changes progresses.

The Manager will need to demonstrate the ability to lead the team through any such change and development initiatives.

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. 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.

VOLUNTARY HEALTH INSURANCE SCHEME

A group scheme operates for those wishing to participate and contributions are deducted from salary.

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 **Monday, 30th September 2019**

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 **week commencing the 14th October 2019.**

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.