HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Director of Human Products Monitoring (HPM)

ROLE SUMMARY

The Human Products Monitoring Department (HPM) is responsible for the ongoing monitoring of the safety of human medicines that have been authorised or licensed for use in Ireland. The post-market surveillance activities employ a range of tools to monitor the safety of medicines including the assessment of reports of suspected adverse events/ incidents, conducting scheduled safety reviews, and evaluating new and emerging data from trials and studies. In co-operation with pharmacovigilance professionals in Europe and further afield, the department is responsible for monitoring adverse reaction reports to identify new types of reactions, signals or changing trends in reporting.

Reporting to the Chief Executive, the role of the HPM Director is:

- Provide strategic and operational leadership to the HPM Department.
- Ensure that the resources and processes of the department operate in an integrated and effective manner to achieve the goals, objectives and targets defined in the strategic and departmental plans.
- Assist the Chief Executive and Management Committee in delivering the overall organisational strategic goals.
- Assist the Chief Executive and Management Committee in the identification and implementation of reform measures for the organisation's approach to the oversight of its regulatory activities for human medicines including appropriate risk management.

The Director will play a full and leading part in managing and further expanding the Authority's national, European and international influence with respect to the post authorisation of human medicines.

The Director will:
Lead the department, including the oversight of complex procedures, with intellectual and scientific rigour, working closely with the department's management team to:

- Ensure that appropriate objectives, analytics and targets are used to drive performance and that these are incorporated into the management plans of the individual teams within the department.
- Ensure that the department has the required technical, managerial and operational skills; and that the department's processes and practices are supported by appropriate standards, policies and guidelines.
- Lead quality improvement in terms of reviewing processes and making them more efficient, smarter, and informed by experience.
- Lead the department's participation in the identification and implementation of change initiatives required to enhance the organisation's approach to lifecycle risk management for human medicines.
- Provide leadership, motivation, encouragement and effective management for all staff to maintain a positive working environment.

- Maintain effective working relationships between the department and other areas of the HPRA, ensuring that any required interactions are adequately defined, effectively managed and reviewed as appropriate.
- The Director, working with other senior colleagues as required, will be responsible for representing the Authority and the State on all safety issues for human medicines and other regulatory activities within the department's remit.
- At national level, engage and build effective relationships with the department of Health and all relevant bodies and other key stakeholders including healthcare professionals and patients.
- Represent the HPRA at European and international level as required.

KEY RESPONSIBILITIES

- Strategic Management
  - Contributing with the management team to the development of organisational strategy and identifying and agreeing strategic objectives
  - Responding to changes in the internal and external environment and adapting strategic objectives to ensure delivery of the Authority's public health protection remit, and its contributions at both national, European and international levels
  - Leading and co-ordinating the process of translating high-level objectives into specific plans for the department that are appropriately comprehensive, realistic, and effective in meeting organisation goals
  - Developing the department to best serve the agreed objectives
  - Developing and managing the annual budget for the department to include responsibility for the effective management and utilisation of resources
  - Fostering the development and communication of a common vision for the department internally and across the organisation
  - Leading the departmental management team in the strategic planning cycle in association with the Chief Executive, developing strategic objectives, priorities, plans and targets to drive management planning at all levels
  - Ensuring that the resource and skills profile of the department is aligned to strategic objectives and development plans
  - Developing the knowledge network concept to ensure access to specialist skill sets as required
  - Facilitating the development of appropriate structures and teams for the department
  - Providing leadership, support and direction to the department

- Technical Management
  - The Director will have a range of responsibilities relating to the specific technical aspects of the work of the department. This will involve the Director supporting and being supported by a team of technical assessors. These responsibilities will include:
  - Overseeing the operation of effective procedures and processes for the monitoring and evaluation of safety of human products
  - Ensuring appropriate development and maintenance of scientific and technical expertise and skills to meet future assessment and evaluation needs in line with progress and innovation
  - Liaison as appropriate with the Human Products Authorisation and Registration (HPAR) Director and staff in relation to areas of post marketing safety of human products

- Liaison with other HPRA Directors/department managers in ensuring that adequate measures are in place to ensure that any defective products can be effectively recalled from the market
- Provision of recommendations to the CE, Management Committee and the Authority and its Advisory Committees regarding the authorisation of human medicines
- Providing formal feedback on monitoring and evaluation issues relevant to the HPM Department
- Liaison with officers of the Department of Health, and other State Bodies and contribution to decisions regarding the safety monitoring and evaluation of human medicines
- Working with professional colleagues to facilitate technical liaison with other regulatory authorities and other regulatory authorities, relevant bodies or individuals in relation to safety monitoring and evaluation issues
- Managing the adoption and implementation of new areas within the department
- Ensuring the optimum use of HPRA resources
- Ensuring that the department is adequately represented at relevant European committees and working groups and that responsibility for these roles is clearly defined
- Ensuring as appropriate that the department is as appropriate to the organisation's remit adequately represented at international level and that these roles are clearly defined
- Ensuring appropriate involvement of the department in the development of proposals for new or amended legislation
- Provision of input to the review and approval process for products where appropriate

- Membership of the HPRA Executive
  - Work with the Chief Executive and other members of the Management Committee to agree the organisation's strategic objectives and work to ensure their delivery
  - Work with the Management Committee to clearly establish priorities for HPRA in developing policies and operational plans
  - With the Management Committee, work to identify a common vision of the organisation and effectively communicate that to the organisation and strive to ensure the vision is embedded in a tangible culture of behaviours that will deliver on that vision
  - Ensure appropriate communication protocols are in place to deal with issues of key importance to the HPRA
  - Working with the HPRA Communication and Information Manager, external communications consultants, the Chief Executive and HPRA Management Committee in the development and delivery of HPRA external communications activities
  - Represent the HPRA within the national media on matters relevant to the department and organisation's remit
  - Reporting on progress of the HPM department at management level
  - Representing the HPRA at national, European and international meetings as required
  - Attend meetings of the Authority and Advisory Committees as appropriate
  - Using the strategic planning cycle to develop short and long range plans for each section within its remit

- Leadership and Motivation
  - Lead, and in conjunction with each section manager, manage and motivate a multi-functional team of staff, proving effective and meaningful leadership, support and clear direction to each section
  - Foster the development of a common vision for the department
  - Encourage a culture of teamwork within the department

- Ensure the provision of performance feedback, coaching and mentoring support to all staff in the department
- Lead, co-ordinate and participate in the effective implementation of the HPRA Performance Development Programme in the department

- Managing Performance and Quality
  - Effectively managing the overall performance and quality of the department to ensure the implementation and on-going development of HPM's objectives
  - Managing the planning cycle, agreeing performance targets with managers within the department, and on-going monitoring of performance and quality
  - Working with the HPM management team in ensuring the capture of individual section performance measures against the agreed strategic/ departmental plan
  - Effectively leading the management team while working directly with individual managers to keep up to date with department performance against stated objectives in the strategic/ departmental plan
  - Interacting directly with individual members of the HPM management team as well as with the HPRA management team to address any issues that are impacting on the HPM Department's ability to meet the targets set down in the strategic or departmental plans
  - Leading the department in active participation in the development and implementation of the HPRA quality management system

- Managing Financial Performance
  - Working with the Finance, Corporate and International Affairs Department and other Directors to ensure the maintenance of a long-term and sustainable approach to funding human medicines regulatory activities
  - Monitoring departmental income and expenditure, including contributing to the development of appropriate budget plans for the department and their on-going review.

- Promoting Communications
  - Facilitating the establishment of an open and effective communications culture and environment where high-quality information flows within the HPM department and throughout the organisation
  - Working with the HPM Management Team in communicating a clear strategic direction and leadership to the department
  - Ensuring that the communications process, particularly at management level, is developed and maintained

- Learning and Continuous Professional Development
  - Facilitate an environment where the currency of skill sets is developed over time
  - Work with the section managers and the Learning and Development section (as required) to enable development requirements of staff to be identified and appropriately addressed
  - Develop and maintain a culture of excellence and continuing development for all staff working in the sections
  - Provide challenging assignments to all staff that provide opportunities for personal and career development
  - Work with all managers and staff to develop and maintain a culture of excellence and continuous improvement within the department
  - Work with HR and Change colleagues as required to manage recruitment and selection to the department

- 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, medicine or in another relevant scientific discipline
  - Over five years' relevant experience at a management level which must include a minimum of three years at a senior level involved in strategic decision making in any of the following areas: the healthcare industry, clinical medicine or regulatory affairs
  - Significant experience in the leadership and motivation of multi-disciplinary team(s); strong track record in the area of performance management with the ability to communicate direction to the team, set standards for high performance and drive the achievement and delivery of results
  - Effective decision-making skills with a results oriented focus - understands what is important - is committed to achieving goals. A tenacious approach to delivery, quality of output and organisation performance
  - Strong representational and negotiation skills, with the ability to develop effective strategies for both national and international issues
  - Strong relationship building skills at all levels, with the ability to inspire confidence, establish credibility and respect
  - Excellent interpersonal and communication skills with the proven ability to deliver appropriate information to the right people, using a range of written, verbal and presentation skills
  - Proven experience in change management programmes
  - Experience dealing with the media

- In addition to this the ideal candidate will have;
  - Prior experience of EU regulatory procedures for medicinal products
  - Experience in the implementation of EU guidelines and legislation
  - A relevant postgraduate qualification
  - Proven ability to drive projects through to completion
  - Proven record in connecting with leadership teams to support, influence and drive for results
  - Displays integrity and professionalism - is sincere in own behaviour and in dealings with others
  - Works with others in a collaborative and solutions focused manner
  - Excellent and proven problem solving ability, able to adapt to changing conditions and display the ability to generate effective and pragmatic solutions to new situations and problems both strategic and operational
  - Demonstrated ability to work successfully with a range and breadth of senior stakeholders, of representing an organisational or policy position and negotiating effectively to maintain that position

REMUNERATION

Salary: €121,352 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 a three year fixed term contract post.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 30 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. Part of this will involve realignment over time of some of the human medicines regulatory activities.
The Director will need to demonstrate the ability to lead the team through these changes and will also have to demonstrate flexibility and anticipate that the role, activities and responsibilities may change as the HPRA's development progresses.

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.

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 the **30th September 2019.**

HOW TO APPLY

To pursue an interest in this position, **candidates must forward a comprehensive Curriculum Vitae and supporting letter by email to Rowan Hillis of Odgers Berndtson** at rowan.hillis@odgersberndtson.com

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.