

Role Profile

Scientific Officer (Acting), Medical Devices Vigilance – Human Products Monitoring

ROLE SUMMARY

Reporting to the Medical Devices Product Manager, the Scientific Officer will work to:

- Ensure effective and efficient responses to all medical device (including active implantable and *in vitro* diagnostic devices) vigilance issues that arise
- Ensure that the assessment of technical data for medical devices is carried out effectively and efficiently e.g. issues arising from vigilance cases or vigilance trends / signals as appropriate
- Ensure that specific projects arising from vigilance trends / signals are carried out as required
- Provide support and technical advice within the section as required

The Scientific Officer will work closely with the Medical Devices Product Manager and will maintain effective working relationships with colleagues in other sections and departments of the HPRA, and with stakeholder sections, to ensure that medical device issues requiring cross functional input are effectively investigated and followed up on.

KEY RESPONSIBILITIES

- Operational Objectives

- Assist the Medical Devices Product Manager in meeting the objectives, goals and targets of the Medical Device Vigilance section.
- Work with the Medical Devices Product Manager to plan and organise work tasks and ensure delivery of work.
- Maintain appropriate records of meetings, activities and submit reports as appropriate.
- Assist in the compilation of data for management reports, annual report etc. as required.
- Promote a positive, open, friendly and professional working environment.

- Technical Objectives

- Implementing the vigilance section activities as directed by the Medical Devices Product Manager and the Medical Devices Vigilance Manager including:
 - Vigilance Cases
 - Receiving, validating, assessing and monitoring incidents, issues and corrective actions
 - Highlighting cases of public health concern to the attention of the Medical Devices Product Manager and Medical Devices Vigilance Manager in a timely manner

- Identifying manufacturers/Authorised Representatives that require site visits/audits by the Audit Section via liaison with the Medical Devices Product Manager
 - Reporting and communicating case outcomes e.g. Safety notices, Competent Authority (CA) reports
 - Identifying areas requiring technical file review or areas for consideration for inclusion within the market surveillance plan or other cross organizational initiatives via liaison with the Medical Device Product Manager and the Medical Device Vigilance Manager
 - Ensuring timely close out of cases
 - Participating in signal detection activities / medical device vigilance projects
 - Participating in European vigilance taskforces when required
- Technical Support
 - Providing technical input to audits when required
 - Providing technical input to the Human Products Authorisation and Registration section when required
- Safety Notices / National Competent Authority Reports (NCARs)
 - Drafting safety notices for approval by the Medical Devices Vigilance Manager
 - Reviewing safety notices published by other competent authorities
 - Circulating HPRA and other competent authority communications (when required) to relevant stakeholders
 - Updating relevant internal and external databases
 - Ensuring circulation of NCARs as appropriate
- General Technical Objectives
 - Responding to queries within the appropriate timeframes
 - Providing relevant advice to the Medical Devices Product Manager and the Medical Devices Vigilance Manager, as appropriate
 - Contributing to any other area or processes which may come within the scope of the Medical Devices Vigilance section
- Quality Management
 - Assist the Medical Devices Product Manager and the Medical Device Vigilance Manager to ensure that medical devices procedures, guidelines and quality documentation are in place and in use, in particular, for the activities of the Medical Device Vigilance section, and that they remain up to date with relevant developments in National, European and International regulations, legislation and guidelines
 - Assist the Medical Devices Product Manager and the Medical Devices Vigilance Manager to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the Human Products Monitoring (HPM) department
 - Contribute to the implementation of the HPRA Quality Management System within the HPM department

- Performance Management
 - Participate in the performance development programme (PDP)
 - Work with the Medical Devices Product Manager to achieve performance targets for the team
 - Report regularly on progress against specified goals/targets and objectives to the Medical Devices Product Manager
 - Ensure that issues impacting performance are identified early to the Medical Devices Product Manager and Medical Devices Vigilance Manager
- Communication/Customer Service
 - Attend and contribute to departmental and organisational meetings as appropriate
 - Ensure that HPRA policies and procedures are communicated in a consistent way to stakeholders
 - Attend external meetings as deemed appropriate by the Medical Devices Product Manager and Medical Devices Vigilance Manager
 - Liaise with relevant external organisations in relation to Medical Devices Vigilance activities and processes
 - Provide technical information, advice, and guidance to industry, regulatory authorities, healthcare professionals and other relevant stakeholders
 - Provide timely input to the medical devices newsletter and HPRA web-site as necessary
 - Attend and participate in information days and other educational conferences as deemed appropriate
- General
 - Perform such other duties as the HPRA may reasonably require

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must:
 - Have a relevant third level degree in engineering, physics, science of materials, computer science, science or a related discipline; or in a healthcare profession such as nursing, physiotherapy or related discipline
 - Be a self-starter, capable of excellent communication, negotiation and decision making
 - Be highly motivated and with the ability to manage deadlines
 - Have excellent administrative and organisational skills
 - Demonstrate initiative and team working capabilities
- In addition, the following would be considered an advantage:
 - A post graduate qualification in biomedical engineering, medical physics, health informatics, science or a related discipline
 - Relevant post-graduate experience in the medical device sector
 - Knowledge of the regulatory environment
 - Knowledge of medical devices or other related healthcare products

REMUNERATION

Salary: €32,831 per annum (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

Duration of Maternity leave

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. 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.

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 **Sunday, 22nd October 2017**.

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 on **3rd November 2017**.

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.