HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer, Assessment & Surveillance - Medical Devices

ROLE SUMMARY

Responsibilities of the Assessment & Surveillance section in the Medical Devices department include:

- Management of all medical device vigilance issues, minimising risk to public health and ensuring compliance to relevant legislation.
- Coordination and implementation of the HPRA's market surveillance activities for medical device and in-vitro diagnostic device technologies.
- Designation and ongoing oversight of the performance of notified bodies for medical devices and in-vitro diagnostic devices.
- Assessment of technical and regulatory aspects of medical device and in-vitro diagnostic device technologies.
- Communication and engagement with stakeholders on medical device and in-vitro diagnostic device issues.
- Management of Safety/Information notices, Competent Authority reports/notifications and other case specific communications.
- Development of technical guidance and capabilities at national and EU level.
- Engagement with the European network on medical device and in-vitro diagnostic device issues, regulatory development and joint working initiatives.
- Contributing to work associated with implementation of relevant legislation, guidance, standards and relevant change and development initiatives.

Working as part of a team within the Assessment & Surveillance section, the Scientific Officer post will work to:

- Ensure effective and efficient responses to all medical device (including active implantable devices) vigilance and market surveillance issues that arise.
- Ensure that the assessment of technical data for medical devices (including active implantable devices) are carried out effectively and efficiently across the HPRA's medical device regulatory activities (e.g. review of clinical investigations applications, notified body designation and oversight).
- Ensure that accurate regulatory information is provided to and understood by economic operators and that medical devices assessed comply with relevant regulatory requirements Ensure that specific projects are carried out as required.
- Provide support and technical advice within the Medical Devices department as required.

The Scientific Officer will work closely with their 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.

It is envisaged that the successful candidate in this role will undertake a broad range of regulatory activities in device assessment throughout the product lifecycle including implementation of the new medical device regulation at both a European and national level.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Support evolving business needs and strategic requirements of the department in undertaking new areas of technical responsibilities in line with these developments.

- Operational Objectives
  - Assist their Manager, Section Manager and Director for Medical Devices in meeting the objectives, goals and targets of your section and the Medical Devices Department.
  - Work with their 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 section activities as directed by their Manager, Section Manager and Director for Medical Devices;
  - Conducting technical and regulatory evaluation of;
    - medical device clinical investigations
    - medical device technical files
    - medical device classifications
  - Contributing to the registration application process.
  - Providing technical input to notified bodies or market surveillance audits when required.
  - Conducting sampling and testing of devices when required.
  - Conducting technical evaluation of other data in relation to the authorisation and registration process as required in line with business needs.

- Vigilance and market surveillance
  - Receiving, validating, assessing and monitoring incidents, issues and corrective actions.
  - Highlighting cases of public health concern to the attention of your Manager in a timely manner.
  - Identifying manufacturers/Authorised Representatives and other economic operators that may require further market surveillance assessment for consideration as part of activity planning within the Department.
  - Ensuring medical devices under assessment meet the relevant regulatory requirements.
  - Reporting and communicating case outcomes e.g. Safety notices, Competent Authority (CA) reports, COEN forms etc.
  - Identifying areas requiring technical file review or areas for consideration for inclusion within the market surveillance plan or other cross organisational initiatives.
  - Ensuring timely close out of cases.
  - Participating in signal detection activities / medical device projects.

- Technical & regulatory support
  - Assist in the drafting of guidance and procedures for medical devices when required.

- Ensure that accurate regulatory information is provided to and understood by economic operators.
- Participation in national and European working groups and taskforces when required.
- Dealing with queries in all of the above elements in a timely manner.
- The Scientific Officer works, as required with the Compliance department to provide technical support in relation to audits; accompany the auditor on site audits/visits where necessary; to identify cases that may require input from the Medical Devices Auditors and to communicate on market surveillance.

- Quality and Knowledge Management
  - Assisting Managers in the section to ensure that medical devices procedures, guidelines and other quality documentation are in place and in use and that they remain up to date with relevant developments in National, European and International regulations, legislation and guidelines.
  - Assisting Managers within the section to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained. As required, working with others within the section to achieve this objective.
  - Assisting Managers within the section to ensure that available information and knowledge across the HPRA is effectively used by the section. As required, working with others within the section to achieve this objective.
  - Assisting other team members to ensure the effective implementations of the HPRA Quality Management system.

- Performance Management
  - Participate in the performance development programme (PDP).
  - Work with your Manager to achieve performance targets for the team.
  - Participate in activity monitoring and reporting initiatives.
  - Report regularly on progress against specified goals/targets and objectives to your Manager.
  - Ensure that issues impacting performance are identified early to your Manager and Section 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 your Manager and Section Manager.
  - Liaise with relevant external organisations in relation to Medical Devices activities and processes as appropriate.
  - Provide technical information, advice, and guidance to industry, regulatory authorities, healthcare professionals and other relevant stakeholders as appropriate.
  - 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
  - Performing such other duties as the HPRA may reasonably require.

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A relevant 3rd level degree in: engineering (e.g. biomedical, electrical/electronic, mechanical, software); science (e.g. biomedical, computer, health, materials, physics, pharmacy); healthcare professions (e.g. nursing, physiotherapy) or related disciplines
  - Be a self-starter, capable of 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
  - Proven ability to work unsupervised
  - Proven organisational, communications, presentation, report writing and interpersonal skills

- In addition, the following would be considered an advantage:
  - A relevant post graduate qualification (e.g. biomedical engineering, medical physics, health informatics, regulatory affairs, science or a related discipline).
  - Relevant post-graduate experience in the medical device sector in manufacturing, quality, research & development or regulatory affairs.
  - Knowledge of the regulatory environment including knowledge of the current and forthcoming European and National legislation.
  - In depth understanding and knowledge of medical devices technologies such as;
    - Cardiovascular implants and associated technologies
    - Orthopaedic devices
    - Implants (incl. orthopaedic)
    - Substance based medical devices
    - Drug/device combination products
    - Ophthalmic devices
    - Wound care devices
    - IVF devices
    - Surgical devices

REMUNERATION

Salary: €34,759 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.

October 2020

DURATION OF POST

This is a three year fixed term contract post.

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 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 Assessment 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 Assessment.

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 provided. 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.

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

CLOSING DATE

The closing date for applications for this post is **12pm November 8th 2020.**

INTERVIEWS

Applicants attending for interview may be required to complete a scenario-based practical - details will be notified to applicants who are shortlisted. Please note these interviews will be conducted via Skype and it is anticipated that the first round and second round of interviews will take place during the week of **16th November 2020.**

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.