HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer, *In Vitro* Diagnostic (IVD) Medical Devices

ROLE SUMMARY

Working within the Medical Devices department, the Scientific Officer will contribute to all activities relating to IVDs in the Medical Devices Assessment & Surveillance section of the Medical Devices department.

The Scientific Officer will work closely with their Manager and will maintain effective working relationships in particular with other members of the Medical Devices Assessment & Surveillance section, the Regulatory and Policy section and the Clinical section, along with the Compliance department and other departments as required. The Scientific Officer will help to ensure effective co-ordination and co-operation across all IVD activities and to ensure that the objectives of the Medical Devices department are met.

Working within the IVD team, the Scientific Officer will work to:

- Ensure effective and efficient responses to all IVD vigilance and market surveillance issues
- Ensure that the assessment of technical data for IVDs is carried out effectively and efficiently across the HPRA's medical device regulatory activities (e.g. review of performance evaluations, notified body designation and oversight)
- Ensure that accurate regulatory information is provided to and understood by economic operators and that IVDs under assessment comply with relevant regulatory requirements
- Support the planning and development of all activities relating to IVDs within the Health Products Regulatory Authority (HPRA).
- Provide support to the implementation of the EU IVD Regulation (IVDR) at national and European level
- Provide support and technical advice within the Medical Devices department as required
- Ensure effective and efficient responses to all IVD queries on regulatory and assessment issues
- Contribute to the implementation of the communications strategy and the development of communication material as required
- Contribute to the implementation of the training strategy and development of training material as required
- Ensure that the assessment of regulatory compliance and application of IVD legislation is carried out effectively and efficiently across the HPRA's medical device regulatory activities (e.g. process development)
- Ensure that specific projects are carried out as required (e.g. development of new regulatory processes as a result of Brexit, input into European Joint Actions where relevant)

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 IVD issues requiring cross functional input are effectively investigated and followed up on.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Support evolving business needs and strategic requirements of the department in the development of legislation and assessment relating to IVDs at national and European level
  - Assist and action the planning, coordination and communication of implementation of the IVDR
  - Assist in and contribute to the assessment of IVD procedures, as required
  - Work closely with the team, legal colleagues and the Department of Health (DoH) to ensure national legislation on IVDs is aligned and supports the IVDR
  - Assist in implementing the communication and training strategy for IVDs
  - Work to enhance communication, guidance and support provided on IVD issues to the public and external stakeholders

- Operational Objectives
  - Assist their Manager and the Deputy Director for Medical Devices in meeting the objectives, goals and targets of the 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
  - Implement the section activities as directed by their Manager, the Section Manager and the Deputy Director for Medical Devices;
  - Evaluate the regulatory, scientific, technical and/or clinical aspects of IVD performance evaluations, technical files and classification requests to support the HPRA's IVD regulatory activities
  - Contribute to the registration application process - conduct technical evaluation of data in relation to the registration process as required in line with business needs
  - Provide technical input to notified body, vigilance or market surveillance audits as required. Work with the Compliance department to provide technical support in relation to audits; accompany the auditor on site audits/visits where necessary; identify cases that may require input from Medical Devices Auditors and communicate on market surveillance
  - Identify the need for and organise sampling and testing of IVDs when required
  - Provide input and support to queries involving Freedom of Information, Media, Legal and regulatory and assessment activities
  - Assist in the development of content for IVD aspects of the HPRA website, newsletters and stakeholder information
  - Contribute to the coordination of training activities as required
  - Ensure that specific projects are carried out as appropriate
  - Assist in the drafting of guidance and procedures for IVDs as required

- Ensure that accurate regulatory information is provided to and understood by economic operators
- Participate in national and European working groups and taskforces as required
- Deal with queries relating to all of the above elements in a timely manner

- Vigilance and market surveillance
  - Receive, validate, assess and monitor incidents, field safety corrective actions, market surveillance issues and corrective actions
  - Highlight cases of public health concern to the attention of their Manager in a timely manner
  - Identify manufacturers/Authorised Representatives and other economic operators that may require further market surveillance assessment for consideration as part of activity planning within the Medical Devices department
  - Ensure IVDs under assessment meet the relevant regulatory requirements
  - Report and communicate case outcomes e.g. Safety notices, Competent Authority (CA) reports, COEN forms etc
  - Identify areas requiring technical file review or areas for consideration for inclusion within the market surveillance plan or other cross organisational initiatives
  - Ensure timely close out of cases
  - Participate in signal detection activities / IVD projects

- Quality and Knowledge Management
  - Assist Managers in the Medical Devices department to ensure that IVD 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
  - Assist Managers within the Medical Devices department 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
  - Assist Managers within the Medical Devices department 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
  - Assist 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 their 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 their Manager
  - Ensure that issues impacting performance are identified early to their 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 their Manager

- Liaise with relevant external organisations in relation to IVD 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 website 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 third level degree in legal studies or a relevant discipline (e.g. life sciences or pharmacy)
  - Knowledge of regulatory systems and relevant European and National legislation
  - Have excellent communication skills with the proven ability to deliver appropriate information to the right people, using a range of written, verbal and presentation skills
  - Be highly motivated with the ability to manage deadlines in a changing regulatory and organisational environment
  - Have excellent administrative, computer and organisational skills
  - Demonstrate initiative and team working capabilities
  - Have a proven ability to work unsupervised
  - Be a self-starter, capable of excellent negotiation and decision making

- In addition, the following would be considered an advantage:
  - A relevant post graduate qualification
  - Relevant post graduate experience in the IVD sector
  - Relevant experience working in a regulatory and/or assessment environment relating to health products, including experience in IVDs
  - Knowledge of regulatory systems and relevant national and European legislation
  - Knowledge of the regulatory environment for IVDs

REMUNERATION

Salary: €33,491 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 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.

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.

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.

CLOSING DATE

The closing date for applications for this post is **04 April 2019.**

INTERVIEWS

Applicants attending for interview may be required to undertake a practical - details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place on the **18 April 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 Assessment.