HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Technology Group Lead, Assessment & Surveillance - Medical Devices

ROLE SUMMARY

The medical devices Technology Group Lead will work as part of the Assessment & Surveillance section in the medical devices department to assess the technical and regulatory aspects of medical devices. These assessment activities include technical documentation review, vigilance, market surveillance and associated activities, clinical investigation classification and regulatory advice.

Reporting to the Assessment & Surveillance Manager, the Technology Group Lead will work closely with other group and section managers, within the medical devices department to achieve HPRA objectives relating to medical devices. The Technology Group Lead also maintains effective working relationships with HPRA departments/sections, in particular with colleagues with responsibility for medical device inspections, to ensure that tasks are effectively managed and reviewed as appropriate.

The Technology Group Lead will work to ensure that:

- Medical device technologies are safe and perform as intended without posing undue risk to patients or public health.
- Responses to all issues that arise in relation to medical devices are managed effectively and efficiently and to ensure that appropriate action is taken to minimise the risk to public health and ensure compliance to relevant legislation.
- The assessment of technical data for medical devices is carried out effectively and efficiently e.g. issues arising from market surveillance, vigilance cases or vigilance trends / signals as appropriate. Ensure that specific projects arising from market surveillance, vigilance cases or vigilance trends / signals are carried out as appropriate.
- The HPRA communicates effectively, both internally and externally on medical device issues and provides relevant information on devices and on our activities.

The Technology Group Lead will work with the Assessment & Surveillance Managers to ensure HPRA medical device activities are developed and delivered in a manner that is effective, value driven and focussed on patients and the public. The Technology Group Lead will help ensure that these activities are impactful, practical and relevant to the stakeholders that we serve.

The Technology Group Lead will work together with colleagues in the department as an adaptive, effective and cohesive team that continuously develops and focuses on continuing to improve in a collaborative, open and supportive environment. The technology group lead will manage the performance of a team by defining objectives, setting targets, co-ordinating activities, agreeing priorities, developing team members, maintaining effective communication lines and ensuring the required standards policies and practices are in place.

The Technology Group Lead will work together with colleagues in the department as an adaptive, effective and cohesive team that continuously develops and focuses on continuing to improve in a collaborative, open and supportive environment.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Supporting the Assessment & Surveillance Managers in the management and the ongoing development of the section and medical devices department to ensure our regulatory activities are centred on scientific & regulatory excellence, are value-driven and optimised to achieve the highest standards of device safety, performance and care for patients and healthcare systems.
  - Contributing to the development of strategic plans within the Assessment & Surveillance section that deliver a patient focussed and risk centred system of regulation that emphasises proactive and preventative measures and that are consistent with those of the Department and the wider HPRA.
  - Working with the Assessment & Surveillance Manager to prioritise work objectives and to ensure that the strategic goals and targets of the medical devices department are achieved
  - Managing and developing staff through change and development initiatives and providing a supportive environment to enable a motivated, impactful and adaptable team.
  - Supporting strategic risk management.
  - Working with colleagues in the medical device department to lead and ensure effective and timely implementation of new legislation and guidance relevant to the department activities.
  - Contributing to the formulation and preparation of national/ international regulatory policies, guidelines and legislation as deemed appropriate.
  - Participation in external, European and international initiatives.
  - Contributing to activities to foster innovation of new medical technologies.
  - Working with colleagues to develop regulatory approaches that are suitable, proportionate and adaptive to existing, new and innovative technologies.

- Operational Objectives
  - Assisting the Assessment & Surveillance Manager in meeting the objectives, goals and targets of the medical devices department.
  - Contributing to the development of operational activities to ensure they are relevant, impactful and continue to provide appropriate benefit and protection to Irish patients and health systems.
  - Managing and supervising a technology group in line with the achievement of strategic and operational goals.
  - Planning, organising and allocating work tasks and resources within the technology group to ensure efficient delivery of work.
  - Promoting effective and efficient use of Assessment & Surveillance resources with a focus on value, impact and relevance of outcomes.
  - Working with the Director of Medical Devices, the Assessment & Surveillance Managers and other Technology Group Leads to plan and organise efficient delivery of the department's activities.
  - 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 technology group.
- Promoting a positive, open, professional working environment.
- Maintaining appropriate records of meetings and activities.
- Contributing to business planning activities including service plans etc.
- Contributing to the preparation developmental and operational planning documents.
- Attending and contributing to team meetings, as appropriate.
- Attending and contributing to meetings of the Advisory Committee for Medical Devices as appropriate.
- Attending and participating in European and international meetings as appropriate and at preparatory and follow up meetings within the HPRA.
- Representing the HPRA at meetings and working groups, as appropriate.
- Assisting in the compilation of data for management reports, annual report etc. as required.

- Technical Management
  - Reporting to the Assessment & Surveillance Manager, the Technology Group Lead, in collaboration with other Technology Group Leads, will work to deliver in the following areas:

  Market Surveillance & Vigilance
  - Receive, validate and assess vigilance incidents, device issues and related corrective actions.
  - Conduct assessment activities to ensure compliance of devices with the relevant requirements and standards.
  - Highlight cases of public health concern in a timely manner.
  - Assess the appropriateness and effectiveness of field safety and, when appropriate, other corrective actions proposed by manufacturers.
  - Identify, validate and risk-prioritise surveillance and assessment activities of devices and the market.
  - Contribute to the development of annual plans for reactive and proactive market surveillance activities based on inputs from team, market analysis activities and each relevant section in HPRA.
  - Maintain focus on proactive and preventative assessment & surveillance activities while ensuring reactive issues are addressed effectively and in a timely manner.
  - Prioritise of cases for assessment/review.
  - Conduct assessments and review assessment reports and documents, as appropriate.
  - Assessing the scientific/technical aspects of medical devices.
  - Report and communicate findings to applicants/manufacturers to inform in a timely manner and provide opportunity, as appropriate, for response to address findings.
  - Identify and prioritise areas requiring technical file review or areas for consideration for inclusion within the market surveillance plan or other cross organisational initiatives in liaison with the Assessment & Surveillance Manager.
  - Promote engagement and dialogue with users and healthcare professionals on device issues.
  - Promote feedback on outcomes and increased transparency of HPRA and regulatory network activities.
  - Support and participate in medical device inspections when required.
  - Contribute to the establishment of the sampling/analysis programme for devices.
  - Identify appropriate test houses/protocols for testing, identify samples for testing and monitor outcomes.

- Support systems for dissemination of safety communication, including HSE eAlert system and HSE's National Patient Safety Alert Committee.
- Ensure timely progression and closure of cases.
- Report and communicate case outcomes e.g. safety/information notices, Competent Authority (CA) reports/notifications.
- Help to identify relevant operators, devices and issues to input into market analysis activities.
- Review safety notices and other information published by other regulatory authorities and relevant parties.
- Update relevant internal and external databases.
- Ensure circulation of inter agency communications as appropriate.
- Any other area or processes which may come within the scope of the section

Classification and qualification of medical devices

- Conduct assessments of cases and provide technical advice for classification & qualification cases.
- Contribute to systems to ensure effective and consistent classification & qualification decisions are made in relation to medical devices.
- Provide support to the OEQ Department and HPRA's Classification Committee.

Clinical investigation & compassionate use applications

- Assess the technical aspects of medical device components of applications for clinical investigation, clinical trials and drug device combinations (marketing authorisations, scientific advice etc.).
- Assess the technical aspects of compassionate use applications for devices.

Compliance department liaison

- Work effectively in close cooperation with the relevant sections within the Compliance Department.
- Engage effectively with the HPRA enforcement team to ensure any enforcement actions are coordinated, planned and supported by appropriate assessment for regulatory compliance.

Other

- Provide input into review and approval processes where appropriate.
- Work with the legal team, and other HPRA colleagues, to ensure that proposed market actions on medical devices are robust, consistent and effective and with due reference to appropriate administrative and legal provisions and procedures.
- Provide effective input into queries, information requests, document development and briefing documents within the appropriate timeframes.
- Work with colleagues to facilitate technical liaison with the EU Commission and other regulatory authorities, relevant bodies or individuals in relation to safety and efficacy issues.
- Attend and contribute to HPRA meetings, as appropriate.

- Quality and Knowledge Management
  - Ensuring that the procedures and policies of the HPRA Quality Management System are maintained, deployed and adhered to within the Assessment & Surveillance section and technology group.

- Contributing to implementing, updating, adapting Standard Operating Procedures (SOPs) and technical guidelines for the section. Ensuring that all changes are communicated on an ongoing basis within the technology group.
- Participating in any relevant internal audits including the identification and implementation of any required corrective actions.
- Assisting in ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the department.
- Assisting the Assessment & Surveillance Manager and other managers/leads 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.
- Contributing to the development of the knowledge network across the HPRA.

- Performance Management
  - Working with the Assessment & Surveillance manger to deliver performance targets for the section and individual staff.
  - Participating in and implementing the performance development programme (PDP) within the technology group.
  - Working with the Section Managers and other Technology Group Leads to promote effective performance and to set appropriate performance targets for the group.
  - Effectively communicating goals, objectives and performance targets to the group.
  - Reporting regularly on progress against specified goals/targets and objectives.
  - Ensuring that issues impacting performance are identified early to the Assessment & Surveillance Manager and taking measures to resolve issues.
  - Contributing to the development and implementation of effective mechanisms to monitor and report on the different assessment activities to appropriate reflect complexity, impact and resource utilisation.
  - Recognising good performance and promoting a culture of performance improvement within the technology group.

- Team Development/People Management
  - Working with HR, the Assessment & Surveillance Manager and other colleagues as required in managing personnel in the group.
  - Contribute to the development of departmental training plans and a training scheme and development of relevant materials relating to our medical devices regulatory activities.
  - Working with HR, the Assessment & Surveillance Manager and other colleagues as required to develop the team's capabilities and expertise.
  - Ensuring effective communication within the Assessment & Surveillance section and to the Medical Device Management Team and the Director.
  - Providing a supportive environment to enable a motivated, high impact and adaptable team that engages actively and openly.
  - 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 team members, as appropriate.

- Providing performance feedback, coaching and mentoring support to team members as required.

- Communications/Customer Service
  - Promoting a culture where are activities are focussed on patients and designed to ensure that our activities are relevant and useful to the public we serve.
  - Promoting a strong customer service focus taking account of broad stakeholder needs (internal and external) and in particular patients, healthcare professionals, notified bodies, economic operators across the sector, Department of Health, other public agencies and industry representative bodies.
  - Working with colleagues in the medical mevice 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.
  - Maintenance and updating of intranet and shared internal information sources/directories, HPRA website, patient communications, guidance and other documents.
  - In consultation with the Assessment & Surveillance manager, and other Technology Group Leads where appropriate, providing relevant regulatory or technical information, advice and guidance to industry, regulatory authorities, healthcare professionals and other relevant stakeholders.
  - Ensuring responses to queries in line with the HPRA service charter.

- General
  - Performing such other duties as the HPRA may reasonably require.
  - Deputising in the absence, on business or leave, for the Assessment & Surveillance Manager.

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - 3rd level degree in a relevant scientific, life-sciences, engineering or related discipline.
  - Minimum of three years relevant experience in a research, healthcare, industry or regulatory environment (preferably relating to medical devices).
  - In depth knowledge of medical devices.
  - Knowledge and understanding of regulatory systems and relevant European and National legislation relating to medical devices.
  - Be a self-starter, capable of excellent communication, negotiation and decision making.
  - 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.
  - Have excellent organisational skills and can demonstrate initiative and team working capabilities.

- In addition to this the ideal candidate will have;
  - A relevant post graduate qualification.
  - Experience in assessing vigilance issues, reviewing technical aspects of clinical investigations, conducting device classifications, risk analysis and assessing device technical documentation.
  - Experience in people management or mentoring staff.

REMUNERATION

Salary: €70,287-81,508 per annum (incremental scale)
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.

DURATION OF POST

This is a 3-year contract post.
Note: The issuing of a 3-year contract is standard HPRA practice prior to moving to permanency for long term roles, such as this.

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.

LOCATION

The successful candidate will be working in the HPRA offices a minimum, of two days per week and can avail of working remotely up to a maximum of three days per week subject to the terms of the policy. The specific days each week when you work at each location will be determined by your manager. The HPRA reserves the right to cease, vary or change the office/home location split during or after the review period. Notwithstanding any applicable hybrid working arrangement, you may be required to work at any specified location as may be reasonably required by the HPRA from time to time.

HOURS OF DUTY

The hours of duty are fixed by the HPRA from time to time. The current arrangements are Monday-Friday (minimum 35 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

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.

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.

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, 19th November 2023.**

HOW TO APPLY

Applications should be submitted directly to recruitment@hpra.ie

INTERVIEWS

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

It is anticipated that interviews for this post will take place on the **30th November 2023**

Note: The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

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.

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.

EQUAL OPPORTUNITIES

The HPRA is an equal opportunities employer. We are committed to equal employment opportunity regardless of gender, civil status, family status, sexual orientation, religion, age, disability, race or membership of the travelling community. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process and can be notified in the course of the interview correspondence.