

Role Profile

Regulatory & Policy Assessor, Regulatory & Policy - Medical Devices

ROLE SUMMARY

The Regulatory & Policy Assessor will work as part of the Policy and Stakeholder Engagement Team within the Regulatory and Policy Section of the Medical Devices Department. The Assessor will contribute to the planning, coordination and development of national and European policy for medical devices and *in-vitro* diagnostics as well as supporting the development of national and European legislation. The Assessor will contribute to the stakeholder engagement strategy and work with the various teams on any communication initiatives.

These activities are undertaken with the aim of ensuring that medical device and *in-vitro* diagnostic technologies in Ireland and Europe are in compliance with national and European requirements and relevant standards. The section's overall objective is to help ensure:

- The HPRA's medical device activities are appropriate, prioritised and relevant to the stakeholders that we serve.
- The HPRA is consistent and clear in its policy and regulatory approach to medical devices and *in-vitro* diagnostics.
- The HPRA communicates effectively, both internally and externally on medical devices and *in-vitro* diagnostic issues and provides relevant information on devices and on our activities.
- Departmental activities are completed with administrative, clinical, legal, regulatory, technical, operational and scientific excellence.

The Assessor will report to the Regulatory & Policy Manager and will contribute to the planning, co-ordination and implementation of the policy and stakeholder engagement activities for medical devices both within the organisation and at a national/international level. This includes the coordination of the HPRA's policy and representation at national, EU and international meetings as well as coordinating the regulatory and policy development work relating to these activities; developing stakeholder engagement initiatives and their delivery.

The Regulatory & Policy Assessor will work with the Regulatory and Policy Manager to help identify and foster relationships, partnerships and strategic alliances with relevant stakeholders and with relevant regulatory authorities. The Assessor will work together with colleagues in the Medical Devices Department (the Regulatory and Policy section, the Devices Assessment & Surveillance section, the Clinical section) as an adaptive, effective and cohesive team that continuously develops and focuses on continuing to improve in a collaborative, open and supportive environment.

In addition, the Regulatory & Policy Assessor will work in close cooperation with the HPRA's Legal Team, Corporate and International Department, the Operational Excellence and Quality Department as well as the Director as appropriate.

KEY RESPONSIBILITIES

- Strategic Objectives
 - Contribute to the delivery of regulatory activities which are centred on regulatory excellence, are value-driven and optimised to achieve the highest standards of device safety, performance and care for patients and healthcare systems.
 - Contribute to the development of policy and legislation relating to medical devices at European and national level.
 - Contribute to the development and management of a stakeholder engagement strategy.
 - Contribute to the development and management of a training strategy for medical devices within the HPRA.
 - Contribute to work relating to outreach and engagement with the public, patients and healthcare professionals.
 - Working closely with the team, legal colleagues and the Department of Health (DoH) to input into national policy and legislation as required.
 - Work with the manager and device colleagues in building strategic alliances and fostering relationships with relevant stakeholders, EU and international regulatory authorities.

- Technical/Operational Objectives
 - Assist the Section Manager and colleagues in meeting the strategic objectives and goals of the section and the Medical Devices Department.
 - Work with the section to plan and organise work tasks and ensure delivery of work.
 - Contribute to HPRA processes to ensure activities and follow up actions are conducted in accordance with appropriate legislation and administrative procedure.
 - Help to draft and coordinate both EU and national policy positions, policy documents, guidance documents taking into account the implications on the HPRA.
 - Participate in initiatives and meetings at national, European and international level to promote cooperation, communication and increased effectiveness of the regulatory system for medical devices.
 - Provide input and support to stakeholder queries including media queries, freedom of information (FoI), GDPR and regulatory and policy activities.
 - Contribute to development initiatives to continuously improve and optimise our operational activities and their effectiveness
 - Assist in the development of specific publications (website, newsletter, training material), promoting stakeholder engagement, as well as internal information sharing and training.
 - Provide regulatory input to the assessment and communication of the scientific, technical or clinical aspects of medical devices and IVDs when required, including process development.
 - Ensure that specific projects are carried out as appropriate.
 - Promote a positive, open, friendly and professional working environment.

- Quality and Knowledge Management
 - Assist the manager and other team members including the Scientific Officer - Planning and Quality, 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.

- Assist the manager and other senior 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 other team members to ensure the effective implementations of the HPRA Quality Management system.
- Contribute to the development of the knowledge network across the HPRA.
- Performance Management
 - Work with the Section Manager to deliver performance targets for the section and individual staff.
 - Participate and implement the performance development programme (PDP) within the team.
 - Work with your Manager to set appropriate performance targets for the team and promote effective performance.
 - Manage performance of any direct staff reports within the team.
 - Report regularly on progress against specified goals/targets and objectives to your manager.
 - Ensure that issues impacting performance are identified early to your manager.
 - Participate in the resolution of issues impacting performance in the section.
 - Provide performance feedback, coaching and mentoring support to direct staff reports.
- Team Development
 - Ensure the provision of adequate technical, non-technical and continuous professional development for direct reports and others within the section as appropriate.
 - Ensure the provision of high-quality induction and ongoing training for all staff, including on the job training.
 - Contribute to the development of departmental training plans and a training scheme and development of relevant materials relating to our medical devices regulatory activities including maintenance of training records and documentation as appropriate.
 - Working with HR, the Regulatory and Policy Manager and other colleagues as required to develop the team's capabilities and expertise.
 - Effectively communicating goals, objectives and performance targets to members of the team.
 - Openly recognising good performance and promoting a culture of performance improvement in the team.
 - Providing a supportive environment to enable a motivated, high impact and adaptable team that engages actively and openly.
- Communication/Customer Service
 - Promote 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.

- Lead in the design and development of stakeholder information programmes to raise awareness of the role of the HPRA in Medical Devices and to promote issues of public and product safety.
 - Work with colleagues across the Department to maintain positive relationships with stakeholders that reflects the professionalism and high standards of the HPRA in the conduct of activities.
 - Work with colleagues in the Department to develop and implement a stakeholder engagement strategy which aligns to the HPRA's corporate communications strategy and meets the needs of all HPRA stakeholders.
 - Attend external meetings as deemed appropriate by your manager.
 - Lead in the development of the medical devices newsletter as well as updates to the HPRA's medical devices web-site as necessary.
 - Lead in the coordination and participate in information days and other educational conferences as deemed appropriate, including internal organisation awareness sessions
- General
 - Performing such other duties as the HPRA may reasonably require.

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have the following skills and experience:
 - Have a third level degree in legal studies, public health or a relevant discipline (e.g. life sciences or healthcare)
 - Minimum of three years post-graduate experience working in a stakeholder engagement and policy environment relating to health products, preferably related to medical devices
 - Knowledge of regulatory systems and relevant European and National legislation
 - Excellent communication skills, with the proven ability to deliver appropriate information to the right people, using a range of written, verbal and presentation skills
 - Experience of regular high-level representation of organisational/national positions at national or European level
 - Excellent decision-making skills with a proven ability to deliver in a capacity utilising these 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
- In addition, the following would be considered an advantage:
 - Relevant post-graduate qualification
 - In depth knowledge of the regulatory environment for medical devices
 - Leading stakeholder engagement Initiatives
 - Proven capability in working in collaborative environments involving liaison and coordination of work processes within organisations and/or with external parties
- Availability to travel for European and international meetings will be a requirement in this role

REMUNERATION

Salary: €73,313 - €85,017 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.

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 (or 40% of available working days) 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 remote 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.

DURATION OF POST

This is a 1-year contract post for the duration of maternity leave.

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](#).

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 the time of application.

CLOSING DATE

The closing date for applications for this post is **15th November 2024 at noon**.

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation or take part in a practical test - details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place between late November and early December 2024. The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

HOW TO APPLY

Applicants should submit their CV and complete their application form through our [recruitment portal](#).

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 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.