Role Profile
Medical Devices Regulatory and Policy Assessor, Regulatory & Policy – Medical Devices

ROLE SUMMARY

The Medical Devices Regulatory and Policy Assessor will work as part of the Communication & Policy Team within the Regulatory and Policy section of the Medical Devices department. The Regulatory and Policy Assessor will contribute to the planning, coordination, development and implementation of the legislative requirements for medical devices and *in vitro* diagnostic medical devices at national and European levels. The Regulatory and Policy Assessor will help inform policy and development decisions and, if required support the planning and development of medical device activities within the Health Products Regulatory Authority (HPRA).

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 and scientific excellence.

The Communication & Policy Team’s overall objective is to:

- Ensure the HPRA is consistent and clear in its policy and regulatory approach to medical devices and *in vitro* diagnostics;
- Implement and maintain the EU Regulations on medical devices and *in vitro* diagnostic devices and the related EU and national legislation in an effective and timely manner;
- Develop and deliver effective communication, reporting and training initiatives, both internally and externally on medical devices and *in vitro* diagnostic issues and on our activities and contribute to the development of communication material;
- Ensure that the assessment of regulatory compliance and application of the medical device legislation is carried out effectively and efficiently across the HPRA’s medical device regulatory activities (e.g. process development, device classification, input into market surveillance cases);
- Ensure effective and efficient responses to all medical device queries on regulatory and policy issues.
- Input into the coordination of the HPRA’s medical device activities ensuring they are appropriate, and relevant to the stakeholders that we serve;

The Regulatory & Policy Assessor will report to the Communication & Policy Lead and will contribute to the planning co-ordination and implementation of the communication and policy 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 strategic communication and stakeholder engagement initiatives and their delivery; management of queries and classification & qualification requests and other projects and development initiatives as required.

The Regulatory and Policy Assessor will 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 Department (the Regulatory and Policy section, the Devices Assessment & Surveillance section, the Clinical section) as well as the Compliance Department 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 and Policy Assessor will work in close cooperation with the HPRA’s; Legal section, Finance, Corporate and International department, the Quality, Scientific Affairs and Communications department as well as the Deputy Director as appropriate.

**KEY RESPONSIBILITIES**

- **Strategic Objectives**
  - Supporting the Communications and Policy lead 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.
  - Working with the Communications and Policy lead to prioritise work objectives and to ensure that the strategic goals and targets of the Medical Devices department are achieved.
  - Contribute to the development of legislation and policy relating to medical devices at European and national level.
  - Assist in the planning, coordination and development of the communication strategy on implementation of new EU legislation on medical devices.
  - Contribute to the development and management of a training strategy for medical devices within the HPRA.
  - Working with the manager and device colleagues in building strategic alliances and fostering relationships with relevant stakeholders, EU and international regulatory authorities.

- **Operational Objectives**
  - Assist their Manager and Section Manager in meeting the objectives, goals and targets of the section and the Medical Devices department.
  - Contributing to HPRA processes to ensure 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).
  - Submitting reports as required and maintaining appropriate records of meetings and activities.
  - Assisting in the compilation of data and preparation of management reports as required.
  - Contributing to Regulatory and Policy section team meetings, as appropriate.

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- Assisting with the preparation of meetings of the Advisory Committee for Medical Devices as required.
- Contributing to the development of policy documents, position documents, guidance documents, discussion documents and comments to internal and external draft documents as required.
- Assisting with the coordination of HPRA contributions to international and EU regulatory activities.
- Representing HPRA and participating in European and international meetings and working groups as appropriate and at preparatory and follow up meetings within the HPRA.
- Ensuring effective communication of national, EU and international regulatory developments and coordinating implementation of actions arising.
- Working closely with the team, legal colleagues and the Department of Health (DoH) to ensure national legislation on medical devices is aligned and supports the new EU Regulations.
- Maintaining appropriate records of meetings, activities and submit reports as appropriate.
- Providing support to other colleagues within the Medical Devices department.
- Assisting in the development and delivery of information and training materials on medical device regulation for internal and external use.
- Promoting a positive, open, friendly and professional working environment.

- Technical Objectives
  - Regulatory development & Management
    - Participate in the coordination, communication and implementation of legislation and policy relating to medical devices and on in-vitro diagnostics.
    - Input to the HPRA’s contribution to EU and international regulatory activities and meetings to ensure they are effective, impactful, consistent and clearly communicated.

  - Information & data management
    - Contribute to information & data management relating to medical devices/in-vitro diagnostics and departmental activities.
    - Supporting knowledge management within the Department.
    - In conjunction with Medical Devices colleagues, the Communication & Information Manager, Legal, the Freedom of Information Officer and other colleagues across the HPRA;
      - Contribute to legal, freedom of information and media queries and support the effective management of such.
      - Contribute to the development of content for HPRA Medical Devices publications such as annual report, consumer leaflets and newsletters.
      - Support the dissemination of HPRA Medical Device publications to relevant stakeholders.
      - Contribute to the drafting of new content for the website.
      - Actively participate in any restructuring/redevelopment of the website including identifying stakeholder needs.

  - Knowledge network management:
    - Maintaining systems to ensure departmental requirements for external expertise are met.
    - Facilitating departmental access to appropriate sources of external expertise.
    - Helping to ensure that the knowledge network reflects the current requirements of the department.
- Other:
  o Coordination of Classification and Qualification of medical devices and in-vitro diagnostic devices.
  o Providing regulatory and policy advice and expertise in medical device audits conducted by the Compliance department, when appropriate.
  o Providing advice and expertise to HPRA colleagues in relation to issues relating to medical devices regulations.
  o Working with the legal team, and other HPRA colleagues, to ensure that medical device issues are addressed appropriately.
  o Attending and contributing to HPRA meetings, as appropriate.

- Quality and Knowledge Management
  o Ensuring that the procedures and policies of the HPRA Quality Management System are maintained, deployed and adhered to within the Regulatory and Policy section and the Communications and Policy team.
  o Ensuring that the procedures and policies remain up to date with relevant developments in National, European and International regulations, legislation and guidelines.
  o 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 team.
  o Participating in any relevant internal audits including the identification and implementation of any required corrective actions.
  o Assisting in ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the Department.
  o Assisting the Communications and Policy Lead 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.
  o Contributing to the development of the knowledge network across the HPRA.

- Performance Management
  o Working with the Communications and Policy lead and section manager to deliver performance targets for the section.
  o Participate in the performance development programme (PDP) within the team.
  o Work with your Manager and other managers to promote effective performance within the section.
  o Reporting regularly on progress against specified goals/targets and objectives.
  o Ensure that issues impacting performance are identified early to your Manager and taking measures to resolve issues.
  o Contributing to the development and implementation of effective mechanisms to monitor and report on the different activities to appropriately reflect complexity, impact and resource utilisation.

- Team Development
  o Working with HR, the Communications and Policy Lead and the Regulatory and Policy Manager as appropriate in supporting the management of personnel in the section.
  o Contribute to the development of departmental training plans and a training scheme and development of relevant materials relating to our medical devices regulatory activities.
  o Working with HR, the Communications and Policy Lead and other colleagues as required to support the development of the team’s capabilities and expertise.
- Ensuring effective communication within the Regulatory and Policy section and to the Medical Device Management Team and the Deputy Director.
- Contribute to 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.) where relevant.
- Support colleagues through organisational change and development initiatives.
- Contribute to the provision of high quality induction and ongoing training for staff, including on the job training.
- Contribute to the provision of adequate technical, non-technical and continuous professional development for team members, as appropriate.
- Provide performance feedback, coaching and mentoring support to team members as required.

- Communication/Customer Service
  - Promote a culture where our activities are focussed on patients and designed to ensure that our activities are relevant and useful to the public we serve
  - 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.
  - Work with colleagues in the Medical Device 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 Communications and Policy lead and the Regulatory and Policy Manager, providing relevant regulatory or technical information, advice and guidance to industry, regulatory authorities, healthcare professionals and other relevant stakeholders.
  - Ensure 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 Communications and Policy lead.

QUALIFICATIONS AND EXPERIENCE
- To be considered for this post, candidates must have the following skills and experience:
  - 3rd level degree in legal studies or a relevant discipline (e.g. life sciences or healthcare)
  - Minimum of three years’ experience working in a communication and policy environment relating to health products, preferably related to medical devices
  - Knowledge of regulatory systems and relevant European and National legislation (current and future) relating to medical devices
  - 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
  - Experience of communication of regulatory and policy provisions
  - 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: €61,641 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.
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.

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 15th May 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 27th May 2019.

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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.