HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Medical Officer, Clinical - Medical Devices

ROLE SUMMARY

Reporting to the Clinical Manager, the Medical Officer in the Medical Devices department is responsible for:

- Providing advice, recommendations and decisions relating to the assessment of clinical data for medical devices and *in-vitro* diagnostic devices and assessing the clinical benefit-risk of devices arising from the HPRA's medical device regulatory activities, and ensuring appropriate actions are taken.
- Assessment of applications for clinical investigations, safety reports relating to ongoing clinical investigations and compassionate use of medical devices and *in-vitro* diagnostic devices.
- Assessment of clinical and technical documentation as part of market surveillance and vigilance of medical device and *in-vitro* diagnostic devices cases.
- Contribution to the development of strategy and proactive market surveillance plans for medical devices based on available data input sources including relevant databases, published literature and epidemiological studies.
- Review of clinical evaluation assessment reports and related documentation as part of notified body oversight and providing clinical advice and input on designation assessments.
- Contributing to scientific opinions on drug-device combination products.
- Effective communication and engagement with colleagues and relevant stakeholders on medical devices and *in-vitro* diagnostic devices issues, in particular patients and healthcare professionals.
- Development of clinical guidance and capabilities at national and EU level.
- Contribution to EU and international activities relating to clinical data and its assessment.

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.
- That medical device and *in-vitro* diagnostic technologies in Ireland and Europe afford patients and healthcare systems clinical benefits and that associated clinical risks are acceptable.

The role will include the provision of clinical support to the Medical Devices department and to other medical devices colleagues across the organisation.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Support the development of strategic plans within the Clinical 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.
  - Support the Clinical Manager in prioritising work objectives to ensure that the strategic goals and targets of the Medical Devices department are achieved.
  - Contribute to the formulation and preparation of national/ international regulatory policies, guidelines and legislation as appropriate.
  - 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 the Clinical Manager in meeting the objectives, goals and targets of your section and the Medical Devices department.
  - Work with the Clinical 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.
  - Participate in external, European and international initiatives, as appropriate.
  - Contribute to activities to foster innovation of new medical devices technologies.
  - Working with the Clinical Manager and other colleagues to develop and promote regulatory approaches that are suitable, proportionate and adaptive to existing, new and innovative technologies.
  - Ensure activities and follow up actions are conducted in accordance with appropriate legislation and administrative procedure.
  - Provide clinical information, advice and guidance to organisations, (such as the Department of Health (DoH), other organisations relevant to public health, healthcare professionals, patient representative groups and lay persons.
  - Ensure knowledge of state-of-the-art technologies through ongoing professional education and review of the published literature.
  - Provide advice and professional expertise to the HPRA's inspectors in the performance of their duties.
  - Participate in the enforcement of regulations governing medical devices.
  - Contribute to the development of national and European legislation on medical devices as required.
  - Contribute to the international harmonisation activities relating to medical devices when required.

- Technical Objectives
  - Responsible for the completion of high level complex assessments, formulating recommendations and, decision making relating to clinical aspects of medical devices and *in-vitro* diagnostic devices.
  - Provide advice and expertise and Clinical assessment input through participation, when appropriate, in medical device audits conducted by the Compliance department (including GCP).

- Assess vigilance and safety reports and associated corrective actions related and safety communications, and engage with manufacturers, notified bodies and professional colleagues in order to facilitate these assessment activities.
- Provide Clinical advice and expertise to HPRA colleagues in relation to issues relating to medical devices and *in-vitro* diagnostic devices (including designation and oversight of notified bodies, classification & qualification, scientific advice and combination products and emerging technologies).
- Provide support to the medical device research community in Ireland by engagement in preliminary or pre-submission meetings with researchers and sponsors and by supporting medical device innovation office queries.
- Provide clinical information, advice and guidance to organisations, (such as the Department of Health (DoH), other organisations, healthcare professionals, patient representative groups and lay persons.
- Work with the legal team, and other HPRA colleagues, to ensure that market actions on medical devices and *in-vitro* diagnostic devices are robust, consistent and effective and with due reference to appropriate administrative and legal provisions and procedures.

- Quality and Knowledge Management
  - Assist the Clinical Manager in ensuring that medical device procedures, guidelines and other quality documentation are in place and that they remain up to date with relevant developments in National, European and International regulations, legislation and guidelines.
  - Assist the Clinical Manager in ensuring the effective implementation of the HPRA quality management system.
  - Assist the Clinical Manager in ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge. As required, working with others within the section to achieve this objective.
  - Assist the Clinical Manager in ensuring that available information and knowledge across the HPRA is effectively used by the section.

- Performance Management
  - Participate in the performance development programme (PDP).
  - Work with the Clinical Manager to promote effective performance and achieve performance targets within the team.
  - Take measures to identify and resolve issues impacting performance in the section.
  - Report regularly on progress against specified objectives, goals and performance targets to the Clinical Manager.
  - Participate in activity monitoring and reporting initiatives.

- Communications/Customer Service
  - Participate in regular departmental meetings, cross-organisational meetings and HPRA meetings.
  - Attend meetings and symposia nationally and abroad and representing the HPRA as appropriate.
  - Conduct clinical liaison with applicants, regulatory authorities, healthcare professionals and other relevant stakeholders.
  - Ensure effective dialogue with the external clinical community and building mechanisms to support these exchanges and collaborations.

- Work with the other members of the Medical Device department, as appropriate, to ensure that relevant and appropriate information, advice and guidance is being disseminated to stakeholders (internal HPRA, industry, healthcare professionals, the public, etc.).
- Liaise with officers of the State, other bodies, and industry representatives, as appropriate, on medical device issues.
- Provide timely input to the HPRA's newsletter and HPRA web-site as necessary.
- Attend and participate in information days and other educational conferences as deemed appropriate.

- General
  - Perform any such other duties as the HPRA may reasonably require.

QUALIFICATIONS AND EXPERIENCE

To be considered for this post, candidates must:

- Registerable with the Medical Council in Ireland
- Be a registered medical practitioner with a minimum of two years' satisfactory service in clinical practice (after becoming entitled to full registration)
- Have excellent planning skills and an ability to adapt to changing conditions and display ability to generate effective and pragmatic solutions to new situations and problems, both strategic and operational
- Have excellent interpersonal and communication skills
- A strong personal work ethos and a proven ability to manage high work throughputs and manage deadlines

In addition to this the ideal candidate will also have one or more of the following;

- An additional undergraduate or postgraduate qualification in a relevant scientific or public health discipline
- Published research in the academic or clinical field of medicine
- Experience with evaluation of medicinal products or medical devices in the industrial, government authority, academic or clinical settings
- Good understanding of methodology and biostatistics, epidemiology and literature review. Experience or a good understanding of risk-benefit analysis, risk assessment or risk minimisation methodologies
- Knowledge or experience of the use and management of medical devices
- Experience representing organisations at meetings
- Experience making presentations to conferences/meetings

REMUNERATION

Salary: €85,884 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 one-year contract post (duration of maternity leave).

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 25 days per annum.

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.

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 **Sunday, 12th January 2020.**

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 on **Monday, 27th January 2020.**

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

HOW TO APPLY

Applications should be submitted via the HPRA 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.

* 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.