HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Medical Devices Inspector, Assessment & Surveillance, Medical Devices Department

ROLE SUMMARY

Reporting to the Medical Device Inspection Operations Manager, the Medical Devices Inspector will be primarily responsible for:

- Planning and conducting proactive and reactive inspections of manufacturers and other economic operators as part of the HPRA market surveillance activities for medical devices.
- Execution of inspections relating to designation of notified bodies for medical devices in Ireland and as part of European joint assessment activities.
- Execution of inspections arising from the HPRA ongoing surveillance and monitoring programme for Notified Bodies, including observation of audits conducted by the Notified Bodies.
- Ensuring alignment of inspection activities with other assessment activities across the Medical Devices Department and appropriate interaction with relevant teams and sections in the preparation, conduct and follow up from medical device inspections.

The content below represents a broad guideline for the role of Medical Devices Inspector. Some aspects may be subject to change in accordance with business needs.

The role of a Medical Device Inspector is to identify and evaluate issues at sites inspected, nationally and internationally, that may result in:

- medical devices being placed on the market that are non-compliant with the requirements of the national legislation (in Ireland), European Community Directives, European Regulations, harmonised standards, and other relevant guidance.
- notified bodies, economic operators and other entities that are non-compliant with their obligations and the requirements of the national legislation (in Ireland), European Community Directives, European Regulations, harmonised standards, and relevant guidance.

The sites to be inspected, nationally and internationally, may include;

- Manufacturers of medical devices
- Authorised Representatives
- Contract Sterilisation sites
- Notified Bodies
- Distributors & importers of medical devices
- Critical suppliers and subcontractors of medical device manufacturers
- Other entities, for example health institutions and laboratories

The Medical Devices Inspector will work closely and maintain effective working relationships with colleagues in all relevant sections across the Medical Device Department, with other departments of the HPRA, and with stakeholders. They will ensure that medical devices inspection issues that require cross-functional input are effectively communicated, investigated and followed up on in a timely manner. The activities undertaken by the Inspector will support the HPRA in fulfilling its obligation as market surveillance authority for medical devices and as the authority responsible for notified bodies.

The role involves inspecting, reporting and forming conclusions in respect of the compliance of the medical device activities under review. The Inspector will coordinate the inspection teams required to undertake specific activities, including any relevant technical, clinical, or regulatory support. The Inspector provides technical information and guidance to relevant individuals and organisations both internal and external to the HPRA.

The inspector will also provide advice and inputs to medical device planning & priorities activities, business planning and reporting, policy and guidance development, and on request, provide technical and scientific inputs into ongoing assessments within their areas of competence.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Supporting the Medical Device Inspection Operations Manager 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 Medical Device Inspection Operations Manager to prioritise work objectives and to ensure that the strategic goals and targets of the Medical Devices Department are achieved.
  - Contributing to the formulation and preparation of national / international regulatory policies, guidelines and legislation as deemed appropriate.
  - Participation in external national, 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
  - Prepare for, organise, and carry out inspections, nationally and internationally, in accordance with HPRA procedures.
  - Ensure appropriate preparation and follow up on inspection activities and other related market surveillance activities are completed.
  - Coordinate with relevant teams across the Department in the preparation, conduct and follow up from the inspection.
  - Coordinate the inspection team required when acting as lead inspector, including technical, clinical, or regulatory assessors when required.
  - Write inspection reports when acting as lead inspector and contribute to the preparation of reports for joint or accompanied inspections.
  - Assist in the compilation of data and preparation of management reports as required.
  - Provide input and data into planning activities relating to market surveillance inspections.
  - Apply risk management principles.
  - Submit reports as required and maintain appropriate records of meetings and activities.
  - Maintain a database of inspections performed.
  - Assist in the development, implementation and maintenance of policy and practice guidelines and procedures.
  - Provide support to other areas of the HPRA where appropriate

- Quality and Knowledge Management

Assist the Medical Device Inspection Operations Manager and the managers of the Assessment & Surveillance section to ensure:

  - The effective implementation of the HPRA Quality Management System
  - That there are effective mechanisms in place to capture, store and communicate key information, experience, and knowledge gained.

- That information and knowledge available across the HPRA is effectively used.
- That inspection procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidance.

- Performance Management
  - Participate in the performance development programme (PDP)
  - Work with the manager to agree appropriate performance related targets.
  - Work effectively to agreed performance related targets.
  - Take measures to identify and resolve issues impacting performance.
  - Report regularly on progress against specified objectives, goals, and performance targets
  - Effectively communicate objectives, goals, and performance targets within the team
  - Promote a positive, open, friendly, and professional working environment.

- Communication/Customer Focus
  - Attend and contribute to meetings as required.
  - Liaise with relevant departments of the HPRA to facilitate the identification, performance, evaluation and follow-up of inspections and market surveillance activities.
  - Contribute by participating or presenting, as required, at seminars, conferences, educational institutes, etc.
  - Represent the HPRA, as required, at national, European and international regulatory meetings and seminars on matters pertaining to medical device inspections and objectives.
  - Respond to queries (technical and procedural) from internal and external customers.

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A relevant third level honours science degree (for example but not limited to: Biotechnology, Biology, Microbiology, Biomedical Engineering, Pharmacy).
  - Min of three years relevant work experience in the medical devices / pharmaceutical / notified body sectors, in at least one of the following:
    - Facility that manufactures medical devices in the following functions for example: quality assurance, regulatory affairs, compliance, R&D, or validation
    - Regulatory Authority / notified body evaluating manufacturing processes generally.
  - Experience working to European and National legislation and international standards.
  - Evidence of excellent communication and report writing skills.
  - A proven ability to assess complex information and make effective decisions, in a time dependent setting.
  - Highly motivated and with the ability to manage deadlines.
  - Demonstrable initiative and the ability to work as part of a multi-disciplinary team.
  - A valid clean driver's licence and a readily available vehicle.

- In addition, the following would be considered an advantage:
  - Post graduate qualification in a relevant scientific discipline.
  - A lead auditor qualification, for example EN ISO 13485.
  - Experience in performing regulatory inspections or industry audits.
  - Experience in the design, manufacture and/or quality assurance of medical devices.

REMUNERATION

Salary: €67,890 per annum (*new entrants – 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 three-year contract post.

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 35 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

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.

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.

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.

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

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.

CLOSING DATE

The closing date for applications for this post is the **26th March 2023**.

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

INTERVIEWS

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

The HPRA will make reasonable accommodations for a person with a disability during the recruitment process.

Interviews are expected to take place in week commencing 3rd April 2023.

CONFIDENTIALITY AND CONFLICT OF INTERES

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.

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 opportunity employer. The HPRA will not discriminate against an employee or prospective employee in relation to the nine discriminatory grounds as per the Employment Equality Acts, 1998-2015.