Role Profile
Graduate Programme, Medical Devices
(Stream 1)

ROLE SUMMARY

The Medical Devices Stream (Stream 1) runs for 12 months, consisting of two 6 month rotations and is structured to ensure graduates gain an insight and exposure to different departments, encouraging graduates to develop and enhance multiple competencies and offer the graduates a comprehensive understanding of medical devices regulation.

The graduate will work closely with the Medical Devices staff at all levels and maintain effective working relationships with colleagues in other sections and departments of the HPRA and to ensure that requirements under the legislative framework are effectively communicated.

The graduate's role in the Medical Devices Stream will include the following:

1. Assessment and Surveillance

- The graduate through their time in the technical assessment team will develop an understanding of the requirements of the Regulations and what is needed to place a device on the market and maintain a product through its lifecycle, how to define and classify a medical device, the types of pre-market assessments conducted on medical devices, the role of notified bodies and their oversight by authorities, the nature of technical documentation for medical devices and its assessment, and the conduct and methods of market surveillance of medical devices by regulatory authorities.

- The functions of the Device Technical Assessment Team are:
    - Market surveillance of medical devices
    - Examination of applications for clinical investigations
    - Maintenance of registration system for self-declared medical devices
    - Provision of advice on classification & qualification of medical devices
    - Designation & monitoring of notified bodies for medical devices
    - Implementation, advice and development of the legislation and related guidance

- In conjunction with this the graduate will be involved in medical device vigilance which is a core element of the competent authority's market surveillance activities. The graduate will build upon their understanding of medical device regulation developed and apply this to real-time medical device vigilance cases. The graduate will gain experience in the assessment of incidents and field safety corrective actions and they will participate in stakeholder engagement work such as issuing safety communications.

2. Regulatory and Policy

- The graduate will learn about the application of legal requirements for medical devices, the structures and objectives of regulatory systems and will gain an understanding of how EU and international regulatory frameworks for medical devices operate. In particular, this will include; training and exposure in the application of the new regulations on medical devices and *in vitro* diagnostics, experience in policy & regulatory development, and exposure to a range of internal & external communication activities.

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 to a range of stakeholders on medical devices and *in-vitro* diagnostic issues, providing relevant information on devices and on our activities;
- Departmental activities are completed with administrative, clinical, legal, regulatory, technical and scientific excellence.

The activities are undertaken with the aim of ensuring that medical device and *in-vitro* diagnostic technologies in Ireland and Europe are in compliance with European & national requirements, including the relevant standard

The activities of the Policy & Regulatory team include:

- Implementation and maintenance of the EU Regulations on medical devices and *in-vitro* diagnostic devices and related EU and national legislation.
- National & international policy development using evidence-informed approaches.
- Coordination on the continued development of the HPRA's regulatory activities for medical devices and *in-vitro* diagnostic devices to meet its legislative obligations.
- Coordination of the Department's Operational and Strategic Planning and activity reporting.
- Development and coordination of the regulatory support function for cross departmental activities.
- Coordination and management of HPRA contributions to European and international activities.
- Knowledge brokering, which includes the coordinated communication of information and knowledge management initiatives for the Department, in addition to some data-analysis.
- Development and delivery of communication, reporting and educational initiatives for the Department.
- Developing and managing stakeholder engagement on medical devices and *in-vitro* diagnostic devices.

KEY RESPONSIBILITIES

- Operational Objectives
  - Assisting their manager in meeting the objectives, goals and targets of each section.
  - Working with their manager to plan and organise work tasks and ensure delivery of work.
  - Validating, assessing, and monitoring issues and corrective actions.
  - Contribute to HPRA processes to ensure activities and follow up actions are conducted in accordance with appropriate legislation and administrative procedure.
  - Maintain appropriate records of meetings, activities and submit reports as appropriate.
  - Assist in the compilation and communication of updates and reports from meetings as well as in the compilation of data for reports as required.

  - Gather information and provide assistance in support of assessment of various issues and medical cases such as classification, market surveillance and vigilance cases.
  - Monitoring issues and highlighting cases of concern to the attention of their manager in a timely manner.
  - Ensuring timely close out of cases.
  - Reporting and communicating case outcomes e.g. Safety notices, Competent Authority Reports (CA reports) etc.
  - Conduct specific projects in the area of Medical Devices as required.
  - Promoting a positive, open, friendly and professional working environment.
  - Compiling data and preparing reports, as required.

- Performance Management
  - Reporting regularly on progress against specified goals/targets and objectives to their manager.
  - Ensuring issues impacting performance are identified early to their manager.
  - Maintaining logbook of work undertaken in a timely manner.

- Quality & Knowledge Management
  - Assisting their manager to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained.
  - Contributing to the implementation of the HPRA Quality Management System.

- Communications/Customer Service
  - Attending and contributing to HPRA internal meetings, as appropriate.
  - Attend external meetings as deemed appropriate by section manager in current rotation.

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must:
    - Be on track for or have achieved a minimum 2:1 honours Bachelor's Degree (NFQ level 8) or equivalent in any of the following disciplines, or other relevant discipline:

Biomedical Engineering	Biochemistry
Mechanical Engineering	Microbiology
Manufacturing Engineering	Molecular Biology
Medical Physics	Immunology
Biotechnology	Or related discipline

    - Excellent communication, teamwork and organisational skills.
    - Interest in contributing to the protection and enhancement of public and animal health through the regulation of medicines, medical devices and other health products.
    - Excellent data analysis skills.
    - Demonstrate initiative and team working capabilities.
    - Highly motivated with the ability to manage deadlines.

REMUNERATION

Salary: €30,140 per annum.

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.

DURATION OF POST

12 months.

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.

REFERENCES

The names and addresses of two referees to whom the applicant is well known but not related must be submitted with the application

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.

The appointee will be required to demonstrate flexibility and anticipate that the role, activities and responsibilities may change in line with business needs and organisational development.

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.

HOW TO APPLY

Applications should be submitted to jobs@hpra.ie

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 **31st October 2023**.

INTERVIEWS

It is anticipated that interviews for this post will take place in **November 2023**.

Note: The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process.

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.

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.