Role Profile

Graduate Programme, Medicines on our Market (Stream 2)

ROLE SUMMARY

The Medicines on our Market Stream (Stream 2) runs for 12 months, consisting of three 4-month rotations and is structured to ensure graduates gain an insight and exposure to different departments, encouraging them to develop and enhance multiple competencies and offer the graduate a comprehensive understanding of the Medicines on our Market.

In this stream, the graduate will be exposed to three key work programmes at the HPRA that focus on the medicines on our market:

1. Vigilance

Monitoring the safety of medicines includes all activities related to the detection, assessment, understanding and prevention of adverse effects and other possible drug-related problems. This monitoring is carried out in a number of ways, including review and evaluation of suspected adverse reaction reports, published literature, epidemiological studies and additional clinical trial results. The HPRA continually assesses new and emerging safety data as it becomes available and undertakes regulatory action as appropriate. In addition, the HPRA is also responsible for monitoring the safety of Blood/Blood components, Tissues & Cells and Organs (BTO), including operation/oversight of the vigilance systems in place for these areas.

Graduates will gain a unique insight into the regulatory structures and activities in place for vigilance and ongoing monitoring of the safety of medicines, Blood/Blood components, Tissues & Cells and Organs (BTO), including the requirements in place for the various stakeholders involved in the processes, under the respective legal/regulatory frameworks.

Working in the Vigilance area will provide the graduate with a platform to gain practical experience and build knowledge around safety monitoring activities, including individual case report processing and evaluation, follow-up of reports, cumulative review, regulatory impact, and interaction/communication across the various stakeholder groups.

The graduate will be exposed to a broad range of vigilance related activities while learning about the applicable vigilance processes. The graduate will have an opportunity to develop competency in these areas and will also gain knowledge of the broader framework of pharmacovigilance in relation to overall regulatory activities and risk assessment.

2. Health Products Distribution

The HPRA Health Products Distribution team support the HPRA in monitoring the integrity of the supply chain for both medicines and active substances after they are released to the market by manufacturers. This is done by ensuring all wholesalers and distributors are authorised by the HPRA and that they comply with Good Distribution Practice (GDP). Compliance with GDP is monitored through inspection at wholesale and distribution sites.

This inspection programme contributes to the HPRA's role in protecting public and animal health by ensuring a secure supply chain to prevent falsified medicines being introduced and also checking that the quality of the medicines is maintained through appropriate storage. The graduate will gain a detailed understanding of how the wholesalers and distributors become authorised/registered with the HPRA and of how GDP inspections are performed. They will also be exposed to the regulations that underpin the inspection activities that the HPRA performs.

The programme will provide the graduate with a platform to learn about the additional control and security requirements for medicines that are classed as controlled drugs under The Misuse of Drugs Act. They will also gain an insight into how the global control system for monitoring the movement of controlled drugs is operated by the International Narcotics Control Board and how the HPRA input to that control system.

The graduate will have an opportunity to develop competencies in many areas and an understanding of increasingly complex global supply chains for medicines.

3. Inspections

Technical staff in the Inspection Section carry out GMP inspections and scientific evaluation across a large range of sites in accordance with the requirements set out in national legislation and EU Directives and Regulations.

Graduates will gain a unique insight into the regulatory structures and activities in place related to the manufacture of active substances and medicines for both human and veterinary use. Working with GMP Inspectors and Scientific Officers area will provide the graduate with a platform to gain practical experience and build knowledge around GMP and licensing and inspection activities for manufacturing.

The graduate will be exposed to a broad range of GMP inspection related activities while learning about the applicable licensing and registration processes and will have an opportunity to develop competency in these areas. They will also acquire knowledge of the broader framework of EU GMP guide development and in relation to overall regulatory activities and risk assessment.

KEY RESPONSIBILITIES

Operational Objectives

- Vigilance
  - Working closely with colleagues to ensure timely, effective and appropriate processing and evaluation of adverse reaction/event data.
  - Contributing to the review, evaluation and follow up of individual vigilance reports and cumulative safety data.
  - Contributing to the review and analysis of adverse reaction reporting trends.
  - Preparing and compiling data for review and assisting with the preparation of reports.

- Contributing to the preparation of Pharmacovigilance (PV) related publications.
- Liaising with and providing information and guidance on vigilance related matters to
- Assist with internal/external responses to queries, as necessary.
- Identifying opportunities for continuous improvement by highlighting quality management issues for review and consideration.
- Participating in the formulation and preparation of regulatory policies, guidelines and procedures.

- Health Product Distribution
  - Learn and understand the complexity of supply chains for medicines.
  - Develop an understanding of the system of authorisation for wholesalers and distributors of medicines and assist with activities in relation to the authorisations.
  - Gain an insight into the legislation and regulatory framework of controlled drugs in Ireland and its relationship with the international control system for these substances.
  - Assist in the review of controlled drug import and export licences.
  - Assist in the review of controlled drug statistics and compilation of the reports submitted to the International Narcotics Control Board.

- Inspections
  - Compile data and prepare reports, in relation to the project, as required.
  - Conducting scientific evaluation of other data in relation to the authorisation and registration process as required in line with business needs.
  - Working with the managers in ensuring the accuracy of relevant data inputted in the computer databases and information systems of the HPRA.
  - Working with colleagues to provide technical information, advice and guidance to relevant stakeholders, as required.
  - Attending, contributing and recording, as required to meetings of the section and Compliance department.

- Quality & Knowledge Management
  - Ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge.
  - Identify opportunities for continuous improvement of standard operational procedures and guidance within the Health Products Distribution team.
  - Contributing to the effective implementation of the HPRA quality management system within the Compliance and HPM departments.

- Performance Management
  - Working with colleagues in the Pharmacovigilance , Health Products Distribution and Inspections to promote effective performance.
  - Reporting regularly on progress against specified goals/targets and objectives.
  - Highlighting issues identified (e.g. with reporting, procedures, compliance monitoring) and contributing to the development of measures to resolve them.
  - Reporting regularly on progress made against specified objectives, goals and performance targets (for project and work-related activities).

- Communication/Customer Service
  - Participating at regular internal team, section and department/organisational meetings.
  - Promote a positive, open, friendly and professional working environment

- Team Development
  - Participating in technical and skills training and continuous professional development.
  - Participating in induction and ongoing training, including comprehensive on the job training.
  - Attending technical quality system training.
  - Promote a positive, open, friendly and professional working environment.

- General
  - Liaising with and providing support to other areas of other sections in the rotation as required.
  - Performing 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 disciplines:

Pharmacy	Toxicology
Pharmaceutical Analysis	Pharmaceutical QA
Pharmaceutical Medicine	Regulatory Affairs
Pharmacology	Science
Immunology & Global Health	Or related discipline

- Excellent communication, teamwork and organisational skills.
- Interest in contributing to the protection and enhancement of public 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.

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.

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.

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.

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.