HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Graduate Programme, Medicines on our Market (Stream 2)

ROLE SUMMARY

The Medicines on our Market Stream (Stream 2) runs for 18 months, consisting of three 6-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. Market Compliance

The Sampling and Analysis programme functions to support the HPRA in monitoring the quality and safety of medicinal products both on the Irish market and produced for export. It allows us to identify medicinal products on the Irish marketplace and / or produced in Ireland which may not be compliant with their marketing authorisations or other expected standards.

We achieve this through a risk-based approach to surveillance testing and product examination. This programme contributes to the HPRA's role in protecting public and animal health by checking the quality of the medicines via laboratory testing and ensuring that any non-compliance issues are followed up on and addressed. It also allows us to identify deficient analytical test methods that may be in use at pharmaceutical company laboratories. The programme also allows us to check that the product information supplied in packs of medicines is correct and up-to-date. The graduate will gain a detailed understanding of how the sampling and the independent testing of medicines contributes to the protection of public and animal health.

The graduate will be exposed to the regulations that underpin the surveillance testing activities that the HPRA oversees and coordinates, as well as the type of product testing and examination work that the HPRA coordinates or carries out. The graduate will apply quality risk management principles in the design of annual surveillance. The programme will provide the graduate with a platform to learn about medicinal product specifications, test methods, marketing authorisations, and contract laboratory operations. It will also address how the HPRA's sampling and analysis programme supports pharmacovigilance investigations. The graduate will also gain an understanding of how the HPRA's surveillance activities fit in with European initiatives and programmes in this area.

The graduate will have an opportunity to develop competencies in dealing with the test results that come from the laboratory testing of medicines, as well as in dealing with the results from packaging and labelling examinations carried out on medicinal products.

3. Shortages in Medicines

Medicine shortages are increasingly prevalent globally, and Ireland, like all European countries, has the potential to be affected. The medicines shortages function within the HPRA co-ordinates the management of medicine shortages and works closely with various key players in the health sector with the aims of preventing a shortage and reducing the impact of a shortages when they do occur.

This is achieved via interaction with multidisciplinary teams with other departments in the organisation and with external stakeholders (including marketing authorisation holders, wholesalers, manufacturers, the HSE, healthcare professionals and patients).

The graduate will gain insight into the activities undertaken by the shortages team in co-coordinating the reaction to an actual or potential shortage of a medicine. This will involve the application of knowledge gained at undergraduate level as well as aspects the graduate will be exposed to in the HPRA graduate programme. Often shortages are unpredictable and the shortages team has to react to emergent situations. Therefore, the graduate will develop skills in handling multiple priorities and a range of different competencies that cultivates a solutions-focused perspective to reduce the impact of a shortage on patient.

Given the diverse nature of the causes of shortages and the variety of stakeholders involved, the graduate will gain a tangible appreciation for the national and global impacts of medicines authorisation and supply chain, up to and including the patient.

The graduate will therefore have an opportunity to develop competencies in understanding the complexities of the medicine supply chain, develop analytical and investigational skills whilst working with stakeholders to understand the root cause of shortages and develop appropriate responses to ensure the impact on patients is reduced as much as possible. The graduate will also gain insight into the latest national and international strategies aimed at long term prevention of shortages.

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.

- Market Compliance
  - Supporting the Sampling & Analysis group in the operation of the programme.
  - Assisting in identifying future risk-based sampling and analysis projects in relation to medicines on the market in Ireland as well as those manufactured in Ireland for export.
  - Working to prioritise Sampling & Analysis work on a case-by-case basis in accordance with risk-based principles.
  - Helping to further develop and improve the risk-assessment methods in use for Sampling & Analysis work.
  - Working within the Sampling & Analysis team to ensure that the goals and objectives of the programme are met.
  - Assisting in the accurate logging, tracking, maintenance and compilation of data.
  - Assisting in the generation and issuance of Sampling & Analysis reports
  - Assisting in the review laboratory reports and certificates of analysis.

- Shortages in Medicines
  - Learn about the complex causes and impacts of medicine shortages.
  - Understand the activities undertaken by the team at HPRA working to prevent shortages and reduce their impact on patients.
  - Assisting in handling shortage cases.
  - Develop critical thinking and solution-focused competencies.

- Helping to develop the shortages function in the HPRA.
- Gain insight into the latest international strategies to deal with medicines shortages.

- Quality & Knowledge Management
  - Ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge.
  - Assisting the Sampling & Analysis team in ensuring that the Sampling & Analysis programme remains up to date with relevant developments in national, European and International regulations and legislation.
  - 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 , Market Compliance and Shortages in Medicines sections to promote effective performance.
  - Taking measures to identify and resolve issues impacting performance in the Sampling & Analysis programme.
  - 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.

- Communication/Customer Service
  - Assisting in the development and implementation of communication and awareness raising strategies activities for the Sampling & Analysis Programme.
  - Participating at regular internal team, section and department/organisational meetings.

- 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.

- 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: €28,203 per annum (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.

DURATION OF POST

18 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 in line with the Hours of work and attendance policy after a period of six months.

The HPRA are operating a hybrid model where work is carried out partly from the office (a minimum of 2 days per week) and partly using a remote working arrangement. This model permits an employee to carry out some of their duties at the HPRA offices and some from a remote location. The HPRA are currently in a test and learn phase of this hybrid working model, which is subject to review.

LOCATION

This role is being offered as part of our hybrid working model. The successful candidate may avail of working remotely for three days per week and working two days per week in the HPRA offices, based in Kevin O'Malley house, Earlsfort Terrace, Dublin 2. The specific days each week when you work at each location will be determined by your manager. The introduction of the hybrid model will be subject to review at the end of 2022.
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.

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 via the HPRA Recruitment Portal.

CLOSING DATE

The closing date for applications for this post is the **31st October 2022**.

INTERVIEWS

It is anticipated that interviews for this post will take place in **November 2022**.

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.

** 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.*