HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Executive Pharmaceutical Assessor, Pharmaceutical Assessment - Human Products Authorisation & Registration

ROLE SUMMARY

Reporting to the Pharmaceutical Assessment Manager/ Senior Pharmaceutical Assessor the role of the Executive Pharmaceutical Assessor is to proactively participate in the management, development and operation of the Pharmaceutical Assessment section and its activities relating to the assessment of medicinal products of chemical origin.

The Executive Pharmaceutical Assessor will achieve this through the following key aspects:

- Effective management of the pharmaceutical team reporting to them by assisting the members of the pharmaceutical assessment management team in:
  - Defining objectives, setting targets, coordinating activities, and agreeing priorities, developing team members, and
  - Maintaining effective communication lines and ensuring that the required standards, policies, and practices are in place for the pharmaceutical assessment of all application types received.
- Pharmaceutical assessment of quality data and bioequivalence studies for generic medicines for all applications received by the Pharmaceutical Section.
- Management of systems and procedures to support pharmaceutical assessment of applications received.
- Deputise for colleagues and to ensure appropriate cover within the Pharmaceutical Assessment section as required.

KEY RESPONSIBILITIES

- Strategic Management
  - Support the pharmaceutical assessment management team in the management and ongoing development of the Pharmaceutical Assessment section.
  - Contribute to the development of strategic plans for the Pharmaceutical Assessment section as required.
  - Work with colleagues in the pharmaceutical assessment management team to prioritise objectives and to ensure that the strategic goals of the section are achieved.
  - Provide leadership, support, and direction within the section as appropriate.
  - Work closely with the pharmaceutical assessment management team to lead and drive the strategic initiative of moving bioequivalence assessments of generic medicines to the pharmaceutical assessment section.

- Operational Management
  - Manage and supervise members of the Pharmaceutical Assessment section in line with the structure of the section.
  - Deputise for Senior Pharmaceutical Assessors, as required.
  - Work with the pharmaceutical assessment management team to plan and organise tasks to ensure efficient delivery of pharmaceutical assessment work.

- Provide support to all staff in the pharmaceutical assessment section to ensure deadline are met on time.
- Promote a positive, open, friendly, and professional work environment.
- Assist in the compilation of data and preparation of management reports as required.
- Working closely with the pharmaceutical assessment management team to ensure efficient delivery of assessments of generic new applications.
- Develop processes to ensure assessment procedures are developed to facilitate timely assessments and to incorporate adequate clinical oversight.

- Technical Management
  - Oversee and participate in the pharmaceutical assessment of quality data bioequivalence studies for generic medicines, submitted in support of applications received by the pharmaceutical section.
  - Ensure pharmaceutical assessors are equipped with the technical skills to assess quality data and bioequivalence studies for generic medicines.
  - Participate and support other areas or processes, which may come within the scope of the Pharmaceutical Assessment section.
  - Work with colleagues to ensure that appropriate policies and procedures are in place for pharmaceutical assessment.
  - Work with colleagues to ensure the development, communication and implementation of internal and external pharmaceutical assessment guidelines as required.
  - Provide technical advice and knowledge including internal and external presentations on reflection of work completed within the pharmaceutical assessment section.
  - Provide support to other areas of the HPRA where appropriate.
  - Implement, in conjunction with the pharmaceutical assessment management team, an efficient and effective review process for assessment work conducted by members of the pharmaceutical assessment team.

- Quality and Knowledge Management
  - Ensure effective implementation and management of the HPRA Quality Management System within the Pharmaceutical Assessment section.
  - Ensure appropriate technical guidelines for work conducted within the pharmaceutical assessment team are developed, implemented, updated, and communicated to the Section on an ongoing basis.
  - Participate and manage the involvement of the Section in any internal audits including the identification and implementation of any required corrective actions.
  - Contribute to ensure that the Section remains up to date with relevant developments in national, European and International regulations and legislation.
  - Contribute to the development of the knowledge network across the HPRA.

- Performance Management
  - Work with the pharmaceutical assessment management team to set appropriate operational objectives and performance targets.
  - Ensure that resources available are aligned to the best effect to manage application output requirements.
  - Effectively communicate goals, objectives, and performance targets to the members of the Pharmaceutical Assessment section as appropriate

- Lead, co-ordinate and participate as appropriate in the performance management programme (PDP) within the section to maximise efficiency gains for the department
- Contribute to the development of management processes within the Pharmaceutical Assessment section.
- Take measures to identify and resolve issues impacting performance.
- Report regularly on progress against specified goals/targets and objectives.
- Openly recognising good performance and promoting a culture of performance improvement in the Pharmaceutical Assessment section.
- Work with colleagues to ensure that assessment processes are continuously reviewed and amended as required to optimise the performance of the section.

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- Communication/Customer Focus
  - Effectively communicating goals, objectives and performance targets to members of the pharmaceutical assessment team.
  - Holding regular team meetings.
  - Work to ensure information flows are successfully managed within the Pharmaceutical Assessment section, to ensure changes which occur in the wider organisation are appropriately communicated to the staff on which they impact.
  - Liaise with relevant external organisations or internal colleagues on assessment issues, as appropriate.
  - Work with colleagues in the Section to maintain positive relationships with stakeholders that reflects the professionalism and high standards of the HPRA.
  - Contribute to answers to parliamentary questions and media queries, as required.

- Team Development
  - Ensure the provision of adequate technical, non-technical and continuous professional development for the pharmaceutical assessment section as appropriate.
  - Ensure the provision of high-quality induction and ongoing training for staff, including on the job training.
  - Contribute to the development of assessment training programmes.
  - Oversee the development of staff, including the development of individual training plans, and maintain training records and documentation.
  - Coordinate the planning and delivery of training for the pharmaceutical assessment section, with HR&C and other colleagues as required.
  - Provide performance feedback, coaching and mentoring support to staff in the pharmaceutical assessment section.
  - Ensure, in conjunction with the pharmaceutical assessment management team that pharmaceutical assessors and other personnel develop their skills and competencies.
  - Liaise with the HR department in providing front-line HR management of staff (e.g., recruitment, managing attendance, probation, performance management etc).
  - Manage and guide staff through organisational change and development initiatives.

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A degree in a scientific discipline relevant to the assessment of chemical medicinal products.
  - A minimum of 2 years pharmaceutical experience in the technical writing, or assessment of, module 3 for new product applications of chemical origin
  - Personal drive to help shape the future and deliver excellent customer service.
  - Excellent leadership skills with a demonstrated ability to lead on the implementation of a new process.
  - A self-starter, capable of excellent communication and decision making and teamwork.
  - Flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome

In addition, the ideal candidate will have:
- A relevant postgraduate qualification
- Experience in the technical writing or assessment of quality dossier submissions for clinical trials submissions.
- Experience in the technical writing or assessment of bioequivalence study submissions for new generic applications.
- Experience interacting with the European Medicines Agency.
- Ability to motivate a team and maintain output and productivity to a high standard.
- Experience in managing or mentoring staff

REMUNERATION

Salary: €76,667 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.

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.

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.

DURATION OF POST

This is a 3-year contract post.
Note: The issuing of a 3-year contract is standard HPRA practice prior to moving to permanency for long term roles, such as this.

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 **25** 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.

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 **Monday 10th April 2023.**

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 **Tuesday 18th April 2023**. The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

HOW TO APPLY

Applications should be submitted **directly to our jobs mailbox** – jobs@hpra.ie

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.

EQUAL OPPORTUNITIES

The HPRA is an equal opportunities employer. We are committed to equal employment opportunity regardless of gender, civil status, family status, sexual orientation, religion, age, disability, race or membership of the travelling community. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process and can be notified in the course of the interview correspondence.