HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Pharmaceutical Assessor (Acting), Pharmaceutical Assessment – Human Products Authorisation and Registration

ROLE SUMMARY

The Pharmaceutical Assessor will work as part of the Pharmaceutical Assessment section in the Human Products Authorisation and Registration (HPAR) department and will assist in the evaluation of the quality aspects of new applications for human medicinal products and variations to/renewal of existing authorisations for pharmaceutical products containing new chemical entities or established active ingredients. While appointees will predominantly be assigned to work with the Pharmaceutical Assessment section, from time to time as business needs dictate, assessors may be assigned to provide assistance within the Clinical Assessment section.

The Pharmaceutical Assessor will work closely and maintain effective working relationships with the other members of the Pharmaceutical Assessment section, and with members of the Human Products Authorisation and Registration department as a whole, to ensure effective co-ordination and co-operation across all areas of assessment and to ensure that the objectives of the HPAR department are met.

The Pharmaceutical Assessor will maintain effective working relationships with colleagues in other sections and departments of the HPRA such as the clinical section of HPAR, and with stakeholder sections, to ensure that Pharmaceutical Assessment issues requiring cross-functional input are effectively investigated and followed up on.

KEY RESPONSIBILITIES

- Technical Objectives
  - Conducting scientific evaluation of quality data submitted in support of applications for marketing authorisation for human medicinal products containing new chemical entities or established active ingredients. Analysis of their risk/benefit profiles; reporting and forming conclusions in respect of their suitability for use as human medicinal products as well as consideration of the public health consequences of their use.
  - Conducting scientific evaluation of quality data submitted in support of:
    - National applications for marketing authorisations, including Parallel Products
    - Centralised applications to the EMA for marketing authorisations when the HPRA is acting as rapporteur, co-rapporteur or peer reviewer on behalf of the EMA
    - EU applications when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure
  - Preparation of assessment reports on applications for marketing authorisation for human medicinal products and submission of reports to other EU member states when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure
  - Analysis in the context of public health, of risk-benefit profiles in respect of applications for marketing authorisation; making recommendations and preparation and presentation of reports to the Board, Advisory Committees and Sub-Committees or the Management

Committee of the HPRA, and/or the CHMP or their representative working parties, regarding the suitability of human medicinal products for marketing approval
    - Assisting the Pharmaceutical Assessment Manager and other managers in the Pharmaceutical Assessment section in ensuring the accuracy of relevant data inputted in the computer databases and information systems of the HPRA

- Operational Objectives
    - Assisting and working with the Pharmaceutical Assessment Manager and other managers in the Pharmaceutical Assessment section to:
        - Meet the goals and objectives of the section
        - Upkeep and further develop the Quality Management System (QMS) procedures for the section in line with the operational goals of the HPAR department
        - Plan and organise their work tasks that ensure efficient delivery of work
    - Providing support to other colleagues within the HPAR department, where required
    - Promoting a positive, open, friendly and professional working environment
    - Assisting in the compilation of data and preparation of reports as required
    - Attending meetings of the HPRA Advisory Committees as required
    - Attending Working Groups/Committees/meetings at the European Medicine Agency (EMA), as required
    - Attending meetings with other Irish Agencies, as required
    - Maintaining appropriate records of meetings and activities
    - Attending and contributing to meetings of the Pharmaceutical Assessment section and HPAR department

- Strategic Objectives
    - Supporting the Pharmaceutical Assessment Manager and other managers in the Pharmaceutical Assessment section in the:
        - Running and on-going development of the section
        - Preparation of work objectives for the section
        - Prioritisation of work objectives and ensuring that the operational goals of the section are achieved and
        - Providing support and direction to colleagues and others within the section and the HPAR department

- Quality and Knowledge Management
    - Assist the managers of the Pharmaceutical Assessment section to ensure:
        - The effective implementation of the HPRA Quality Management System within the section
        - That there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the section
        - That available information and knowledge across the HPRA is effectively used by the section.
        - That procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidelines.

- Performance Management
    - Participating in the performance development programme within the Pharmaceutical Assessment section to maximise efficiency gains for the Human Medicines Department
    - Working with the Pharmaceutical Assessment Manager and other managers in the Pharmaceutical Assessment section to promote effective performance within the section

- Taking measures to identify and resolve issues impacting performance in the Pharmaceutical Assessment section
- Reporting regularly on progress against specified goals/targets and objectives

- Communications/Customer Service
  - Conducting technical liaison with applicants, regulatory authorities, healthcare professionals and other relevant stakeholder
  - Provision of technical information, advice and guidance to regulatory authorities, healthcare professionals and other relevant stakeholder
  - Liaising with officers of the State, other bodies and industry sections, as appropriate, on Pharmaceutical Assessment issues
  - Provide timely input to the HPRA's newsletter and website as necessary
  - Participate in regular team/section meetings
  - Ensure that HPRA policies and procedures are communicated in a consistent way to stakeholders

- Team Development
  - Working with the Pharmaceutical Assessment Manager and other managers in the Pharmaceutical Assessment section:
    - To ensure the provision of adequate technical, non-technical and continuous professional development for colleagues in the section and within HPAR
    - To ensure the provision of high quality induction and ongoing training for colleagues in the section
    - In co-ordinating the planning and delivery of training for colleagues in the section

- General
  - Represent the HPRA at both national and international meetings and/or conferences as required
  - Perform such other duties as the HPRA may reasonably required

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A degree in pharmacy, chemistry or other relevant scientific discipline
  - A minimum of 3 years relevant industrial, regulatory and/or research experience in the pharmaceutical industry, a regulatory authority or in a related field
  - A postgraduate qualification in a relevant scientific discipline or an additional three years relevant experience
  - A proven track record of working within multidisciplinary teams
  - Proven ability demonstrating excellent interpersonal, communication and presentation skills
  - Proven ability to meet deadlines
  - Direct experience working with stakeholders/customers
  - Demonstrated initiative and team working capabilities
  - A demonstrated ability to think critically and independently

- In addition, the following would be considered an advantage:
  - Industrial / regulatory background and the necessary breadth of experience to review the quality sections of a marketing authorisation application
  - Experience in dealing with EMA
  - Experience with herbal medicines

REMUNERATION

Salary: €62,720 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.

HOURS OF DUTY

The hours of duty are fixed by the HPRA from time to time. The current arrangements are Monday-Friday (minimum 37 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

DURATION OF POST

This is an eighteen-month contract post as a result of maternity leave.

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.

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 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 **22nd June 2020.**

INTERVIEWS

Applicants attending for interview may be required to complete a scenario-based practical - details will be notified to applicants who are shortlisted. Please note these interviews may be conducted via Skype and it is anticipated that these will take place in **July 2020.**

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

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.