HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Assessor, Clinical Assessment - Human Products Authorisation and Registration

ROLE SUMMARY

The Clinical Assessor will be responsible for the assessment of the clinical components of applications related to human medicinal products (medicines) and clinical trials submitted to the HPRA. The clinical components include assessing pharmacology (eg PK & biopharmaceutical studies), efficacy and safety studies. The assessment also includes reviewing the content of the product information and the overall benefit risk analysis of a medicine and clinical trial.

The Clinical Assessor will provide clinical assessment support to other sections in the Human Products Authorisation and Registration (HPAR) department and will interact across the HPRA as needed.
The Clinical assessor will report to an Executive Assessor or a Senior Assessor in the HPAR Department.

KEY RESPONSIBILITIES

TECHNICAL OBJECTIVES

- Assessment of pharmacology, efficacy and safety data submitted in support of applications for marketing authorisation, variations or renewals for medicines.
- Assessment of pharmacology, efficacy and safety data submitted in support of applications to conduct clinical trials.
- Analysis of risk-benefit profiles of applications for marketing authorisation and clinical trials, including the preparation and presentation of reports.
- Review of safety information originating from clinical trials.
- Provision of support in the assessment of pharmacokinetic and pharmacodynamic studies, and assessment of bioanalytical methods, if required.
- Involvement in European Medicines Agency (EMA) scientific advice/protocol assistance procedures, and national scientific advice procedures, if required
- Providing technical information, advice and guidance to applicants, regulatory authorities, organisations (including the Department of Health), to healthcare professionals and lay persons.
- Representing the HPRA on national and international bodies, especially European organisations, as nominated by manager.

STRATEGIC OBJECTIVES

- Working with the manager(s) in the Clinical Assessment section to prioritise work objectives and to ensure that the strategic and operational goals of the section are achieved.

- Supporting the manager(s) in the Clinical Assessment section in the running and on-going development of the section within the HPAR department.
- Working with portfolio leads across HPAR supporting the strategic and operational goals.

QUALITY AND KNOWLEDGE MANAGEMENT

- Assisting the manager(s) to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the Clinical Assessment section.
- Assisting the manager(s) to ensure that assessment procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidelines.

- Assist the managers of the section to ensure the effective implementation of the HPRA Quality

Management System within the section

PERFORMANCE MANAGEMENT

- Participating in the performance development programme (PDP) within the Clinical Assessment team to maximise efficiency gains for the HPAR department and reporting regularly on the progress against specified goals/deliverables outlined in PDP.
- Working with managers and colleagues of the section to promote effective performance within the Clinical Assessment teams.
- Participating in a knowledge sharing culture; promoting a learning, self reflection, feedback and coaching environment.
- Assisting and complying with the HPRA capacity planning system & capability workstream strategy.
- Taking measures to identify and resolve issues impacting performance in the section.

COMMUNICATION/CUSTOMER SERVICE

- Participation in regular team, departmental and HPRA meetings.
- Present on behalf of HPAR, as required.
- Attendance at meetings and symposia at home and abroad and representing the HPRA as appropriate.
- Execute professional duties in such a manner so as to contribute to the efficiency and effectiveness of the HPRA.
- Conducting technical liaison with applicants, regulatory authorities, healthcare professionals and other relevant stakeholders.
- Provision of technical information, advice, and guidance to regulatory authorities, healthcare professionals and other relevant stakeholders.
- Support the HPAR Policy & Stakeholder Management assessor as they develop an internal process to manage & respond to queries.

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A 3rd level degree in pharmacy or other relevant scientific discipline.
  - A postgraduate qualification in a relevant scientific discipline
  - A minimum of three years relevant experience in practice, academic research, regulation, or the pharmaceutical industry.
  - Relevant experience in the collation, evaluation, and presentation of clinical/scientific data
  - Ability to work to tight deadlines and manage own capacity of workload.
  - Ability to work within multi-disciplinary teams.
  - A demonstrated ability to problem solve.
  - Strong analytical skills.
  - Ability to peer review & provide / receive feedback.
  - Display flexibility in an agile work environment
  - Experience with effective knowledge sharing and presentation skills.

- In addition, the following would be considered an advantage:
  - Industrial / regulatory background with a breadth of experience to enable review the clinical sections of a marketing authorisation applications.
  - Experience in interacting with the European Medicines Agency
  - Experience in writing reports for external clients, organisations, or the general public

REMUNERATION

Salary: €70,287 - €81,508 per annum (incremental scale)
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.

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 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 the time of application.

CLOSING DATE

The closing date for applications for this post is **26th November 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 week commencing 4th December 2023. The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

HOW TO APPLY

Applications should be submitted via the HPRA 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.