HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Pre-clinical Assessor, Clinical Assessment – Human Products Authorisation and Registration

ROLE SUMMARY

The Pre-Clinical Assessor will provide a pre-clinical assessment and consultancy resource to the Human Products Authorisation and Registration (HPAR) department.

The Pre-Clinical Assessor will be responsible for the examination and evaluation of the pre-clinical (pharmacology and toxicology) components of applications submitted to the HPRA and furnishing recommendations in respect of likely hazards associated with the use of the relevant substances in humans and their potential risk to the environment. The Pre-clinical assessor will report to a Senior Medical Officer or a Clinical Assessment Manager.

The Pre-Clinical Assessor will provide clinical assessment and support to the clinical assessment section, as the HPRA may reasonably require.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Supporting the Senior Medical Officer and other managers in the Clinical Assessment section in the running and on-going development of the section within the HPAR department
  - Working with the Senior Medical Officer and other managers in the Clinical Assessment section to prioritise work objectives and to ensure that the strategic and operational goals of the section are achieved
  - Providing support and direction to colleagues and others within the Clinical Assessment section and the HPAR department

- Operational Objectives
  - Assisting the Senior Medical Officer and other managers in the section in meeting the goals and objectives of the section
  - Working with the Senior Medical Officer and other managers in the section to plan and organise work tasks that ensure efficient delivery of work
  - Promoting a positive, open, friendly and professional working environment
  - Maintaining appropriate records of meetings and activities

- Technical Objectives
  - Examination and evaluation of the pharmacological and toxicological components of dossiers submitted to the HPRA

- Assessment of the risks for humans associated with or derived from the use of medicines, herbal medicines, cosmetics and medical devices on the basis of extrapolation from the results of pharmacological and toxicological studies
- Assessment of the suitability of methodologies used, of validity and significance of results obtained
- Preparation/review of assessment reports describing the pharmacological and toxicological characteristics of medicinal products / relevant substances as required during participation in national and European authorisation procedures
- Identification and use of external expert advice as required
- Assessment of relevant data in published literature
- Involvement in European Medicines Agency (EMA) scientific advice/protocol assistance procedures, and national scientific advice procedures
- Provide support to the clinical and pharmaceutical assessment of submitted applications both pre and post authorisation
- Assessment of risk minimisation plans and provision of support to the pharmacovigilance unit in the development of pharmacovigilance and risk minimisation plans in so far as they refer to pre-clinical information on products for human use
- Assessment of environmental risk assessment reports as submitted for authorisation of medicinal product use
- Provide internal technical expertise to pharmaceutical assessment, medical device and compliance departments, as required
- Attendance at meetings on behalf of the HPRA at home or abroad

- Quality and Knowledge Management
  - Assisting the Manager(s) to ensure the effective implementation of the HPRA quality management system within the HPAR department
  - Assisting the Senior Medical Officer and other managers in the section 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 Senior Medical Officer and other managers in the section to ensure that available information and knowledge across the HPRA is effectively used by the Clinical Assessment section
  - Assisting the Senior Medical Officer and other managers in the section to ensure that Clinical Assessment procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidelines

- Performance Management
  - Working with the Senior Medical Officer and other managers in the section to promote effective performance within the HPAR department
  - Participating in the performance development programme (PDP) within the HPAR department
  - Assisting and complying with the HPRA quality management system within the HPAR department
  - Assisting and complying with the HPRA capacity planning system
  - Taking measures to identify and resolve issues impacting performance in section
  - Reporting regularly on progress against specified goals/targets and objectives

- Communication/Customer Service
    - Participation in regular departmental and team meetings and HPRA meetings
    - Present at the advisory committee for 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
    - Providing timely input to the HPRA's newsletter and HPRA web-site as necessary

- General
    - Perform other duties as the HPRA may reasonably require, such as the provision of clinical assessment and support to the clinical assessment team

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
    - A 3rd level degree in a relevant scientific or related discipline e.g. toxicology, pharmacology, physiology, biochemistry or chemistry
    - A Ph.D. qualification in a relevant scientific of related discipline
    - Knowledge of relevant European and National legislation
    - Relevant experience in the collation, evaluation and presentation of scientific data
    - Computer literacy

- In addition, the ideal candidate will also have:
    - Two years' relevant post-doctoral experience in research, healthcare, industry or regulatory environment
    - A proven ability to work within a multidisciplinary team
    - The ability to demonstrate excellent interpersonal, communication and presentation skills
    - A proven ability to manage a high workload and meet deadlines
    - Direct experience working with stakeholders/customers
    - Demonstrated initiative and problem solving skills
    - Evidence of effective decision making skills

REMUNERATION

Salary: €63,974 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.

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 role is for the duration of maternity leave.

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.

VOLUNTARY HEALTH INSURANCE SCHEME

A group scheme operates for those wishing to participate and contributions are deducted from salary.

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 **12 noon on 11th November 2020.**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation/complete a practical test -details will be notified to applicants who are shortlisted. Please note these interviews will be conducted via Skype and it is anticipated that the first round of interviews will take place during the week of **23rd November 2020,** with the second round of interviews taking place during the week of **30th November 2020.**

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.