HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer, Biostatistics – Human Products Authorisation & Registration

ROLE SUMMARY

The role of the Scientific Officer is to support the evaluation and regulation of the safety and efficacy of medicinal products (drugs), in Ireland and the European Union, through the provision of biostatistical and technical support to the assessment sections within Human Products Authorisation and Registration (HPAR) and assist in the review and finalisation of documentation relating to marketing authorisations in order to facilitate the efficient licensing of medicinal products.

Reporting to a Clinical Assessment manager, the Scientific Officer will work closely and maintain effective working relationships with a Biostatistician, other members of the clinical assessment section, and with members of the HPAR 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 Scientific Officer will maintain effective working relationships with colleagues in other sections and departments of the HPRA, and with all other stakeholders.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Working with the Biostatistician to support the pre-and post-authorisation review of the safety and efficacy of medicinal products, analysis of their risk/benefit profiles; reporting and forming conclusions in respect of their suitability for use as medicinal products as well as consideration of the public health consequences of their use.
  - Assisting in the review and finalisation of documentation relating to marketing authorisations, and in the context of renewal applications, variations and product information review
  - Technical liaison with HPRA colleagues, applicants, regulatory authorities and other relevant bodies, healthcare professionals and the community.
  - Review and technical input on other types of human healthcare products e.g. food supplements, if required.

- Operational Objectives
  - Working with the Biostatistician and Section Managers to meet the goals, objectives and targets of the HPAR Clinical Assessment section
  - Working closely and maintaining effective working relationships with other members of the section to achieve HPAR's objectives
  - Promoting a positive, open, friendly and professional working environment
  - Assisting in the compilation of data and preparation of reports as required

- Maintaining appropriate records of meetings and activities
- Attending and contributing to meetings of the section and HPAR department

- Technical Objectives
  - Support the analysis and critical appraisal of statistical aspects relating to the assessment of safety and efficacy data submitted in support of applications for marketing authorisation, variations or renewal of authorisations for human medicinal products.
  - Support the analysis and critical appraisal of statistical aspects relating to the assessment of safety and efficacy data submitted in support of applications to conduct clinical trials in respect of human medicinal products (containing new chemical entities or established active ingredients).
  - Review and technical input to assessment activities relating to other types of healthcare products e.g. medical devices, if required.
  - Liaison with, and advice to, applicants and professional colleagues in order to facilitate the assessment process.
  - Assisting in the provision of scientific advice on behalf of HPRA to stakeholders such as investigators, sponsors, and other public-sector organisations
  - Maintain and enhance personal and technical competence by keeping abreast of new statistical methodology, occasional analysis of data and other personal development activities
  - through ongoing professional education and review of the published literature.
  - Providing advice and professional expertise to the HPRA's assessors and inspectors in the performance of their duties.

- Quality Management
  - Complying with HPAR biostatistical and clinical assessment procedures, technical guidelines and quality documentation and supporting their maintenance to ensure that they remain up to date with relevant developments in national, European and international regulations, legislation and guidelines
  - Assisting Assessors and Managers within the section to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by section as required, working with others within the section to achieve this objective
  - Assisting Assessors and Managers within the section to ensure that available information and knowledge across the HPRA is effectively used by the section as required, working with others within the section to achieve this objective
  - Assisting other team members to ensure the effective implementations of the HPRA Quality Management system

- Performance Management
  - Participating in the performance development programme (PDP) within the section
  - Working with the managers and colleagues in the section to promote effective performance within the Section
  - Reporting regularly on progress against specified objectives and tasks, and ensuring that issues impacting on performance are identified early to their manager

- Communication/Customer Service
  - Representing the HPRA on national and international bodies, especially European Bodies if required
  - Participation at all levels (HPRA, national and international) in the formulation and preparation of regulatory policies, guidelines, legislation and opinions
  - Maintaining effective working relationships with colleagues in all sections and departments of the HPRA
  - Conducting technical liaison with applicants, regulatory authorities, healthcare professionals and other relevant stakeholders
  - Provision of technical information, regulatory advice, and guidance to regulatory authorities, healthcare professionals and other relevant stakeholders
  - Participating in regular section and department meetings

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A third level degree in Mathematics, Statistics or another relevant discipline
  - Relevant experience in the collation, evaluation and presentation of scientific data
  - Computer literacy
  - Proven ability to evaluate complex information from a variety of sources and make effective decisions.
  - The ability to demonstrate excellent interpersonal, communication and presentation skills
  - The ability to meet deadlines
  - Demonstrated initiative and team working capabilities
  - Excellent attention to detail

- In addition, the following would be considered an advantage:
  - A postgraduate qualification in Biostatistics or Statistics (M.Sc./PhD)
  - The ability to develop a sound understanding of a wide range of statistical and clinical trial methodology, including state-of-the-art techniques, relevant to the regulation of medicinal products
  - Experience and knowledge with statistical software packages
  - The ability to clearly communicate statistical issues and methods to both statisticians and non- statisticians
  - Knowledge of regulatory (e.g. ICH, EMA and FDA) guidelines

REMUNERATION

Salary: €34,077 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 a two-year contract post.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 22 days per annum.

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.

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.

CLOSING DATE

The closing date for applications for this post is **3rd November 2019.**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation-details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place **on 15th November 2019.**

Note: 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 Recruitment Portal.

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.