HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Biostatistician, Clinical Assessment – Human Products Authorisation and Registration

ROLE SUMMARY

The position of Biostatistician will be based in the Human Products Authorisation and Registration (HPAR) department and will report to the Clinical Assessment Manager.

The Biostatistician will use their statistical expertise to review Marketing Authorisation Applications and advise on good drug development, interacting with medical colleagues and multi-disciplinary advisory committees and company representatives as required.

The Biostatistician will work closely and maintain effective working relationships with 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 Biostatistician will maintain effective working relationships with colleagues in other sections and departments of the HPRA, to ensure that issues requiring cross-functional input are conducted effectively and followed up on.

KEY RESPONSIBILITIES

- Strategic Objectives
  - Supporting the Clinical Assessment Manager and other managers in the Clinical Assessment section in the on-going development of the section within the Human Products Authorisation and Registration (HPAR) department
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section in the preparation of work objectives for the section
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section to prioritise work objectives and to ensure that the operational goals of the section are achieved
  - Providing support and input to colleagues and others within the Clinical Assessment section and the HPAR department

- Operational Objectives
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section to plan and organise work tasks that ensure efficient delivery of work
  - 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
  - Attend meetings with other Irish Agencies, as required
  - Attend meetings at the European Pharmacopoeia, as required
  - Maintaining appropriate records of meetings and activities

- Attending and contributing to meetings of the Clinical Assessment section and HPAR department
- Providing support to other colleagues within the HPAR department, where required

- Technical Objectives
  - The analysis and critical appraisal of statistical aspects of pre marketing application including dossiers for medicines, scientific advice applications and clinical trial applications, and the preparation of assessment reports. The assessment includes but is not limited to statistical methods, statistical design, statistical analyses plans, sample size, sensitivity analyses and imputation methods for missing data
  - Liaise with assessment teams in the assessment of the above mentioned applications
  - Provision of advice to HPRA and to National or EU scientific committees and to contribute to the peer review of EMA scientific evaluation documents.
  - Informing and influencing National and European advisory and decision-making committees, including the Commission on Human Medicines (CHM) and the Committee for Medicinal Products for Human Use (CHMP)
  - Provide statistical advice on behalf of HPRA to stakeholders such as investigators, sponsors, and others to ensure that any planned study/project results and conclusions are presented accurately and without bias
  - Represent HPRA at relevant National and EU meetings, when required
  - Maintain and enhance personal and technical competence by keeping abreast of new statistical methodology, occasional analysis of data and other personal development activities
  - Contribute to and assist in the delivery of teaching technical staff on clinical statistics
  - Providing data analysis to support policy direction, and other functions as may be determined depending on the needs of the HPRA
  - Assisting the Clinical Assessment Manager and other managers in the Clinical Assessment section in ensuring the accuracy of relevant data inputted in the computer databases and information systems of the HPRA

- Quality and Knowledge Management
  - Assist the managers of the Clinical Assessment section to ensure the effective implementation of the HPRA Quality Management System within the section
  - Assist the managers of the Clinical Assessment section to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the section
  - Assist the managers of the Clinical Assessment section to ensure that available information and knowledge across the HPRA is effectively used by the section
  - Assist the managers of the Clinical Assessment section to ensure 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 (PDP) within the Clinical Assessment section to maximise efficiency gains for the Human Products Authorisation and Registration (HPAR) department
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section to promote effective performance within the section
  - Taking measures to identify and resolve issues impacting performance in the Clinical 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 Clinical 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 Clinical Assessment Manager and other managers in the Clinical Assessment section to ensure the provision of adequate technical, non-technical and continuous professional development for colleagues in the section and within the HPAR Department
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section to ensure the provision of high quality induction and ongoing training for colleagues in the section
  - Working with the Clinical Assessment Manager and other managers in the Clinical Assessment section in co-ordinating the planning and delivery of training for colleagues in the section
  - Promoting a positive, open, friendly and professional working environment

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates should meet the following criteria:
  - Have a Masters or PhD in Biostatistics or Statistics with significant experience in clinical trials methodology.
  - Knowledge and experience of drug development (clinical and post-approval) and understanding drug development as a continuum.
  - Experienced with ICH GCP, regulatory (e.g. EMA and FDA) guidelines
  - Sound understanding of a wide range of statistical and clinical trial methodology, including the most up-to-date techniques available that are relevant to the regulation of medicines, as employed across the breadth of the drug development process.
  - Significant work experience in the design, analysis and interpretation of randomised, controlled clinical trials across all stages of clinical development and in a wide range of therapeutic areas.
  - The ability to evaluate complex information from a variety of sources and make effective decisions.

- Effective problem solving skills, proven critical appraisal skills, including the ability to anticipate problems and recognise when to involve other parties (at the appropriate time and level).
- Experience and knowledge with statistical software packages.
- Demonstrate strong organisational skills, including the ability to prioritise workload.
- Ability to work under pressure to tight timelines.
- Good strategic ability (including problem solving, critical thinking skills and thinking cross-functional).
- Excellent oral and written communication skills. Ability to work as part of a cross-functional team and clearly communicate statistical issues and methods to both statisticians and non-statisticians.
- Excellent attention to detail.

- In addition, the following would be considered an advantage;
  - Experience in medical informatics.
  - Work experience in applying statistical methods in biomedical research, pharmaceutical or CRO industry or drug regulatory agency.
  - Experience in methodological issues associated with observational research.

REMUNERATION

Salary: €61,641 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 a two-year contract post.

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 Policy 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 policy.

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.

CLOSING DATE

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

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.

It is anticipated that interviews for this post will take place **mid to late March 2019.**

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.