HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

GCP/Pharmacovigilance Inspector, Inspection – Compliance

ROLE SUMMARY

Reporting to the GCP/Pharmacovigilance Inspection Manager, the role of an Inspector is to evaluate the compliance of sites inspected, both in Ireland and internationally, with the requirements of National legislation (in Ireland), European community directives, regulations and guidance. These sites may include:

- Sites where clinical trials are conducted (e.g. hospitals, clinics, healthcare centres, clinical research facilities)
- Sites responsible for management, administration or data collection activities for clinical trials (e.g. sponsor organisations, clinical research organisations)
- Clinical trial testing laboratories, including bioanalytical facilities
- Sites where pharmacovigilance data is collected, evaluated or processed by, or on behalf of, marketing authorisation holders
- Marketing authorisation holders or affiliate offices

The Inspector provides technical information and advice to relevant individuals both internal and external to the HPRA and provides support to the enforcement and execution of National regulations in relation to human and veterinary medicinal products. The role involves inspecting, reporting and forming conclusions in respect of the suitability of a site for the activities which it has responsibility for. The standards that apply include;

- Good Clinical Practice (GCP)
- Good Vigilance Practice (GVP)

KEY RESPONSIBILITIES

- Operational
  - Preparing for, organising and carrying out inspections in accordance with HPRA and Union procedures
  - Evaluating complex information, identifying relevant standards and assessing compliance
  - Compiling inspection reports when acting as lead inspector, contributing to preparation of reports for joint or accompanied inspections
  - Assisting in the compilation of data and preparation of management reports as required
  - Applying risk management principles
  - Submitting reports as required and maintaining appropriate records of meetings and activities
  - Ensuring a database of inspection details is maintained
  - Assisting in the introduction of new legislation, and development of policy and practice guidelines and procedures
  - Providing support to other areas of the HPRA, where appropriate

- Quality and Knowledge Management
    - Assisting in the effective implementation of the HPRA's Quality Management System within the Compliance department
    - Assisting the managers in the Inspections section to ensure that there are effective mechanisms in place to capture, store and communicate information, experience and knowledge gained
    - Assisting the managers in the Inspections section to ensure that available information and knowledge across the HPRA is effectively used by the Inspection section
    - Assisting the managers in the Inspections section to ensure that inspection procedures remain up to date with relevant developments in National, European and international regulations, legislation and guides

- Performance Management
    - Participating in the performance development programme (PDP) within the Inspections section to maximise efficiency gains for the Compliance department
    - Working with the Inspection Manager to agree appropriate performance related targets
    - Taking measures to identify and resolve issues impacting performance
    - Reporting regularly on progress against specified objectives, goals and performance targets
    - Effectively communicating objectives, goals and performance targets within the team
    - Promoting a positive, open, friendly and professional working environment

- Communication/Customer Focus
    - Attending and contributing to meetings of the Compliance department as required
    - Liaising with relevant departments of the HPRA to facilitate the identification, performance, evaluation and follow-up of inspection and compliance activities
    - Contributing by participating, as required, at national and international seminars in the areas of GCP and pharmacovigilance inspections
    - Representing the HPRA, as required, at national, European and international regulatory meetings and seminars
    - Responding to queries (technical and procedural) from internal and external customers

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

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
    - 3rd level degree in a relevant scientific or related discipline.
    - A minimum of three years' relevant work experience in a clinical trial (preferred) or a pharmacovigilance environment. Whilst clinical trial experience is preferred, those with relevant experience in pharmacovigilance and transferrable skills relevant to GCP, and an ability to learn the principles and concepts of GCP are also encouraged to apply.
    - Knowledge of relevant European and national legislation and guidance concerning GCP and pharmacovigilance.
    - A proven ability to assess complex information and make effective decisions, in particular in a time dependent setting.
    - A valid full driving licence and vehicle.

- Evidence of excellent communication and report writing skills.
- Good computer skills.
- Proven ability to work as part of a multi-disciplinary team.
- Availability to travel regularly for national and international inspections is a requirement in this role.

- In addition to this the ideal candidate will have:
  - Expert knowledge of clinical study operations, preferably having had responsibility for study/site management, data management or regulatory affairs.
  - Experience in performing regulatory inspections or industry audits.
  - Experience in bioanalytical methods.
  - Ability to be flexible, to prioritise and manage work load and to show initiative when required.
  - A proven ability to react effectively to emerging work-related issues.
  - A proven ability to communicate effectively.
  - A proven ability to work unsupervised.

REMUNERATION

Salary: €62,720 per annum (*new entrants - incremental scale).

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.

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.

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.

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.

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.

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 9pm, **Sunday 21st June 2020.**

INTERVIEWS

Applicants attending for interview may be required to complete a pre-interview practical exercise -details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place on **Thursday, 2nd 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.