HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

GMP Inspector, Inspection – Compliance

ROLE SUMMARY

Reporting to a Senior Inspector, the Inspector will be primarily responsible for assessing the compliance of manufacturers with EU Good Manufacturing Practice (GMP). The role of an Inspector is to evaluate the compliance of sites inspected, in Ireland and abroad, with the requirements of National legislation (in Ireland), European Community Directives, Regulations and Guidance. These sites may include;

- Manufacturers and distributors of medicinal products.
- Manufacturers of investigational medicinal products.
- Sites involved in the importation and / or storage of medicinal products.
- Manufacturers of active pharmaceutical ingredients and certain excipients.
- Quality control laboratories.
- Office based sites involved in batch certification activities only.

The role involves inspecting, reporting and forming conclusions in respect of the suitability of a site for the activities which it has sought or for which it is already authorised. The Inspector provides technical information and advice to relevant individuals and organisations both internal and external to the HPRA. The Inspector will provide support to the enforcement and execution of national regulations in relation to medicinal products.

The content below represents a broad guideline for the role of Inspector. Some aspects may be subject to change in accordance with business needs.

KEY RESPONSIBILITIES

- Operational Objectives
  - Preparing for and performing inspections in accordance with HPRA procedures
  - Writing and compiling inspection reports when acting as lead inspector and contributing to preparation of all other inspections reports
  - Reviewing inspection reports where required
  - Assisting in the compilation of data and preparation of management reports as required
  - Submitting reports as required and appropriate records of meetings and activities
  - Maintaining a database of inspections performed
  - Review and approval of new applications for manufacturer's authorisations / registrations and variations to existing authorisations / registrations
  - Providing guidance to external and internal stakeholders related to Good Manufacturing Practice and implementation of associated legislation.

- Assisting in the development and implementation of policy and practice guidelines
- Providing support to other areas of the HPRA where appropriate

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

- Performance Management
  - Participating in the performance development programme (PDP) within the Inspection section to maximise efficiency gains
  - Working with the line 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 evaluation and follow-up of inspection and compliance activities
  - Participating, as required, at national and international seminars in the areas of GMP
  - Representing the HPRA, as required, at national, European and international regulatory meetings and seminars on relevant topics
  - Responding to queries (technical and procedural) from internal and external customers

- General
  - Perform 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 a relevant scientific discipline
  - A minimum of 3 years relevant work experience, in at least one of the following:
    - Experience in a facility that manufactures biological active substances or finished medicinal products in any of the following functions: quality assurance, compliance, production, technical services or validation
    - Experience in a Regulatory Authority evaluating manufacturing processes generally

- Experience working to European and National legislation and EU GMP guidelines
- A valid driver's licence and vehicle
- The ability to work as part of a multi-disciplinary team
- Evidence of excellent communication, report writing and decision-making skills
- A proven ability to prioritise and deliver to timelines

- In addition to this the ideal candidate will have;
  - Experience in biological / sterile product manufacture and / or microbiology
  - A post-graduate qualification in a relevant scientific or related discipline
  - Experience as a Qualified Person
  - Experience at a management/supervisory level
  - A proven ability to work unsupervised

- Availability to travel for national and international inspections is a requirement in this role.

REMUNERATION

Salary: €69,248 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.

LOCATION

This role is being offered as part of our hybrid working model. The successful candidate can avail of working remotely for two days per week, and working three days per week in the HPRA offices, based in Kevin O'Malley house, Earlsfort Terrace, Dublin 2. The specific days each week when you work at each location will be determined by your manager. The introduction of the hybrid model will be subject to review at the end of 2022.
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 in line with the Hours of work and attendance policy after a period of six months.

The HPRA are operating a hybrid model where work is carried out partly from the office (a minimum of 2 days per week) and partly using a remote working arrangement. This model permits an employee to carry out some of their duties at the HPRA offices and some from a remote location. The HPRA are currently in a test and learn phase of this hybrid working model, which is subject to review.

DURATION OF POST

For the duration of maternity leave (12-18 months).

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 **11th June 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 in June. 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.

May 2023

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.