HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
BTO Inspector, Inspections – Compliance

ROLE SUMMARY

Reporting to the Blood, Tissues & Organs (BTO) Manager, the Inspector will be primarily responsible for assessing the compliance of blood establishments, tissue establishments, organ procurement centres and organ transplant centres, with the requirements of European and National legislation and associated good practice guidelines.

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

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 Directives, Regulations and relevant guidance. These sites may include:

- Blood Establishments
- Tissue Establishments
- Organ Procurement Centres
- Organ Transplantation Centres
- Manufacturers of advanced therapy medicinal products
- Other sites regulated by the Health Products Regulatory Authority (HPRA)

The role involves inspecting, reporting and forming conclusions in respect of the suitability of a site for the activities which it has sought authorisation or is already authorised for. The standards that apply include:

- Good Practice guidance for tissues and cells, including relevant European Commission and Council of Europe guidance.
- Good Practice guidance for blood and blood components, including relevant European Commission and Council of Europe guidance.
- National and European guidelines in relation to organ procurement and transplantation.
- Good Manufacturing Practice (GMP); Good Distribution Practice (GDP); Good Laboratory Practice.

The Inspector will provide technical information and advice to relevant individuals and organisations both internal and external to the HPRA.

The Inspector will provide support to the development and execution of national regulations in relation to, blood, tissues and cells and organs.

The Inspector will participate in the review and assessment of annual reports received from stakeholders.

The inspector will interact and provide relevant input into the continued development of systems relevant to the Inspections section.

KEY RESPONSIBILITIES

- Operational Objectives
  - Preparing for, organising and carrying out inspections in accordance with HPRA procedures
  - Write inspection reports when acting as lead inspector and contributing to preparation of reports for joint or accompanied inspections
  - Assisting in the compilation of data and preparation of technical and management reports as required
  - Applying risk management principles
  - Submitting reports as required and maintain appropriate records of meetings and activities
  - Updating databases in place for the management of workflow in the HPRA
  - Assisting in the development and implementation of policy and good practice guidelines
  - Providing support to other areas of the HPRA where appropriate

- Communication/Customer Focus
  - Attending and contributing to meetings of the Compliance Department
  - Attending and contributing to meetings with stakeholders
  - Liaising with relevant departments of the HPRA to facilitate the identification, performance, evaluation and follow-up of inspections and compliance activities
  - Contributing by participating, as required, at national and international seminars in the areas of blood, tissues and cells, organs and advanced therapy medicinal products, European and international regulatory meetings and seminars on matters pertaining to inspections
  - Responding to queries (technical and procedural) from internal and external customers

- Quality and Knowledge Management
  - Assisting in the effective implementation of the HPRA Quality Management System within the Compliance department
  - Assisting the managers in the Inspection section 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 the managers in the Inspection section to ensure that available information and knowledge across the HPRA is effectively used by the Inspection section
  - Assisting the managers in the Inspection 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 Inspection Section to maximise efficiency gains for the Compliance department
  - 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
  - Promoting a positive, open, friendly and professional working environment

- General
  - Perform 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' experience working in any of the following areas:
    - The donation, collection, testing, processing and distribution of blood and blood components
    - The donation, procurement, testing, processing and distribution of tissues and cells for human application
    - The procurement and transplantation of organs
    - Performing inspections of blood establishments, tissue establishments, or organ procurement or transplant centres.
    - Performing audits of hospital blood banks.
  - Knowledge of relevant European and National legislation
  - Relevant technical knowledge and quality system experience
  - A full valid driving licence and vehicle
  - Excellent communication and report writing skills
  - Proven ability to gather information and apply analytical skills to reach decisions on technical issues
  - A proven track record of working within a multi-disciplinary team
  - A proven ability to work unsupervised

- In addition to this the ideal candidate will have;
  - A postgraduate qualification in a relevant scientific or related discipline
  - Experience working in the following areas:
    The manufacture and / or quality assurance of biotech medicines, sterile medicinal products, medical devices and/or cell based medicinal products; a relevant hospital laboratory setting; adverse event and reaction reporting mechanisms; testing biological products; auditing; batch acceptance and approval of critical suppliers
  - A thorough knowledge of validation requirements (including facility and equipment qualification and process, computer and assay validation)
  - Ability to be flexible, manage workload and to show initiative when required
  - Experience in the use of Quality Risk Management principles and tools

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

REMUNERATION

Salary: €62,720 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 three year fixed term 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 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. 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.

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 **Wednesday 2nd October 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 **Friday 18th October 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.