

## Role Profile

# Health Products Distribution Inspector – Inspection, Compliance

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### ROLE SUMMARY

Reporting to the Health Products Distribution Inspections Manager, the Health Products Distribution (HPD) Inspector will be primarily responsible for assessing the compliance of a wide range of national operators involved in certain activities of the pharmaceutical, cosmetic, chemical and medical device industries.

The role of the HPD Inspector is to evaluate the compliance of sites inspected, with the requirements of national legislation, European Community Directives, Regulations and Guidance. These sites may include:

- Distributors of human medicinal products & medical devices
- Brokers of human medicinal products
- Importers and distributors of active substances for use in the manufacture of human medicines
- Manufacturers & distributors of cosmetic products
- Manufacturers, distributors and other entities utilising controlled drugs and precursor chemicals
- Other inspection activities as may be required.

The role involves conducting inspections, forming conclusions and reporting in respect of the suitability of a site for the activities which it has sought, or is already, authorised / registered for. Where no system of authorisation or registration is in place, inspection involves the assessment of compliance against the relevant European and national legislation and guidance.

The role requires excellent communication skills, a high degree of flexibility and the ability to respond to changing priorities. The successful candidate will work closely with the other members of the HPD team and liaise effectively with the Licensing, GMP inspection and Enforcement teams and any other sections of the HPRA that require support.

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

## KEY RESPONSIBILITIES

- Operational Objectives
  - Preparing for, organising and carrying out inspections in accordance with HPRA procedures
  - Writing of inspection reports when acting as lead auditor and contributing to preparation of reports for joint or accompanied inspections
  - Applying risk management principles in all areas of inspection activity
  - Assisting in the compilation of data and preparation of management reports as required
  - Submitting reports as required and maintenance of appropriate records of meetings and activities
  - Assisting in the development and implementation of policy and practice guidelines
  
- Quality and Knowledge Management
  - Assisting the HPD Inspections Manager and the HPD Manager to ensure the effective implementation of the HPRA Quality Management System within the Compliance Department
  - Assisting the managers in the HPD section to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the HPD section
  - Assisting the managers in the HPD section to ensure that available information and knowledge across the HPRA is effectively used by the HPD section
  - Assisting the manager in the HPD section to ensure that HPD procedures remain up to date with relevant developments in National, European and International regulations, legislation and guides
  
- Performance Management
  - Working with the line manager to agree and reach 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
  - Participation within the HPRA's Performance Development Programme (PDP)
  
- Communication/Customer Focus
  - Attending and contributing to meetings of the HPD section 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 at national and international seminars as required
  - Representing the HPRA, as required, at national, European and international regulatory meetings and seminars on matters pertaining to compliance inspections
  - Responding to queries (technical and procedural) from internal and external customers
  
- General
  - Perform such other duties as the HPRA may reasonably require

## **QUALIFICATIONS AND EXPERIENCE**

- To be considered for this post, candidates must have:
  - A relevant primary honours science degree
  - A minimum of three years relevant experience in the pharmaceutical or related environment
  - A full valid driving licence and car
  - Evidence of excellent decision making skills
  - Evidence of excellent communication and report writing skills
  
- In addition to this the ideal candidate will have;
  - Experience in performing regulatory or industry audits or inspections
  - A post-graduate qualification in a relevant pharmaceuticals-related discipline
  - A proven track record of working in an environment requiring a high degree of flexibility
  - Experience in the use of Quality Risk Management principles and tools
  - A proven ability to work as part of a team
  - A proven ability to react effectively to emerging work-related issues
  - A proven ability to work unsupervised

## **REMUNERATION**

Salary: €63,974 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.

## **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**

Applications for this role will be reviewed on a rolling basis until the role has been filled.

## 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 **April/May 2021**. 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.

## 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.