HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Quality Defects and Recall Inspector, Market Compliance - Compliance

ROLE SUMMARY

Reporting to the Quality Defects and Recall (QDR) Manager, the QDR Inspector works within the QDR Programme of the Market Compliance section. The role involves performing risk-based technical evaluations and assessments of suspected and confirmed Quality Defect reports on medicines and active substances, and performing for-cause GMP and other inspections, as required, in relation to serious QDR issues. The Inspector reviews and/or recommends actions that are designed to remediate and correct the non-compliance issue at hand, to ensure patient and animal safety.

The QDR Inspector works closely with the other members of the QDR team, and provides technical support to the Scientific Officers in the QDR area, as well as to other members of the Market Compliance section and the Compliance department as a whole.

The QDR Inspector maintains effective working relationships with colleagues in other sections and departments of the HPRA and with external stakeholder groups, to ensure that QDR issues requiring cross-functional and external input are effectively investigated and followed up.

KEY RESPONSIBILITIES

- Strategic Objective
Protection of public and animal health through the work of the Quality Defects and Recall (QDR) programme.

- Operational Objectives
    - Support the development and implementation of the QDR programme.
    - Development and implementation of the QDR elements of the HPRA Quality Management System (QMS), including the development and upkeep of controlled documents.
    - Provide support and input to other departments, sections and groups at the HPRA, in particular the Inspections section, the Sampling and Analysis programme, and the Advertising Compliance programme.
    - Provide training and support to scientific officers and new entrants to the QDR team.
    - Assist the Market Compliance Manager and QDR Manager in the development, implementation and improvement of all aspects of the QDR programme.

- Technical Objectives
    - Perform screening and risk assessments on incoming reports of suspected quality defects in medicines and active substances, identifying high-risk cases for prioritisation.

- Perform technical investigations of suspected quality defects, including approval of risk classifications and proposed market actions in line with relevant policies, procedures and guidelines, including Quality Risk Management principles.
- Coordinate recall actions, where required, including drafting, reviewing and approving recall letters, and reviewing recall reports.
- Coordinate the issuance of Rapid Alert notifications to other competent authorities, where required, including drafting, reviewing, approving and signing.
- Approve opinions on QDR issues for communication to the EMA.
- Approve or request for-cause GMP and GDP inspections, in relation to serious QDR issues, where required.
- Lead for-cause GMP and GDP inspections, where required.
- Generate, maintain and review records of meetings, QDR investigations and actions, including case files and QDR registers.
- Attendance at HPRA Advisory Committee meetings, when required.
- Membership of Rapid Alert Network, EMA or HPRA working groups, when required.

- Quality and Knowledge Management
  - Together with the QDR Manager, ensure the QDR programme remains up to date with current EU and national legislation, international standards and guidelines.
  - Support the Market Compliance Manager and QDR Manager in the generation of annual, monthly and other QDR reports, as required.
  - Compilation of data to identify trends and key learnings from the QDR programme.
  - Work to ensure that available information and knowledge across the HPRA is effectively used by the QDR programme.
  - Development and implementation of the Quality Management System (QMS), including the development and upkeep of controlled documents within the section

- Performance Management
  - Work to promote effective and efficient performance within the QDR programme.
  - Participate in the HPRA Personal Development Programme (PDP).
  - Support the QDR Manager to identify and resolve issues impacting performance of the QDR team.
  - Taking measures to identify and resolve issues impacting performance
  - Report on progress against specified targets/goals and objectives, when requested.

- Communication/Customer Service
  - Assist the QDR Manager with the development of a communication strategy for the QDR programme.
  - Responding to queries (technical and procedural) from internal and external customers
  - Together with the QDR Manager, develop and implement communication and/or education strategies for stakeholders in relation to QDR issues.
  - Together with the QDR Manager, liaise with other competent authorities, state bodies and industry on QDR issues.
  - Represent the HPRA at stakeholder and other meetings, seminars etc., when requested

- Team Development
  - Promote a positive, open, friendly, respectful and professional working environment.
  - Provide ongoing support, coaching and mentorship to scientific officers and new entrants to the QDR team.

- Assist the QDR Manager in identifying any skills gap/training needs within the team.
- Assist the QDR Manager in the development and implementation of QDR induction and technical training programmes for new entrants.
- Provide class-room based and on-the-job training on inspections to new entrants.
- Participate in technical, Quality System, and/or other skills training as well as continuous professional development, where available.
- Participate in induction and on-the-job training, as required.

- General
  - Deputise for the QDR Manager, when required
  - Attend Market Compliance and QDR team meetings, as needed.
  - Perform any other relevant duties as the HPRA may reasonably require.

QUALIFICATIONS AND EXPERIENCE

To be considered for this post, candidates must have:

- A 3rd level (honours) degree in a relevant scientific or related discipline
- A minimum of three years of relevant experience in one or more of the following:
  - A facility that manufactures medicinal products
  - A Regulatory Authority - working as an investigator of quality defects in medicinal products or as a GMP Inspector or in pharmaceutical assessment, or in another relevant area
  - A Retail or Hospital Pharmacy – working as a dispensing pharmacist

Note: it is acceptable if a candidate's three years of relevant experience is spread across one or more of the areas listed above.

- An excellent working knowledge of the EU GMP requirements, particularly those elements relating to the Pharmaceutical Quality System, Quality Defect/Complaint investigations, Root Cause Analysis and CAPA (Corrective Actions and Preventative Actions).
- A good working knowledge of Quality Risk Management
- A proven ability to work unsupervised and in a leadership role.
- A proven ability to work with others in a collaborative and solutions-focused manner.
- A proven ability to work effectively as part of a multi-disciplinary team
- A proven ability to gather technical and other information and to apply analytical skills to reach risk based decisions on technical issues.
- A proven ability to deal with large volumes of cases and workload and to prioritise based on quality risk management principles.
- A high level of motivation and the ability to comply with and manage deadlines.
- A high level of demonstrated initiative.
- Excellent computer skills, in particular MS Office applications
- Excellent communication skills with the proven ability to deliver appropriate information to the right people using a range of written, verbal and presentation skills

In addition, the following would be considered an advantage:

- A post-graduate qualification in a relevant scientific or related discipline.
- Direct experience in the investigation of quality defects in medicinal products will be a distinct advantage.
- Relevant experience in the collation, evaluation and presentation of scientific data

- Experience in the development or implementation of quality management systems
- Exposure to, or experience of, GMP and/or GDP Inspections

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

REMUNERATION

Salary: €64,614 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 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.

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 time of application.

CLOSING DATE

The closing date for applications for this post is **14th November 2021.**

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation or 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 **late November 2021** on a date to be confirmed. 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.

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.