HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Director of Compliance

ROLE SUMMARY

The role of the Director of Compliance is to provide strategic and operational leadership to the Compliance department.

The Compliance (COM) department is responsible for:

- Inspection and authorisation of manufacturers (Human (H) and Veterinary (V)) and wholesalers (H) of medicinal products.
- Inspections of Good Clinical Practice and Pharmacovigilance systems.
- Issuing of GMP Certificates and GDP Certificates to manufacturers of medicinal products.
- Inspection and issuing of GMP Certificates to manufacturers of active substances.
- Issuing of Export Certificates for medicinal products and cosmetics.
- Inspection and authorisation of blood establishments, tissues and cells establishments and establishments for organ procurement and transplantation.
- Sampling and analysis of medicinal products.
- Investigation of quality defects in medicinal products and oversight of recalls.
- Monitoring of advertising of medicinal products (H).
- Inspection of marketing authorisation holders.
- Controlled drugs and drug precursor licensing and inspection (in conjunction with Department of Health).
- Notification system for exempt (unauthorised) medicinal products.
- Monitoring of the technical and scientific requirements for cosmetics including market surveillance and safety evaluation.
- Enforcement of legislation governing medicinal products for human use and medical devices, blood, tissues & cells, organs and scientific animal protection.
- International representative function on relevant working groups at European Medicines Agency (EMA), European Commission, Pharmaceutical Inspection Co-operation Scheme (PIC/S), Heads of Medicines Agencies (Working Group of Enforcement Officers), World Health Organisation (WHO) Member State Mechanism on Substandard and Falsified Medical Products, Permanent Forum on International Pharmaceutical Crime (PFIPC) and Official Medicines Control Laboratories (OMCL) Network.

The Director leads the department, working closely with the Management team, to ensure that inspection, licensing, market compliance and enforcement activities are carried out to agreed quality, safety and legal standards.

The Director is a member of the Management Committee of the organisation and along with the Chief Executive, senior colleagues and the Authority is responsible for setting and achieving the strategic goals of the HPRA.

Reporting to the Chief Executive, the role of the Director of Compliance is to:

- Ensure that the resources and processes of the department operate in an integrated and effective manner to achieve the goals, objectives and targets defined in the strategic and service plans.
- Assist the Chief Executive and Management Committee in delivering the overall organisational strategic goals.
- Assist the Chief Executive and Management Committee in the identification and implementation of reform measures for the organisation's approach to the oversight of its regulatory activities for health products including appropriate risk management.

The Director will play a full and leading part in managing and further expanding the Authority's national, European and international influence with respect to the activities within the Compliance department's remit.

The Director will also:

Lead the department, including the oversight of complex inspections, and investigations, working closely with the department's management team to:

- Ensure that appropriate objectives, analytics and targets are used to drive performance and that these are incorporated into the management plans of the individual teams within the department.
- Ensure that the department has the required technical, managerial, investigative and operational skills; and that the department's processes and practices are supported by appropriate standards, policies and guidelines.
- Lead quality improvement in terms of reviewing processes and making these more efficient, smarter, and informed by experience.
- Lead the department's participation in the identification and implementation of change initiatives required to enhance the organisation's approach to risk management and inspections, authorisations and investigations.
- Provide leadership, motivation, encouragement and effective management for all staff to maintain a positive working environment.
- Maintain effective working relationships between the department and other areas of the HPRA, ensuring that any required interactions are adequately defined, effectively managed and reviewed as appropriate.
- The Director, working with other senior colleagues as required, will be responsible for representing the Authority and the State on relevant regulatory activities within the department's remit.
- Lead the HPRA's representation to the relevant industry sectors that fall under the Department's remit at both national and European level.
- At national level, engage and build effective relationships with the Department of Health, Department of Agriculture, Food and the Marine, Health Service Executive, other State agencies and all relevant bodies and other key stakeholders including healthcare professionals and patients.
- Build effective working relationships with other regulatory and enforcement agencies at European and international level as relevant to the Department's remit.
- Represent the HPRA at European and international level as required.

KEY RESPONSIBILITIES

- Strategic Management
    - Contribute to the Management Committee in the development of organisational strategy and identifying and agreeing strategic objectives.
    - Develop, implement, and operate appropriate strategies, solutions, policies and procedures that enable the HPRA deliver in line with the requirements of the organisation's mission, vision, strategic plan, culture and emerging business needs.
    - Respond to changes in the internal and external environment and develop strategic objectives to ensure delivery of the Authority's public health protection remit, and its contributions at both national, European and international levels in line with scientific progression of the regulated sectors.
    - Ensure that the resource and skills profile of the department is aligned to strategic objectives and development plans.
    - Facilitate the development of appropriate structures and teams for the department.
    - Develop short, medium and long range plans for the department to achieve strategic objectives and to contribute to the overall HPRA strategic goal of the protection of public and animal health in Ireland and in those markets where products exported from Ireland are used.
    - Lead and co-ordinate the process of translating high-level objectives into specific plans for the department that are appropriately comprehensive, realistic, and effective in meeting organisational goals.
    - Develop the department to best serve the agreed objectives.
    - Develop and manage the annual budget for the department to include responsibility for the effective management and utilisation of resources.
    - Foster the development and communication of a common vision for the department internally and across the organisation.
    - Lead the departmental management team in the strategic planning cycle in association with the Chief Executive, developing strategic objectives, priorities, plans and targets to drive management planning at all levels.
    - Develop the knowledge network concept to ensure access to specialist skill sets as required.
    - Lead the Department through change and development initiatives and providing a supportive environment to enable a motivated, impactful and adaptable team.
    - Provide leadership, support and direction to the department.

- Technical Management

  Working closely with the Management team, the Director is responsible for:
    - Overseeing the various inspection and authorisation processes of the Compliance department, including; GMP, GDP, Blood, Tissues and Cells, Organs for transplantation, GCP, Controlled Drugs and Pharmacovigilance inspection.
    - Managing changes in activities and ways of working within the department as they may arise following the ongoing development of the organisation.
    - Ensuring the optimum use of HPRA resources.
    - Ensuring that appropriate technical, administrative and investigative standards, policies, practices and guidelines are in place to support the activities of the department.

- Coordinating the provision of relevant advice to the Chief Executive, Management Committee, Authority, Departments of State, State agencies, Professional Bodies and other Bodies, as appropriate.
- Ensuring that the Compliance department is adequately represented at relevant European committees, working groups and at international level, and that responsibility for these roles is clearly defined.
- Ensuring appropriate involvement of the department in the development of proposals for new or amended legislation.
- Providing input to review and approval processes, where appropriate.
- Providing technical support to the department as required.

- Membership of HPRA Executive
  - Work with the Chief Executive and other members of the Management Committee to agree the organisation's strategic objectives and work to ensure their delivery.
  - Work with the Management Committee to clearly establish priorities for HPRA in developing policies and operational plans.
  - With the Management Committee, work to identify a common vision for the organisation and effectively communicate that to the organisation and strive to ensure the vision is embedded in a tangible culture of behaviours that will deliver on it.
  - Ensuring appropriate communication protocols are in place to deal with issues of key importance to the HPRA.
  - Working with the Communications team, external communications consultants, the Chief Executive and HPRA Management Committee in the development and delivery of HPRA external communications activities.
  - Representing the HPRA at national, European and international meetings as required.
  - Reporting on progress of the Compliance department at Executive level.
  - Attending meetings of the Authority and Advisory Committees as appropriate.
  - Using the strategic planning cycle to develop short and long range plans for each section within the Compliance department's remit.

- Leadership and Motivation
  - Provide effective and meaningful leadership, support and clear direction to the management team.
  - Work with the management committee and departmental section managers to ensure the core competencies of the HPRA are promoted across the business and become embedded in all interactions with staff.
  - Lead, and in conjunction with each section manager, manage and motivate a multi-functional team of staff, providing effective and meaningful leadership, support and clear direction to each section.
  - Encourage a culture of teamwork within the department.
  - Ensure the provision of performance feedback, coaching and mentoring support to all staff in the department.
  - Build a strong, integrated and effective management team in the Compliance department.
  - Develop an integrated Compliance department by fostering collaboration, strong professional relationships, and team working among the individual areas of the department and other areas of the HPRA.
  - Promote a positive, open, friendly and professional working environment.

- Performance, Quality and Knowledge Management
    - Effectively manage the overall performance and quality of work of the department to ensure the implementation and on-going development of the objectives with a drive for results and success for the department.
    - Manage the planning cycle, agreeing performance goals and targets with managers within the department, on-going monitoring and reporting against performance and quality objectives and effective communication throughout the department.
    - Effectively lead the management team while working directly with individual managers to keep up to date with department performance against stated objectives in the strategic/service plan.
    - Interact directly with the individual members of the Compliance team as well as the management team to address any issues that are impacting on the department's ability to meet the targets set down in the strategic/service plan.
    - Lead, co-ordinate and participate in the effective implementation of the HPRA Performance Development Programme (PDP) within the department, and ensure that performance improvement is actively managed at all levels.
    - Openly recognise good performance and promote a culture of performance improvement.
    - Lead the department in active participation in the development and implementation of the HPRA quality management system.
    - Foster an environment where the collective knowledge and experience of the Compliance department is available as a resource to those who need it in order to carry out their roles in a more efficient and effective manner.
    - Work with the management team to ensure that SOPs, guidelines and policies are used as a means for ensuring quality and consistency of processes across all areas of the department.
    - Ensure that the Compliance team remains up to date with relevant developments in national, European and International regulations and legislation.

- Managing Financial Performance
    - Work with the Finance, Corporate and International Affairs department and other Directors to ensure the maintenance of a long-term and sustainable approach to funding human and veterinary medicine regulatory activities.
    - Monitor departmental income and expenditure, including contributing to the development of appropriate budget plans for the department and their on-going review.
    - Ensure vendors and all associated procurement, negotiation and contractual arrangements for the department are managed appropriately.

- Promoting Communications
    - Facilitate the establishment of an open and effective communications environment where high-quality information flows smoothly around the Compliance department.
    - Work with the Compliance management team in communicating a clear strategic direction and leadership to the department.
    - Ensure that the communications process, particularly at management level, is developed and maintained.
    - Work with the management team to develop and implement a communications strategy for the department.

- Liaise with officers of the State, representative associations, other bodies, and industry groups as appropriate.
- Ensure that appropriate communications mechanisms with industry are developed and implemented.

- Learning and Continuous Professional Development
  - Facilitating a professional development environment where the currency of individuals' skills sets are maintained and aligned with the strategic objectives of the department.
  - Work with the section managers and the Learning and Development section (as required) to enable development requirements of staff to be identified and appropriately addressed.
  - Develop and maintain a culture of excellence and continuing development for all staff working in the department.
  - Provide challenging assignments to all staff that provide opportunities for personal and career development.
  - Support staff development and performance management.
  - Work with all managers and staff to develop and maintain a culture of excellence and continuous improvement within the department.
  - Work with HR and Change colleagues, as required, to manage recruitment to and selection of staff for the department.

- 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 3rd level degree in life-sciences or healthcare.
- Over five years' relevant experience at senior management level which must include strategic decision making in any of the following areas: the pharmaceutical industry, regulatory affairs, medicines regulation, or healthcare sector with a focus on product quality.
- Demonstrated ability to work successfully with a range and breadth of senior stakeholders, of representing an organisational or policy position and negotiating effectively to maintain that position.
- Working knowledge and understanding of relevant legislation and policy at National, EU and international regulatory structures for medicines, and other health products.
- Significant experience in the leadership and motivation of multi-disciplinary team(s); strong track record in the area of performance management with the ability to communicate direction to the team, set standards for high performance and drive the achievement and delivery of results.
- Experience in strategy development and implementation.
- Effective decision-making skills with a results oriented focus - understands what is important - is committed to achieving goals.
- A tenacious approach to delivery, quality of output and organisation performance.
- Strong representational and negotiation skills, with the ability to develop effective strategies for both national and international issues.
- Strong relationship building skills at all levels, with the ability to inspire confidence, establish credibility and respect.

- Excellent interpersonal and communication skills with the proven ability to deliver appropriate information to the right people, using a range of written, verbal and presentation skills.
- Proven experience in change management programmes.

In addition to this the ideal candidate will have;

- Prior experience, at a senior level, of regulation of health products to include a strong focus on quality or manufacturing and/or of operating at a senior level in a corresponding regulated environment.
- Experience in the implementation of EU guidelines and legislation.
- A relevant postgraduate qualification.
- Proven ability to drive projects through to completion.
- Proven record in connecting with leadership teams to support, influence and drive for results.
- Experience in dealing with the media
- Integrity and professionalism - is sincere in own behaviour and in dealings with others.
- Works with others in a collaborative and solutions focused manner.
- Excellent and proven problem solving ability, able to adapt to changing conditions and display the ability to generate effective and pragmatic solutions to new situations and problems both strategic and operational.
- Clear understanding of risk and its assessment, mitigation and avoidance.

REMUNERATION

Salary: €123,134 per annum*.

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 permanent post.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 30 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 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 time of application.

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.

EQUAL OPPORTUNITIES

The HPRA is an equal opportunity employer. The HPRA will not discriminate against an employee or prospective employee in relation to the nine discriminatory grounds as per the Employment Equality Acts, 1998-2015

* Candidates should note that the rate of remuneration may be adjusted from time to time in line with Government pay policy.