# Job Description

| 1 Position in the Organization | |
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| Job Title: | Director of Quality – Responsible Person (RP) |
| Department: | Quality |
| Location: | Dublin, Ireland |

## 2 Description

The Director of Quality/RP is primarily responsible for ensuring regulatory compliance for all medicinal products distributed by Nabriva Therapeutics Ireland, DAC in the EU and OUS regions and supporting through proactive monitoring, the quality performance of contract manufacturers, distributors and material suppliers to applicable GXP standards. Additionally, the Director of Quality/RP is responsible for implementing Quality Management systems and monitoring the operation of the systems in place under the company's Manufacturer/Importation Authorization according to current legislative requirements including EU Good Distribution Practice, Irish legislation, and guidance from the HPRA to ensure that the provisions of the Authorization are observed.

## 3 Duties and Responsibilities

- Represent the Quality Unit for Nabriva in EU matters related to Quality.
- Ensure that a Quality Management system is implemented and maintained, proportionate to the MAH's activities.
- Lead the Quality efforts for new market launches.
- Prepare and host the EU site regulatory inspections from a GDP/GMP, WDA, MIA, MAH or PV perspective.
- Establish and ensure compliance with Product Complaints and Recall process for EU & OUS.
- Support the qualification of new vendors and Contract Service Providers for EU and OUS.
- Work with US counterparts on driving the release of products on time and within standards to our external partners.
- Coordinate with US and EU counterparts to manage QA operations at Contract Manufacturers.
- Responsible for leading resolution of assigned open investigations, deviations, CAPAs and change controls together with the QP in order to ensure timely release of supplies to market.
- Provide support and oversight of batch review and disposition, reviewing and approving product complaints, deviations, and change controls.
- Lead product related investigations and support product quality related priorities and tasks at the respective contract manufacturers, distributors and/or suppliers.
- Design, implement, and improve quality systems to realize the highest global quality standards attainable for all quality related activities conducted by the company, supporting Product Quality Review and annual report completion on time.
- Build authentic relationships and lead business meetings and audits of critical suppliers and contract manufacturers.
- Ensure implementation, management, and maintenance of all product related Quality Technical Agreements (QTAs), including leading QA negotiation with contract acceptors.
- Lead internal and external audits and regulatory agency inspections as needed.

## Job Description

- Ensure compliance of all respective distribution partners and contract manufacturers/suppliers to both internal company requirements and country specific regulations.
- Highlight any risks associated with maintaining supply of commercial drug products to all markets and offer innovative and effective solutions to minimize such risks.
- Collaborate with all contract distribution partners, manufacturers, packagers and testing laboratories to resolve any quality issues and ensure an uninterrupted supply of drug product to the markets.
- Participate in due diligence activities associated with strategic partnerships or new company acquisitions, as needed.
- Ensure the successful outcome of regulatory inspections associated with company business, both internally and at contract manufacturers, packagers and laboratories, as required.
- Maintain quality and regulatory compliance to ensure that there are no significant regulatory agency citations associated with any company specific GMP/GDP activities.
- Evaluate proposed changes to the manufacturing and supply chain processes, including conducting regulatory impact assessments, and provide guidance and QA approval, where appropriate.
- Support management of the supplier qualification programme and execute supplier audits as required.
- Ensure that a quality management system proportionate to the distributor's activities is implemented and maintained including: training; self-inspection; quality risk management; corrective and preventative actions (CAPA) to address deviations; recall; change control; vendor management; measurement of performance indicators and management review.
- Ensure compliance with GDPs and advise senior management in relation to activities with potential impact on GMP and in particular GDP relating to wholesale distribution.
- Collaborate cross-functionally with local and global colleagues to ensure all quality standards are adhered to and identify and implement process improvements in distribution of materials and finished products
- Liaise and co-operate with all regulatory bodies on behalf of the company.

## 4 Qualifications and Skills

- Bachelor's degree in Science or a healthcare related field required.
- 8-10+ year's relevant practical and managerial experience of medicinal products is required.
- Eligibility to act as a Responsible Person (RP) is required.
- Ability to act as a QP is preferable, but not required.
- Demonstrated pharmaceutical knowledge and experience to ensure full discharge of responsibilities.
- Experience supporting the complexity of Ireland Manufacturer/Importation Authorization and wholesale operation, including experience of working in a virtual supply chain environment and collaborating cross-functionally with local and global colleagues.
- Demonstrated knowledge of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Wholesale Distribution Authorisation (WDA) and Marketing Authorisation Holder (MAH) Compliance regulations.
- Working knowledge of the legislative basis pertaining to the manufacture, marketing and wholesaling of medicinal products at both European and local Irish level, including the following:

- Title VII of Directive 2001/83/EC of the Community code relating to medicinal products for human use, as amended
- The Medicinal Products (Control of Wholesale Distribution) Regulations 2007 - 2013 (S.I. No. 538 of 2007)
- HPRA Guides:
  - Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland IA-G0008-4 16 January 2016
  - Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances IA-G0011-1 5 October 2011
  - Guide to Quality System for General Sale Wholesale Distributors - IA-G0038-2 1 November 2013
  - Guide to Good Distribution Practice of Medicinal Products for Human Use - IA-G0046-2 10 April2014
  - Guide for Recall of Medicinal Products for Human and Veterinary Use - SUR-G0019-2 15 November 2010
  - Guide to Applying for a Manufacturer's/Importer's Authorisation
  - Eudralex Volume 4 Good Manufacturing Practice (GMP) guidelines
  - MAH compliance in the context of GxP activities

## 5 Competencies

- **Customer-centric mindset**. Ability to address issues, communicate, and develop programs, and take on other tasks with a customer/patient focus based on a foundation of ethics, integrity, and quality.
- **Results-driven individual** with strong levels of perseverance, resilience, and resourcefulness; works toward both individual and team goals. Demonstrates personal initiative/self-leadership, self-motivation and the ability to be involved at various levels and willingness to "roll up sleeves" to drive results and outcomes. Ability to adapt quickly and act with urgency.
- **Continuous learner** using critical thinking skills to solve complex business problems and provides innovative, value added solutions, while following standard policies and procedures.
- **Superior organizational/project management skills**. Demonstrated ability to manage multiple assignments/projects, strict timelines, and to identify project interdependencies, resource needs, potential risks/pitfalls and mitigation plans. Focus on attention to detail and accuracy in work.
- **Highly collaborative**; with an ability to see the "big picture' and influence others across businesses, functions, geographies and levels, motivated by collective success. Leads without authority.
- **Communicates effectively:** Communicates clearly and concisely. Ensures messages are aligned to audience and purpose. Seeks and provides meaningful feedback. Trusted advisor.