Job Title: Qualified Person (QP)
Location: Longford, Ireland
Reporting to: Head of Quality (GMP)

Purpose of Job

- To fulfil the Company's requirements with respect to Qualified Person services, in accordance with Annex 13 and Annex 16.
- To provide input for development and implementation of the Quality Management System
- To ensure compliance in terms of GMP
- To host regulatory agency inspections and customer audits
- To support internal and external quality audits as required
- To provide training in GMP as required

Qualifications and Role Requirements

- Degree in a scientific discipline: Chemistry, Pharmacy, Pharmaceutical Chemistry or biology.
- A minimum of 5 years pharmaceutical industry experience
- Attainment of the status of Qualified Person in accordance with the HPRA's educational requirements, experience, training, and licensing (compliance with the requirements of Directive 2003/94/EC)
- The QP shall reside and operate in the EEA
- The QP should have a complete programme of Continuous Professional Development (CPD)
- The QP should have skills for the management of the quality functions of the Company
- Ability to work cross functionally within the Company and apply GMP and associated legislation

Main Duties and Responsibilities

- To perform the Qualified Person duties in accordance with Article 51 of Directive 2001/83/EC as amended and Clinical Regulation 536/2014 These duties shall include:
    - Ensuring all activities associated with manufacture and testing of the medicinal product have been conducted in accordance with the principles of GMP
    - Ensuring the starting materials used comply with the requirements, the supply chain is known, and audits have been carried out.
    - Ensuring that the manufacturing processes and testing methods are validated and in accordance with the marketing authorisation.
    - Ensuring changes have been assessed and completed accordingly
    - Ensuring that the requirements of the product registration and of the manufacturer's licence have been met
    - Ensuring that the legal requirements for nationally manufactured and imported products have been met.
    - For products imported from outside the European Union (EU) or European Economic Area (EEA) the QP should ensure testing within the EU/EEA to requirements of the product registration and any other tests to assure quality of the products, unless a Mutual Recognition Agreement exists between the EU and the third country concerned

    - Certify in a register that each batch satisfy the above-mentioned requirements
- Maintain and manage the Quality Management System of the company in accordance with the requirements of ICH Q 10
- To provide oversight control of the company's Standard Operating Procedures
- To manage agency inspections of the company
- To undertake or arrange for regular auditing as required of:
    - Drug substance manufacturers
    - Drug product manufacturers
    - Drug product testing sites
    - The company's internal quality systems

Benefits Package

We offer a competitive salary in accordance with experience and a desirable employee benefits package including 30 days holiday. We also offer a variety of additional schemes.

Internal and external training will be provided, and opportunities will be available to develop your career within the business.