Quality Assurance Manager (Dublin, Ireland)
The QA Manager is responsible for supporting the creation, execution and maintenance of quality management systems (QMS) to ensure adherence to Quality standards and Regulatory requirements for their commercial and development products/projects which encompass, small and large molecule products.
This position provides strategic and tactical management of Quality activities collaborates with cross-functional team members and or contract manufacturers and external service providers. This position reports to the Quality Director to provide robust and timely Quality and Regulatory support that aligns across functions to execute the plan and accomplish results. This position is a 12 month contract position.

ESSENTIAL FUNCTIONS:

- Develop an intimate understanding of drug product manufacturing processes and products and apply quality management system procedures to these. This includes batch review and release.
- Review and release of manufacturing and analytical test documentation in support of the release of batches of product for commercial distribution. Coordination of review processes with 3rd party support vendors.
- Understand the relationship between regulatory filings and QMS and utilize these in the oversight of compliant Quality activities.
- Develop, adapt, and optimize change control, deviation, and risk management processes. Apply these systems to various quality issues as they arise.
- Conduct detailed and effective root cause analysis and CAPA systems management.
- Conduct label reviews to support Regulatory filings and manufacturing activities.
- Ability to collate stability data from third party partners and conduct statistical analysis and interpretation.
- Support the company Quality complaint system and conduct complaint investigations and report these.
- Provide QA support in projects relating to commercial and investigational medicinal products.
- Partner with internal partners and contract manufacturing and services organizations and other cross functional groups to ensure the proper application of design controls, risk management and the investigation/correction of design failures/challenges.
- Develop strong technical and business relationships with contract manufacturing and services partners to support addressing supply chain goals, objectives, and process improvements.
- Works in close partnership with other cross functional partners to meet timelines and achieve business results.
- Ensure compliance with all laws, regulations and policies that govern the conduct of the company.

KNOWLEDGE AND SKILL REQUIREMENTS:

- Demonstrated skills and experience in the conduct of Quality activities as described above in support of pharmaceutical and/or biotech products or combinations of same.
- Initiative, creativity, and the ability to manage change and work effectively in a complex, rapidly changing environment and feel comfortable in this environment.
- Strong communication skills and multi-tasking capabilities
- Ability to navigate cross functionally and strategically leverage relationships to achieve business results
- Knowledge of quality standards and regulatory guidelines and requirements relating to pharmaceutical and/or biotech products or combinations of same. An ability to adapt these regulations and standards to real world scenarios resulting in a successful compliant resolution.
- Highly motivated, intelligent individual with strong project management, analytical, problem solving and interpersonal skills
- Demonstrate high ethical and professional standards, and demonstrates company values consistently with all customers and business partners
- Excellent collaboration skills to optimize the relationship with internal and external partners.
- Strong analytical background with strategic thinking capabilities and attention to detail
- Self-starter and able to work on their own initiative
- Strong inter-personal skills including the ability to work effectively in a team environment and to build collaborative relationships with peers and with other stakeholders
- Ability to communicate effectively with all levels of management both verbally and in writing
- Comfortable working in a fast-paced, high-energy, diverse environment
- Ability to multi-task, consistently meeting deadlines on multiple projects and activities

SKILLS AND EXPERIENCE:

- Product quality experience in the QA management of commercial biological drug products.
- Candidate should have minimum 5-7 years direct pharmaceutical/biotech (or combinations) quality related experience.