Quality Manager - Re-Vana Therapeutics

Company Headquarters Belfast Nth Ireland

Reports to:	Chief Operating Officer
Department:	R&D - Quality
Location	Belfast, Northern Ireland
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Introduction

Re-Vana Therapeutics, founded in 2016 and incorporated in both the U.K. and U.S. is a spin-out from Queen's University Belfast (QUB) Northern Ireland. We are developing innovative and proprietary biodegradable sustained-release technologies for the delivery of biologics and small molecules drugs, with a focus on ophthalmic indications.

Our value proposition is the ability to develop "customized" sustained-release implants capable of delivering both biologics and small molecules for as long as 6 months or more, thus reducing the frequency of ocular injections and reducing or eliminating the need for topical eye drops. The sustained delivery of biologic drugs is recognized as one of the major unmet needs within ophthalmology. Currently, ophthalmic biologic drugs represent a $14B market worldwide with growth projections reaching more than $22B by 2024.

Our dual strategy includes the internal development of sustained-release therapeutics alongside the development of external strategic collaborations with major pharmaceutical partners. To date Re-Vana has achieved significant progress and global awareness, raising seed money in 2017, a pre-Series A in 2020 and a Series A in 2022 that included leading U.S. Ophthalmic and U.K. Venture Capital Investors. We have been awarded two significant Innovate U.K. government grants for the development of sustained-release ocular biologics. In 2022, we were awarded the prestigious Ophthalmic Innovation Summit Retina Award for "Drug Delivery Innovation" and the Belfast Chamber "Business Innovation" company of the year. In addition, Re-Vana has established a compelling Scientific Advisory Board (SAB) that includes global ophthalmic opinion leaders.

We are seeking to further strengthen the team by hiring a full-time Quality Manager to develop and manage a Quality Control system within the company.

The successful candidate will be a key member of the Belfast based team. Reporting to the COO, he/she will work extensively with the CEO and CTO and the internal scientific team.

This is an outstanding opportunity to help build and contribute significantly to the strategic success of a well-capitalized, highly innovative startup company within a multibillion dollar market potential.

Brief Description of Role:

Re-Vana is looking for an individual to assume responsibility for the initial management of the Quality Control/Assurance and Document Controls functions for Re-Vana, as the organization grows these will become separate well-defined roles. The role will include oversight, identification, development and maintenance of R&D quality processes including analytical data, documentation, development and maintenance of internal and in process materials, Finished Goods lot release and stability testing for in vivo testing, internal and external technology development, evaluation and investigation of OOS. Act as Quality Control expert providing support for product development and commercialization of drug/device combination products. Support analytical method development/validation/transfer.

Responsibilities:

- Develop, implement and own a Quality System including all procedures and processes
- Distribute documentation throughout the organization, on time, to the people who need it
- Oversee testing for raw materials, intermediate materials and final polymer based photo crosslinked drug delivery products
- Responsible for the identification, selection, qualification, and oversight of analytical laboratories conducting Quality Control testing, including contract negotiations, future on-site audits and supplier development activities
- Act as the primary company liaison for Quality Control testing; including communicating testing priorities, review and approval of OOS investigations, and test method maintenance
- Oversee and own the process for review and approval of analytical data for future GMP testing of raw materials, in-process materials and finished drug product
- Act as Quality Control during inspections and conferences with FDA, Notified Body, Competent Authority and other regulatory agencies
- Proactively identify quality related vulnerabilities and champion improvements in company wide activities
- Facilitate effective communication and collaboration between the R&D team and senior management
- Maintain current knowledge of federal, state and international regulations and guidance documents, as applicable (QSR, cGMP, ISO, ICH, etc.)
- Support NCMR, CAPA, Complaint and Internal Audit investigations as needed
- Thoroughly document all issues related to quality control, QSR, cGMP, ICH and ISO compliance
- Support company goals and objectives, policies and procedures

Requirements:

- B.Sc. in Life Sciences, Chemistry, Chemical Engineering
- Minimum 5 years related experience in the pharmaceutical industry supporting GMP testing activities - start up experience a bonus
- A willingness to work hard, with a driven outlook and with a strong desire to succeed, as a scientist, as a team, and as a company
- An inventive aptitude balanced with discipline and concern for detail
- Motivated to initiate a new Quality Control system in an academic based, pre-clinical start-up company
- Experience working on drug/device combination products and / or pharmaceutical development and manufacturing, from concept through commercialization

- Strong knowledge of domestic and international CGMP, CMC and Analytical regulatory requirements
- Ability to translate regulations and guidance documents into company procedures and provide training to cross-functional teams
- Excellent communication and time management skills required
- Strong team player with ability to work with diverse cross functional teams
- Ability to work independently and be able to manage tight timelines and changing priorities
- Working knowledge of statistical techniques (*e.g*. sample size determination, tolerance intervals, capability analysis, Regression, ANOVA, DOE) using statistical software packages (e.g. Excel, Minitab, JMP)

Additional

Remuneration to be based on a fixed salary, bonus and stock options relevant to a startup organization

Contact

Please send an updated CV with supporting letter to

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