Quality Assurance Manager

Contract Type:	Full-time Permanent
Location:	Oxford

About Oxular

"One treatment a year. Life changing."

Oxular is developing technology to transform the treatment of retinal disease, offering patients life-changing solutions to their unmet needs. Oxular's sustained-release formulations are engineered to last up to one year following single administration to specific small spaces in the eye. This approach provides unique and precise drug distribution to tissues specifically involved in retinal diseases. Oxular's drug administration technology is engineered to access these critical tissues through minimally invasive delivery. This novel combination aims to substantially improve patient quality of life by increasing therapeutic effectiveness and patient safety, while reducing side-effects and minimizing the frequency of treatments. Oxular's product development pipeline includes treatments for prevalent retinal diseases, such as diabetic macular edema and age-related macular degeneration, as well as rare and orphan indications, such as ocular cancers.

Joining Oxular

Oxular is a rapidly growing company, built on innovative technology, a highly differentiated pipeline, and an experienced management team. We have ambitious plans to solve some of the most significant, unmet patient needs in the retinal therapeutics' arena, and we are looking for smart, dedicated individuals to join us.

About Oxular

"One treatment a year. Life changing."

Oxular is developing disruptive technology to transform the treatment of retinal disease, offering patients life-changing solutions to their unmet needs. Oxular's sustained-release formulations are engineered to last up to one year following single administration and perform in specific small spaces in the eye. This approach provides unique and precise drug distribution to tissues specifically involved in retinal diseases. Oxular's drug administration technology is engineered to access these critical tissues through minimally-invasive delivery. This novel combination aims to substantially improve patient quality of life by increasing therapeutic effectiveness and patient safety, while reducing side-effects and minimizing the frequency of treatments. Oxular's product development pipeline includes treatments for prevalent retinal diseases, such as diabetic macular edema and age-related macular degeneration, as well as rare and orphan indications, including treatments for ocular cancers.

The Opportunity

Reporting to the VP of Quality, this is an exciting opportunity to join us as we enter the next exciting phase of development.

You will be joining a highly collaborative, small, but fast growing, multi-disciplinary dynamic team that are passionate about making a difference. You'll be exposed to advanced technical and scientific skills that are in high demand in the rapidly growing field of life science.

Primary responsibilities

As a QA Manager, you will focus mainly on the

- Oversee all QA activities, including document control, SOP implementation for QMS and analytical functions.
- To Maintain and update Documentation Controls and tracking tools to ensure proper tracking of all SOPs/controlled documents/Change controls in the routing/approval process and batch record management.
- Creation/revision of documentation (SOPS, batch records, logbooks and other documentation as needed) as required,
- Support all Validation and Qualification activities
- Managing documentation from CMO's / CROs, clinical trial partners,
- Routine review of GMP SOPs/documents and batch documents to support QA batch review and QP release and improving processes to drive down non-conformances and failures.
- The duties will include effective reporting and investigation of incidents and deviations and other batch related and non-batch related investigations and working in multifunctional teams to identify and drive process improvements.
- Approving laboratory SOP's, protocols and reports, specifically reviewing any changes and investigating any deviations, Deviation Management and CAPA system, change control, complaints.
- Development and preparation of documentation for the Quality Management Systems (QMS), Plan and conduct internal audits to verify the effectiveness of the management system.
- Participate in both internal and external audits when required.

Education and Experience

- A degree or equivalent in Chemistry, Pharmacy or other appropriate life sciences.
- Substantial experience within a pharmaceutical industry preferably within Quality Assurance, Production or Quality control. minimum of 3 years' experience from a GLP/ GMP/ GCP regulated environment. You must be a strong communicator with excellent attention to detail.
- Proven industry experience in QA (5 years minimum). A working knowledge and practical experience with GMP, experience writing & reviewing SOPs, drafting Deviations, Investigations, CAPAs desirable.
- Good knowledge and understanding of cGMP, quality systems and quality practices associated with production, analytical testing and documentation.
- Effective written and verbal skills, quality audit experience would also be preferable.
- Excellent interpersonal skills are required as this position requires daily contact with other internal departments. Strong team working, problem solving (deal with problems in stressful situation), plan and task organizing, willingness to learn, work to deadline, initiative.
- Support/provide training to the organization about the Quality System.

In return

We offer you a permanent position in an exciting, growing life science company at Oxford Science Park. You can expect an attractive workplace with versatile and varied activities in an innovative, collaborative environment.

- Competitive Salary
- Discretionary bonus, subject to Board approval: up to 15%
- Company contributory pension scheme – statutory rate
- 25 days holiday, plus Bank Holidays
- Private Medical Insurance
- Death in Service

Location: Oxford

Terms: Permanent | Full Time

Hours of work: Monday-Friday | 09:00hrs - 17:30hrs (with 1-hour lunch)

We are an Equal Opportunities Employer

If this role is of interest to you, then we would like to hear from you!

Please apply in writing and include a covering letter explaining what interests you most about the position and the company to recruitment@oxular.com

CLOSING DATE for applications is 15 March 2021.