Senior RAQA Specialist - GLP/GMP
Seattle, USA

Rayner is a leading developer and manufacturer of ophthalmic implants and pharmaceuticals; it specialises in intraocular lenses (IOLs) and related products used in cataract and refractive surgery.Since the development of the first IOL, Rayner has continuously pioneered IOL design with a goal to improve vision and restore sight worldwide. Today, Rayner's mission remains to deliver innovative and clinically superior ophthalmic solutions that respond to the expectations of our global customersto improve sight and quality of life for their patients.

Today, we have offices in New York and Memphis. Rayner Surgical Inc and Omeros Corporation announced the signing of an agreement to transfer Omeros' ophthalmology assets, including OMIDRIA and the teams to support the product to Rayner in December 2021.

Why work for Rayner?

Rayner is a unique place to work with its own special culture and people, who are all driven to provide the best visual outcomes for clinicians and patients. We are driven by science to improve performance and safety, and we commit ourselves to be a great partner and to be easy to do business with. Whilst our visiondrives and guides what we do, it is our culture and the way we work as well as treat ourselves plus others that form the foundation of what we do. That's why at Rayner we strive to create a workplace where we live our values every day. We invite you to join us on our exciting journey!

Our Careers

Rayner is more than an IOL manufacturer. We have an entrepreneurial spirit that drives us to pursue our vision, supported by a dedicated team who share our beliefs – from research and development engineers toproduction, sales and support.

Being ambitious, focussed, open, respectful and keeping our promises enable us to take on challenges thatother businesses simply won't entertain, and it's those qualities we value and nurture in the people we workwith. Rayner is also proud to be an equal opportunities employer.

Rayner has a broad portfolio of products across the patient pathway, including monofocal and premiumIntraocular Lenses (IOLs), a full range of Ophthalmic Viscosurgical Devices (OVDs), a family of Ocular Surface Disease (OSD) solutions and RayPRO, our recently launched patient outcomes digital platform.

We are looking for an experienced professional to provide QA support for contractor manufacturing operations and ensure compliance with applicable regulatory requirements, ensuring the product dossiers are accurate and compliantly maintained. Self-motivated and able to function effectively within team is essential. This key position will be responsible for meeting, within a demanding environment, strict timelines and protocols but also building and maintaining positive relationships with vendors, management, peers, and subordinates.

Your key responsibilities will be:

- Conduct audits of CMOs, CROs, and other service providers, write audit reports and follow up on observations/CAPAs
- Perform in-phase inspections in support of GLP studies, write inspection reports, follow up on observations/CAPAs, and prepare QA statement
- Review of GMP controlled documents such as master batch production records, test methods, specifications and managing implementation of required changes to meet GMP and internal standards
- Review executed batch production records ensuring compliance with approved procedures and GMP expectations. Communicating and resolving discrepancies with CMO
- Review release test and stability data ensuring data accuracy, conformance to test procedures, specifications, and documentation standards
- Provides support in the review of change controls related to manufacturing
- Provide QA support for validations including reviewing protocols and reports
- Working collaboratively with development, manufacturing, and QC staff to respond to and resolve deviations and incidents
- Follow through on corrective and preventive actions from deviations, OOS and audit observations
- Maintain databases for investigations, audit observations and CAPAs
- Review, analysis, and trending of data related to production, testing and stability
- Write and review Standard Operating Procedures as needed
- Ensure compliance with regulations

Qualifications/ Experience:

Essential

- BS and/or MS degree in science and 5 years of experience in Quality Assurance or related area
- Prior audit and batch record review experience is required.
- In-depth knowledge and experience with GMP and GLP regulations, and industry standards (USP, Ph.Eur., ICH, FDA, EU guidance)
- Knowledge of the principles and practices of computer applications including word processing, spreadsheet, database management, and presentation software and internet search engines
- Excellent written and verbal skills required
- Must display strong analytical and problem-solving skills
- Attention to detail is extremely important, as is the ability to adapt quickly to changing regulations.

Desirable

- Experience within the Ophthalmology sector

Please apply by sending an up-to-date CV & covering email to recruitment@rayner.com

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