presage BIOSCIENCES *a new era in cancer drug development realized*

Quality Assurance Manager

Our Company

Presage Biosciences, Inc. is an innovative oncology company with an entirely novel platform for assessing new drugs and combinations to treat solid tumors. Our proprietary technology platform, CIVO®, simultaneously analyzes multiple cancer drug candidates and drug combinations within a single living tumor.

Presage is a growing, privately held company led by an experienced management team and is headquartered in the vibrant South Lake Union area of Seattle, WA.

Key Responsibilities

- Act as the SME for all initiatives related to company QMS, representing the GxP voice of the organization.
- Lead and support the development, implementation, maintenance, and continuous improvement of various components of the QMS per ISO 13485:2016 and 21 CFR 820 requirements.
- Write, edit, approve standard operating procedures, manuals, work instructions and policies. Ensure documents reflect current company practices and facilitate compliance.
- Work with department and functional leads to monitor, review, and regularly report on all operations that affect quality and regulated activities to ensure compliance to applicable Regulatory statutes and Industry standards.
- Manage the implementation and maintenance of the QMS, including SOPs and other controlled documents.
- Provide cross-functional support to any QMS related requests or issues.
- Lead troubleshooting and investigations of QMS issues to ensure comprehensive and timely resolution.
- Plan, execute, and document internal and external audits and inspections.
- Provide QA support for outsourced product design and manufacturing activities, including vendor qualification and oversight.
- Provide training, infrastructure and best-practice guidance to those involved in regulated activities.
- Proactively engage in cross-functional communication to ensure Quality is a priority in the organization
- Assist in quality assurance related to the company's clinical trial operations.
- Actively assess and comprehensively manage risk across company programs, ensure appropriate mitigations and actions are implemented between functions.
- Proactively stay informed of current GxP Quality practices relevant to our industry
- Provide guidance to vendor selection to ensure partnership agreements meet appropriate Quality deliverables
- Prepare company to be inspection-ready by partners and regulators. Provide on-going job-related support to laboratory team members and other internal stakeholders.

- Other quality related duties as assigned.

Qualifications

- A Bachelor's degree, in a scientific discipline preferred
- 5+ years quality management experience preferably in the areas of medical devices and clinical research
- Experience in developing and maintaining QMS under ISO 13485 and 21 CFR 820, GMP.
- Experience in design controls, verification, and validation plan development with cross-functional engineering and clinical teams.
- Experience leading internal and external quality inspections and audits.
- Experience leading and implementing corrective and preventive measures.
- Experience developing Risk Management planning for product and clinical study.
- Technical proficiency including experience with electronic document management systems.
- Excellent communication skills across all organizational levels.
- Commitment to attention to detail, solid execution, meeting aggressive timelines, strong interpersonal skills and being a team player.
- A desire to help others and the company do their best work.
- Willingness to assist others in developing solutions and process improvement.

Work Environment

In-office 100% time. Travel may be required.

Physical Demands

While performing the duties of this job, the employee is occasionally required to stand; walk; sit; use hands to handle or feel objects, tools or controls; reach with hands and arms; climb stairs; balance; stoop, kneel, crouch or crawl. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by the job include close vision, distance vision, peripheral vision, depth perception, color vision, and the ability to adjust focus.

Join Us!

If you enjoy a stimulating office environment, are based in the Seattle area, and most importantly, have a passion for improving the lives of patients with cancer, come join us!

To apply for this position, please send your CV with cover letter to:

Presage Biosciences, Inc.
Attn: Human Resources
530 Fairview Ave N, Suite 1000
Seattle, WA 98109
E-mail: hr@presagebio.com

Presage Biosciences, Inc. is an Equal Opportunity Employer.