Title: Program Manager, Clinical Projects

Department: Program Management Office

Location: Marlboro, MA

About Akoya Biosciences:

As 'The Spatial Biology Company®', Akoya Biosciences' mission is to bring context to the world of biology and human health through the power of spatial phenotyping. The company offers comprehensive single-cell imaging solutions that allow researchers to phenotype cells with spatial context and visualize how they organize and interact to influence disease progression and treatment response. Akoya offers two distinct solutions, the CODEX® and Phenoptics™ platforms, to serve the diverse needs of researchers across discovery, translational and clinical research.

Position Summary:

Akoya Biosciences is looking for a Program Manager to lead the development of novel clinical applications for our technology under the guidance of Akoya's Program Management Office (PMO). Our Advanced BioPharma Solutions (ABS) group provides staining, imaging, and analysis services to industry leading BioPharma companies. The individual will lead projects that expand our Advanced BioPharma Solution (ABS) offerings and ultimately create new products for customers in the clinical and translational spatial biology market. The role will lead and partner with our ABS and clinical applications groups, R&D, Quality, and Product Management.

The Marlborough site and our design and development processes are ISO-13485 compliant.

Duties & Responsibilities:

- Holistically manage novel clinical application projects (reagent, software, and/or system) that expand ABS offerings and lead to new products that support translational and clinical applications of our technology.
- Leverage Akoya's design and development process to lead multi-disciplinary, cross-functional teams to develop new ABS offerings and products.
- Create and execute program plans with key program stakeholders that include timelines, resources, and budgets.
- Guide product management in the creation of User/Customer Requirements and lead the flow down to design requirements.
- Manage internal verification and validation at external customer sites.
- Manage the transfer of new offerings to ABS and new products to contract manufacturers.
- Partner with Quality to ensure adherence to Akoya's Quality System and identify/mitigate risks throughout the project lifecycle.
- Provide periodic updates to upper management on project status, risk, and risk management strategies.
- Bring knowledge and experience to expand/improve the new Program Management Office (PMO) and its responsibilities.

Skills & Requirements

- 5+ years of project/program management developing new products, preferably related to the life sciences or medical device industries.
- Bachelor's Degree, Master's Degree, or Ph.D. in Science (Biology, Chemistry) or Engineering (Biomedical) or related fields.
- Excellent communication skills (enjoys working with diverse team members)
- Effectively manage experts from multiple technical disciplines
- Experience working within an ISO 13485 (9001) compliant Quality System
- Experience with 21 CFR Part 820 compliant Quality Systems
- Proficiency in Microsoft Office (Microsoft Project a plus, but not required).
- Ability to multi-task and manage priorities.
- Strong organizational skills and attention to detail
- Flourishes in a highly dynamic and small company environment
- PMP Certification (a plus, but not required)
- Knowledge of fluorescent imaging, reagents, tissue pathology, and immunohistochemistry (or similar technologies) (a plus, but not required)

Akoya Biosciences, Inc. proudly affords equal employment opportunity to all qualified persons regardless of race, color, religious creed, national origin, age, military status, sexual orientation, disability, genetic information, gender identity, gender expression or gender unless based upon a bona fide occupational qualification.

Apply at: careers@akoyabio.com