Flagship BIOSCIENCES
Expert insights for your tissue data.

QA Specialist II – Job Description

About Flagship. At Flagship Biosciences, we are dedicated to improving the health of patients everywhere by pioneering the most advanced tissue image analysis, clinical support, and diagnostics services that help pharmaceutical companies develop the solutions to treat, manage, and cure the world's most challenging medical conditions. Flagship develops its analytic and infrastructure technology in-house, providing truly unique capabilities not available anywhere else in the market. None of this can be done without a strong, talented team of people dedicated to moving medicines forward.

Our Cultural Values

- Smart and Hungry: We simplify complex problems. We are never satisfied and we love to learn.
- Find a Way: We find solutions for any problem. We must collaborate to win.
- Get the Right Stuff Done: The right strategy and execution to positively impact patients' lives.
- Respect: Open communication, refer to the expert but respect equal say at the table.

Job Classification: Full time, Exempt **Reports to:** Quality Assurance Manager

Salary Range: $53,733 - $67,166

Position Summary

The Quality Specialist II, under minimal supervision, performs activities to ensure that Flagship's laboratory and image analysis programs meet the high-quality standards of our clients and regulatory agencies. This will include; helping to design and build components of the quality management system, managing the day-to-day activities of the QA Department, such as independently writing and reviewing Standard Operating Procedures (SOPs), reviewing study protocols and associated documentation, writing and reviewing audit questionnaires and audit responses, and assisting during on-site client audits. The Quality Specialist II may also be directly responsible for certain quality sub-systems such as maintaining the vendor management system, hosting client audits, and independently performing internal process audits and study audits. The Quality Specialist II will also be responsible for the application of FDA and CAP/CLIA regulations to Flagship's quality activities and identifying quality issues and opportunities for improvement of current processes.

The Quality Specialist II will be joining a small team in a dynamic, fast-paced environment that is involved with all aspects of Flagship's business, including clinical trials, CAP/CLIA, FDA and medical device development. The candidate should possess basic knowledge of FDA and CAP/CLIA regulations, superior organization skills, exceptional attention to detail, ability to interact with all levels of the organization and juggle multiple tasks effectively.

Essential Job Functions

- Assist in designing and building components of Flagship's Quality Management System
- Manage the day-to-day operations of the QA Department
- Supports QA Department in facilitating GCP/GCLP and CAP/CLIA activities
- Independently write/review SOPs, study procedures, client audit questionnaires, client audit responses
- Maintain certain quality management sub-systems such as;
    - Vendor management system, planning and conducting vendor audits

  - Equipment management system, ensuring equipment is qualified appropriately
  - Issue management system, ensuring issues are handled appropriately
- Assist/host during on-site client audits
- Independently perform internal audits and clinical study audits
- Assist QA team members and Flagship internal customers to identify quality issues and improve operational processes
- Other duties, projects as assigned

Basic Qualifications

- Bachelor's Degree in a science-related discipline
- 3-6 years of experience in Quality Assurance
- Knowledge and application of FDA, CLIA and GCP/GCLP regulations and FDA guidances
- Experience with technical writing
- Proficient in MS Office (Word, Excel and PowerPoint at an intermediate level)
- Superior organization skills with a focus on attention to detail and accuracy
- Ability to manage/prioritize multiple tasks simultaneously
- Ability to work independently in a very fast-paced, changing environment
- Exceptional interpersonal and communication skills, both verbal and written
- Ability to interact/communicate effectively with team members across all departments and levels of the organization
- Quick learner with excellent judgment and problem-solving skills
- Ability to work independently with limited direction and as part of a team
- Upbeat attitude and willingness to learn
- Fluent in English, both verbal and written

Preferred Qualifications

- Experience in a regulated scientific, medical device or healthcare area with direct QA/QC experience and direct application of FDA regulations and guidances
- Experience with many aspects of Quality Management

To apply, submit your application through this link: https://flagshipbio.bamboohr.com/jobs/view.php?id=68