WHO IS CELLPHIRE? Cellphire, Inc. is a biotech company in Rockville, MD focused on addressing the global shortage of platelets, a critical blood component necessary to stop bleeding and promote healing. Cellphire currently has freeze dried canine platelets commercially available on the market and has freeze dried human platelets in human clinical trials.

WHO ARE WE LOOKING FOR? We are currently looking for candidates to fill the position of Quality Assurance Associate to assist us in the continuous improvement of our quality management systems. The job description is below.

WHO DO I CONTACT? *Contact Rob Woods at rwoods@cellphire.com.*

Title: Quality Assurance Associate	**Reports to: Quality Assurance Director**
Employee Name:	**Start Date:**

GENERAL RESPONSIBILITIES:

Applies fundamental philosophies, principles, systems, methods, and tools of quality management to achieve operational excellence.

RESPONSIBILITIES/DUTIES:

- Designs, implements, maintains and improves assigned processes within Cellphire's quality system. These systems include:
  - Training
  - Equipment management
  - Supplier management
  - Process controls (e.g., Change control; line clearance; batch record reviews; QA product release, labeling and inventory management; materials control; environmental monitoring trending; validations/verifications/qualifications; review of quality control data/trends)
  - Document and record control
  - Deviations and Corrective/Preventive Actions; Nonconformances
  - Internal assessments
  - Facilities and Safety
- Works with operations staff (quality control, manufacturing, development) to plan, qualify, verify, and validate new testing or manufacturing processes and facilities. Assists staff in developing validation plans, protocols, and reports. Reviews and approves validation plans, protocols, and reports.
- Applies principles of continuous improvement (e.g., quality control tools, quality management and planning tools, continuous improvement methods and lean tools) to product and process development/improvement and CAPA projects.
- Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations.
- Supports Management Review Meetings, reporting to BARDA, submissions to FDA, etc. by preparing data and presentations, developing and reporting on metrics.
- Supports development and implementation of quality systems related to BodeVet operations. Assists in developing and implementing processes for Cellphire QA oversight of BodeVet quality systems.
- Updates knowledge by studying trends in the developments in quality management; participating in educational opportunities; reading professional publications; maintaining

personal networks; participating in professional organizations.

- Enhances department and organization reputation by accepting ownership for accomplishing new and different requests; explores opportunities to add value to Cellphire.
- Works under specific supervision of senior management.

POSITION QUALIFICATIONS:

Supervisory Duties:

- Non-applicable

Qualifications:

- **Education**
  - Bachelor's or Master's degree
- **Experience**
  - 5-10 Years' experience in quality assurance
  - 3-10 Years' experience in commercial GMP organization(s)
  - Experience in improving and maturing a company's quality systems, project lead role a plus
  - Experience in assuring and improving compliance with FDA regulations
  - Experience in materials management, supplier management, and/or process validation a plus
  - Professional certifications in quality topics (e.g., ASQ Certification) a plus

Physical Demands:

- **Travel:** infrequently