Position: CMC Quality Assurance Manager

Reports to: Head of Quality
Location: Remote – Seattle area

Blaze Bioscience is the Tumor Paint Company® developing technology to improve surgery through real-time, high-resolution visualization of cancer. Our first Tumor Paint product candidate, BLZ-100, is being evaluated in a pivotal clinical study in pediatric brain cancer, and the manufacturing process is currently being validated in preparation of an NDA filing. BLZ-100 is a conjugated peptide drug with a fluorescent dye beacon.

We are seeking an experienced Quality Assurance representative who will provide oversight for cGMP activities occurring at Blaze's contract manufacturing organizations (CMOs) and will maintain internal controlled documents (including policies, procedures, and specifications).

This position will assist in or have responsibility for the following:

- Management of Blaze Quality Management System deliverables associated with drug development
- Participate as the Quality SME on cross-functional teams developing process control strategies and performing risk assessments
- Track CMO performance for Senior Management Review meetings
- Provide oversight of quality activities occurring at contract manufacturing organizations (CMOs) including but not limited to the following:
    - Auditing CMOs and maintaining audit program
    - Participate in weekly meetings and provide insight on behalf of Quality
    - Review, approval, and tracking of CMO Quality events (deviations, non-conformances, CAPAs)
    - Review and approval of master and executed batch records
    - Review and approval of product-specific test methods and method validation documentation
    - Participate in risk assessment activities (e.g., FMEA) and review and approve resultant reports
    - Review Quality Agreements
    - Review and approval of specifications
    - Review and approval of process validation documentation
- Creation and management of internal disposition documentation
- Author and/or approve internal CMC Quality events (including Deviations and CAPAs), procedures, policies, and forms
- Review and approval of internal reference standard qualification protocols and reports, and certificates of analysis
- Review and approval of master specifications, including justification of specification documentation
- Assist in authoring, reviewing, and approving regulatory submissions (e.g., IND updates)

Candidates should have relevant education and experience, including:

- Minimum: Bachelor's degree in Chemistry, Biochemistry, or a related field with at least 5-6 years of Quality Assurance experience.
- Comprehensive working knowledge of Good Manufacturing Practices (cGMPs) and Regulatory Guidance Documents (US and EU)

- Experience managing contract manufacturing organizations, including auditing.
- Experience authoring and reviewing controlled documentation.
- Previous experience in late stage and commercialization desired.

Special skills/knowledge:

- Self-motivated and ability to effectively prioritize and deliver high-quality results on tight timelines
- Excellent written and verbal communication skills
- Accuracy and attention to detail
- Excellent cross-functional team participation skills
- Ability to travel on a periodic basis

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

Blaze Bioscience, Inc.
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530 Fairview Avenue N, Suite 1400
Seattle, WA 98109
Email: careers@blazebioscience.com

Blaze Bioscience, Inc. is an Equal Opportunity Employer.