



QA Manager

Ayana Bio

Ayana Bio leverages cellular technology to produce bioactive ingredients that support health and wellness. Ayana Bio collaborates with global industry leaders in food & beverages, consumer-packaged goods, brands, supplements, specialized nutrition, animal care, and cosmetics to bring standardized plant and fungal bioactives to market. We provide consumers with confidence in quality and reliability. Ayana Bio has partnered with Ginkgo Bioworks, a synthetic biology platform company that is redesigning the living world to solve some of the globe's growing challenges in health, energy, food, material, and more. Ayana Bio is backed by Viking Global Investors and Cascade Investment to democratize nature's bioactives in a way that is standardized, safe, and sustainably sourced. For more information visit www.ayanabio.com.

General Role Description

Quality is a foundational pillar of Ayana Bio. This role will serve as an integral part in commercializing Ayana Bio's products. The successful applicant will develop a QA/QC program that helps Ayana Bio meet our internal expectations and those of our customers. This role reports to the Head of Commercial Operations. This position is full-time and located in Boston, MA or Aliso Viejo, CA.

Responsibilities

- Develop a Quality program including the implementation of a QMS
- Direct, plan and execute Ayana Bio's QA and QC activities and ensure they align with the company's business goals
- Define priorities, delegate responsibilities and plan quality operations globally, including batch record review and product release
- Provide leadership and support for the company to establish and maintain an industry-leading culture of quality
- Maintain QA program and ensure vendors & CMO partners are meeting Ayana Bio's Quality requirements
- Create and enforce Quality Agreements with CMO partners
- Develop and manage the QA/QC budgets
- Determine, implement, and manage a balanced pool of internal and external resources that meets company quality/product safety needs including 3rd party testing labs
- In collaboration with Platform, Process Development and Product Development, define and develop 'fit for purpose' QA support for innovation and process technology programs
- Work with supply chain, operations and various other functions to streamline business processes. Take ownership of business processes that involve quality and product safety
- Ensure QC work (analytical and non-analytical) meets quality and timing expectations to support operations
- Author, review, and update relevant company's SOPs and maintain the document control system
- Liaise with inspectors for audits (internal and external) to maintain GMP compliance
- Represent the company with government agencies, vendors, and customers



- Support regulatory efforts for the company in all product lines
- Communicate QA & QC goals and progress with executive management and external partners as needed
- Provide strategic input to Product Development, Manufacturing, and Platform Development initiatives to align with quality plans and budgets
- Manage 3rd party testing laboratories including sample logistics

Qualifications

The successful applicant will have:

- A Minimum of Bachelor's Degree (Biology, Microbiology, Chemistry, or related fields) with 5 years industry experience
- A working knowledge of 21CFR117 and 21CFR111 FDA regulations
- A working knowledge of FSVP (preferably already certified)
- Superior reading and writing skills
- Demonstrated leadership
- The ability to communicate effectively to all levels of the organization
- An approachable demeanor and strong interpersonal skills; the ability to facilitate positive interactions between different departments and employees
- The ability to work well on dynamic teams
- Integrity and an ability to build trust with a team
- The ability to effectively work on different projects in parallel
- A deep knowledge of cGMP
- The ability to learn and determine the FDA and other country regulatory guidelines
- >5 years of quality experience in the food or dietary supplement industries
- >3 years in a Quality management role
- A track record working in an operations environment and managing Quality activities involving contract manufacturers in the food and dietary supplement industries

We also feel that it's important to state the obvious here: Our industry lacks diversity, and that needs to change. Our goal is to help drive that change. Ayana Bio is deeply committed to diversity, equity, and inclusion in all its practices, especially when it comes to growing our team. Our culture promotes inclusion and relishes the opportunity to work with people from all walks of life.

We are developing a powerful biological engineering platform and must remain mindful of the many ways our technology can – and will – impact people around the world. We care about how our platform is used. Having a diverse team to build our platform gives us the best chance to create something we'll be proud of as it continues to grow. It is critical that we incorporate diverse voices and visions to create a more equitable future of biology.

It is the policy of Ayana Bio to provide equal employment opportunities to all employees and employment applicants.

Applying for This Position

Please send your CV to careers@ayanabio.com. Write "QA Manager" in the subject line. You will receive an application form to fill out if you are selected for an interview. Thank you!