Job Details

Manager/Sr. Manager, Regulatory Affairs

Job Code: 25REG-1MSM
Status: Exempt, Full Time
Reports to: Vice President, Regulatory Affairs & Quality Assurance
Department: Regulatory & Quality Assurance
Contact: careers@actiobio.com

About Us!

Actio Biosciences, Inc., is a drug discovery and development company grounded in the science of precision medicine. Actio is developing a portfolio of drugs to modulate the activity of proteins responsible for rare diseases with the goal to also translate these findings into treatments for common diseases with shared underlying disorders. Actio has built an integrated discovery engine with deep human genetics, bioinformatics, and drug discovery expertise. Actio was founded in October 2021, and is funded by Canaan, Deerfield Management, Droia, EcoR1 and Euclidian Capital.

Come join an exciting and rapidly growing team dedicated to discovering transformational therapies for patients with severe unmet medical needs. At Actio, our employees are passionate about their work and believe in the power of teamwork, collaboration, and mutual respect.
Visit: www.actiobiobiosciences.com

About You!

We are seeking an organized Manager/Sr. Manager, Regulatory Affairs ("Manager, RA") who will partner with VP, Regulatory Affairs & Quality Assurance to oversee and provide key support to the Regulatory Affairs department and pipeline programs. This position has responsibility for experience-based regulatory leadership, coordination, review and assembly of regulatory submissions and documents for health authorities (US FDA and global equivalents). The Manager, RA may serve as a regulatory study or program lead, with responsibility to contribute to and implement regulatory strategy, interpret guidance and ensure regulatory compliance for assigned projects. The ideal candidate should have an advanced knowledge of at least one functional discipline (e.g., Clinical, Nonclinical, Clinical Pharmacology or Chemistry Manufacturing and Controls) and a working knowledge of the other disciplines. This is a unique opportunity to be part of a growing and talented team that is committed to operational excellence.

You will be responsible for:

- In collaboration with the Vice President, Regulatory Affairs & Quality Assurance, oversee the planning and execution of submissions and responses to regulatory authorities, while maintaining clear communication of important project decisions or issues.
- Provide regulatory support and guidance to various cross-functional teams, ensuring all applicable regulatory requirements are considered and appropriately incorporated into activities and deliverables for clinical and commercial products and programs.
- Assist regulatory management, project teams and Clinical Research Organization (CRO) counterparts in the development of regulatory strategy, implementation of regulatory plans, timely delivery, and submission of regulatory documentation or information necessary to health authorities in accordance with regulations, guidelines or queries.
- Research and identify regulatory risks and provide recommendations for risk-benefit assessments and risk mitigations.

- Develop, maintain, and communicate timelines for regulatory submissions in collaboration with CROs, Project Management or independently based on project deliverable.
- Oversee CRO counterparts for delegated regulatory activities for assigned projects (e.g., review of submissions, TMF filing), to ensure alignment with project plans.
- Present and lead kick-off and project-based meetings related to regulatory submissions, strategy, and comment resolution.
- Author and edit regulatory documents (e.g., forms, cover letters, meeting requests, query responses).
- Participate in the review of critical documents (e.g., protocols, ICFs, IBs, CSRs, DSURs) to ensure compliance with regulatory obligations, relevant regulations, and guidance.
- Maintain archival copies of health authority submissions (e.g., IND, CTA, NDA, and MAA), correspondence and a record of health authority obligations, and commitments.
- Maintain current knowledge of applicable US and global regulations, guidance, and standards for drug development and product registration. Inform team members of new applicable guidelines and conduct training sessions on new guidelines/regulations if necessary.
- Execute assigned projects in alignment with department, leadership and company goals while independently planning daily work tasks to complete projects on time. Proactively seek guidance on priorities as needed.
- Create or contribute to Standard Operating Procedures (SOP) and training Materials for Regulatory department activities. Review SOPs for other departments as requested.
- Mentor and train junior staff and other members of the team.
- Contribute to a work environment that fosters support, collaboration, professionalism, mutual respect, and focus on unmet patient needs.

You have the following qualifications, skills & abilities:

- Bachelor's degree in health/life sciences or related field required; advanced degree (MS, PhD, PharmD, or MBA) preferred.
- Minimum 6 – 8 years' experience working in Regulatory Affairs in the biotechnology or pharmaceutical industries.
- Small to mid-sized biotech organization experience required.
- Experience in Regulatory project management with knowledge of the drug development process, clinical trials and US and ex-US requirements regarding content and format of health authority submissions.
- Previous experience with IND filings or maintenance and eCTD formatted submissions required.
- Direct experience maintaining an in-house repository for archiving regulatory submissions and health authority correspondence in 21 CFR Part 11 compliant system (e.g., Veeva) preferred.
- Experience with pediatric, rare disease, neurology, or genetic disorders (as relevant to the company's pipeline) preferred.
- Knowledge of FDA and/or EMA Regulations (or relevant local regulations), ICH Guidelines, and GCP governing the conduct of clinical development activities.
- Strong attention to detail and time management skills are essential to work on multiple tasks and prioritize to meet company objectives.
- Superior communication skills: oral & written, with proven negotiation skills, and strong ability to distill and effectively communicate key information to the intended audiences.
- Creative problem solver with the ability to address issues quickly and independently.
- Clear understanding of the critical path and a drive to find solutions to meet or exceed timelines.
- Demonstrated ability to collaborate effectively with cross-functional teams including research, clinical, and CMC.
- Ability to work independently in a fast-paced, dynamic environment and to lead through influence.
- Ability to take ownership of a given assignment, proactively consult and collaborative with other project team members and department representatives for information or guidance, as necessary.

- An equivalent combination of education and experience sufficient to successfully perform the job duties as listed above is acceptable.

Why Actio?

The work culture at Actio fully embraces teamwork, collaboration, and mutual respect. We believe that our employees are our greatest asset, and we strive to create an inclusive and empowering environment where everyone feels valued and respected for who they are. We encourage our employees to bring their unique perspectives and experiences to the table, and we believe that this diversity is what makes us stronger as a team. We invest in supporting our employees to succeed both at work and at home, and we believe that a good work-life balance is essential for everyone's well-being. If you thrive in an environment where you are inspired by others and empowered to participate to your fullest potential alongside exceptionally talented and kind human beings - - -Actio is the place for you!

We are committed to ensuring all employees, both current and future, receive fair and equitable pay. Base pay is one component of the total compensation package, and is determined within a range according to role, level, and location. This provides the opportunity for growth as you gain experience and develop within a role, while also allowing for differentiation based on performance. The base pay range for this role is between **$143,000 and $176,000** and reflects our good faith estimate of the minimum and maximum target for the position as of the date of posting and may be modified in the future. The final base pay within the range will be determined by work location and additional factors, including job-related skills, experience, relevant education or training, and market demand for your expertise.

Benefits programs offered include:

- Medical, dental and vision insurance (employee premiums covered by Actio at 90%)
- Health Savings Account with a rich employer contribution
- Flexible Savings Account for healthcare and dependent care
- Mental health and wellness benefits
- 401k plan participation
- Equity Incentive Plan participation (stock options)
- Life/AD&D/ST and LT Disability Insurance (premiums covered by Actio at 100%)
- Supplemental benefits including legal service, pet insurance and other optional coverage
- Weeklong winter holiday shutdown
- Generous paid time off and holiday policies
- Parental, caregiving, and various leaves programs
- Flexible and dynamic work environment where unique strengths of employees at all levels are cultivated
- Regular company events and opportunities to participate in team-building gatherings and activities designed to foster open communication and engagement

Details of participation in these benefit plans will be provided with an employment offer. Actio benefits and compensation programs are subject to eligibility requirements and other terms of the applicable plan or program.

Actio is committed to building a diverse workforce and providing equal employment opportunities to all employees and applicants for employment. We prohibit discrimination and harassment of any kind based on race, color, sex, religion, sexual orientation, national origin, disability, genetic information, pregnancy, or any other protected characteristic as outlined by federal, state, or local laws.

The above is intended to describe the general content of, and requirements to perform this job. It is not to be construed as an exhaustive statement of duties, responsibilities, or requirements.

To apply, please send your CV/resume and cover letter by email to: careers@actiobio.com, and reference **Job Code #: 25REG-1MSM** in the subject field.