Job Title	Senior Director, Head of Quality Assurance
Position Type	Full-Time
FLSA	Exempt
Department	Tech Ops/CMC
Reports To	Vice President, Tech Ops
Salary Range	$264,000 - $291,000

Job Summary:

The Senior Director/Director of Quality Assurance will lead quality strategy and compliance activities across GCP, GLP, and GMP for Atrium's advancing pipeline. This role is responsible for ensuring adherence to global regulatory requirements, implementing robust quality systems, and driving training and compliance programs to support clinical and manufacturing operations. The ideal candidate will have extensive experience in quality assurance for clinical and manufacturing environments, strong leadership skills, and a proven ability to manage internal teams and external partners in a small biotech environment.

Job Responsibilities:

- Develop and lead QA strategy for GCP, GLP, and GMP compliance across all phases of development.
- Oversee implementation and maintenance of quality systems, including SOPs, training programs, and compliance monitoring.
- Ensure QA oversight of clinical trials, manufacturing operations, and vendor activities.
- Manage internal QA team and provide leadership for quality-related initiatives.
- Partner with Clinical Operations, CMC, Regulatory Affairs, and CMOs/CROs to ensure compliance with applicable regulations.
- Lead inspection readiness activities and support regulatory inspections (FDA, EMA, and other authorities).
- Drive continuous improvement initiatives in quality systems and compliance processes.
- Oversee training programs to ensure staff and vendor compliance with GCP, GMP, and other applicable standards.
- Author and review QA-related sections of regulatory submissions, including INDs, amendments, and BLAs.
- Identify and mitigate risks related to quality and compliance impacting clinical and commercial programs.
- Ensure adherence to FDA, EMA, ICH, and Atrium policies and procedures.

Education and Experience Requirements:

- Bachelor's degree in life sciences or related field required; advanced degree preferred.
- Minimum 10 years of pharmaceutical/biotech industry experience in Quality Assurance, with expertise in GCP and GMP compliance.
- Proven experience managing QA teams and external partners.
- Strong knowledge of global regulatory requirements (FDA, EMA, ICH) for clinical and manufacturing operations.
- Experience supporting regulatory inspections, authoring and reviewing Quality Agreements with third parties and authoring QA sections of submissions.
- Excellent leadership, communication, and problem-solving skills.
- Ability to manage multiple priorities in a fast-paced environment.
- Demonstrated ability to build and maintain effective cross-functional relationships.

Knowledge, Skills and Abilities:

- Excellent interpersonal skills, ability to work in a matrix environment and develop relationships with key stakeholders.
- Excellent communication and presentation skills to efficiently relay information to staff, project teams, executive leadership and other key stakeholders
- Proven ability to work independently and be self-motivated

Work Environment & Physical Requirements

- This position operates in a professional office and/or laboratory environment.
- Standard office equipment such as computers, phones, photocopiers, filing cabinets, and fax machines are used regularly.
- The role may occasionally require work in controlled laboratory or manufacturing settings, following applicable safety and PPE requirements.
- Noise levels are generally low to moderate, consistent with office or lab environments.
- Some roles may involve occasional travel between company sites or to external meetings, conferences, or events.
- Prolonged periods of sitting at a desk and working on a computer.

- Frequent communication with others, including speaking, hearing, and seeing to exchange accurate information.

- Occasional standing, walking, bending, or reaching may be required.

- Must be able to lift up to 20 pounds occasionally (e.g., office materials or lab supplies).

- Specific roles may require the use of specialized lab equipment, manual dexterity, or fine motor skills.

- Many of the essential functions of this role are captured by the Job Responsibilities, Knowledge, Skills and Abilities, Work Environment and Physical Requirements. The company is committed to providing reasonable accommodations to qualified individuals with disabilities to enable them to perform the essential functions of their jobs, in accordance with applicable federal, state, and local laws.

- Job descriptions are intended to describe the general nature and level of work performed; they are not an exhaustive list of all responsibilities, duties, and skills required. Other duties may be required