Associate Director or Director
Regulatory Strategy (Clinical & Nonclinical)

Job Title: Associate Director or Director, Regulatory Strategy (Clinical & Nonclinical)
Department: Regulatory
Reports To: VP of Regulatory
Location: Remote or Onsite

Position Summary:

The **Associate Director / Director, Regulatory Strategy (Clinical & Nonclinical)** will lead global regulatory strategy and execution for the company's gene therapy programs from early research through clinical development and commercialization. This individual will be responsible for developing nonclinical and clinical regulatory strategies, supporting regulatory submissions, and serving as the regulatory liaison to internal nonclinical and clinical teams.

This role requires strong experience in regulatory strategy for biologics or gene therapies and the ability to work cross-functionally with clinical development, clinical operations, nonclinical, quality and program leadership. This individual will also support interactions with global regulatory authorities such as the U.S. Food and Drug Administration and the European Medicines Agency.

Key Responsibilities:

Regulatory Strategy Development

- Develop and implement global regulatory strategies for gene therapy programs from preclinical through clinical development and commercialization.
- Provide regulatory guidance on nonclinical, clinical, and translational development plans.
- Identify regulatory risks and propose mitigation strategies to support program timelines.
- Contribute to overall product development strategy and lifecycle planning.

Regulatory Submissions

- Lead preparation and submission of global regulatory filings including: INTERACT and PreINDs, INDs and IND amendments, CTAs and IMPDs, orphan drug designation applications, Fast Track, RMAT and other expedited program submissions
- Ensure high-quality regulatory documentation aligned with agency expectations.

Health Authority Interactions

- Prepare regulatory briefing documents and support agency meetings.
- Serve as a subject matter expert for interactions with agencies including the FDA and EMA.
- Coordinate and author responses to health authority questions and information requests.

Cross-Functional Collaboration

- Partner closely with internal teams including: Clinical Development, Clinical Operations, Nonclinical, Quality
- Serve as a regulatory representative on cross-functional program teams.
- Ensure alignment of development plans with global regulatory requirements.

Regulatory Intelligence & Compliance

- Monitor evolving regulations and guidance related to gene therapies and biologics.
- Interpret guidance documents and communicate regulatory expectations internally.
- Contribute to development of internal regulatory processes and best practices.

Qualifications:

Education

- PhD, PharmD, MD or MS in life sciences, molecular biology, pharmacology, or related discipline.

Preferred Qualifications

- Direct experience with AAV, lentiviral, or other gene therapy platforms.
- Experience with rare disease development programs.
- Experience with global regulatory submissions including US and EU.
- Prior participation in regulatory agency meetings.

Associate Director Experience

- 7–10 years of experience in regulatory affairs within biotech or pharmaceutical industry.
- Experience supporting INDs, CTAs, and early clinical development.

Director Experience

- 10–15+ years of experience in regulatory affairs with demonstrated leadership of regulatory strategy for development programs.
- Proven experience leading regulatory submissions and interactions with agencies.

Knowledge & Skills

- Strong understanding of regulatory pathways for biologics and gene therapy products.
- Experience with nonclinical regulatory requirements for biologics.
- Excellent regulatory writing and communication skills.
- Ability to lead cross-functional teams and influence program strategy.
- Strong project management and organizational skills.

Key Competencies

- Strategic thinking and problem solving
- Strong scientific and regulatory knowledge
- Cross-functional leadership and collaboration
- Clear communication and influence
- Ability to work in a fast-paced, early-stage biotech environment