



## Associate Director or Director CMC Regulatory Affairs

**Job Title:** Associate Director or Director, CMC Regulatory Affairs

**Department:** Regulatory

**Reports To:** VP of Regulatory

**Location:** Remote or Onsite

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### Position Summary:

The **Associate Director / Director, CMC Regulatory Affairs** will lead global CMC regulatory strategy and execution for the company's gene therapy programs from early research through clinical development and commercialization. This role is responsible for developing CMC regulatory strategies across product development stages, supporting regulatory submissions, and serving as the regulatory liaison to internal CMC teams and external contract manufacturing organizations.

The individual will work cross-functionally with process development, analytical development, manufacturing, quality, and program leadership to ensure that CMC development plans meet regulatory expectations for gene therapy products. The role will also support interactions with global regulatory authorities such as the U.S. Food and Drug Administration and the European Medicines Agency.

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### Key Responsibilities:

#### CMC Regulatory Strategy

- Develop and implement global CMC regulatory strategies for gene therapy programs from early development through clinical stages and commercialization.
- Provide regulatory guidance on viral vector manufacturing, process development, analytical characterization, and product comparability.
- Assess regulatory risks related to manufacturing changes and propose mitigation strategies.

#### Regulatory Submissions

- Lead preparation and review of CMC sections of global regulatory submissions, including: INDs and IND amendments, CTAs and IMPDs, BLA/MAA submissions and supplements, annual reports and regulatory updates
- Ensure submissions meet regulatory expectations for gene therapy products.

#### Health Authority Interactions

- Prepare CMC regulatory briefing documents and support agency meetings.
- Serve as the subject matter expert for CMC topics during interactions with agencies including the FDA and EMA.
- Coordinate and author responses to regulatory agency questions related to CMC.

#### Cross-Functional Collaboration

- Partner closely with internal teams including: Process Development, Analytical Development, Manufacturing, Quality
- Serve as the CMC regulatory representative on cross-functional program teams.

- Provide regulatory guidance for manufacturing changes, comparability strategies, and lifecycle management.

### **Regulatory Intelligence & Compliance**

- Monitor evolving regulatory guidance related to gene therapy and advanced biologics.
  - Interpret regulatory requirements and communicate implications to internal teams.
  - Support development of internal regulatory policies and processes.
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### **Qualifications:**

#### **Education**

- PhD or MS in biochemistry, molecular biology, chemical engineering, pharmaceutical sciences, or related field.

#### **Preferred Qualifications**

- Direct experience with AAV, lentiviral, or other gene therapy platforms.
- Experience supporting late-stage development or BLA/MAA submissions.
- Familiarity with global regulatory frameworks for advanced therapy medicinal products (ATMPs).
- Prior experience participating in regulatory meetings.

#### **Associate Director Experience**

- 7–10 years of experience in regulatory affairs and CMC.
- Experience contributing to CMC sections of IND/CTA submissions.

#### **Director Experience**

- 10–15+ years of experience in regulatory affairs with leadership responsibility for CMC regulatory strategy.
- Demonstrated experience leading CMC regulatory submissions and health authority interactions.

#### **Knowledge & Skills**

- Strong knowledge of global CMC regulatory requirements for biologics and gene therapies.
- Understanding of viral vector manufacturing processes.
- Experience with analytical characterization, comparability, and manufacturing changes.
- Excellent regulatory writing and communication skills.
- Ability to work effectively in a fast-paced startup environment.

#### **Key Competencies**

- Strategic thinking and problem solving
- Strong scientific and regulatory expertise
- Cross-functional leadership
- Excellent communication and collaboration skills
- Ability to manage multiple programs and timelines