Byte

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Associate Director Director Regulatory Affairs

Hiring organization
Cogent Biosciences

Job Location
Remote

Base Salary
$ 62500 - $ 107500

Date posted
June 9, 2024

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Description

We are looking for an Associate Director or a Director, Regulatory Affairs who will be responsible for day-to-day regulatory activities of early/late phase investigational products, leads the writing and submission of IND/CTA/amendments and future marketing application submissions, provides guidance to the team on regulatory filings and responses, and provides critical regulatory intelligence and guidance back to the team. This role participates in a cross-functional team, partners with key internal/external team members/stakeholders, and partners with Regulatory CMC and Regulatory Operations to ensure the scientific data and submissions fulfills agency expectations in a compliant manner. This position will report to the Senior Director, Head of Global Regulatory Affairs.nWhat You Will DoProvide input and regulatory support to cross-functional development teams responsible for the translation, development and registration of Cogent's productsDevelop and execute regulatory strategy in support of overall program goals and objectivesProvide day-to-day management of all regulatory aspects of ongoing and planned clinical development programsLead the coordination, preparation and timely submission of regulatory documents and responses to queries from authorities (e.g., INDs, NIH/RAC submissions, BLAs, MAAs)Contribute to the development of regulatory content to support regulatory agency submissionsCoordinate with external publishing resources for on-time delivery of high-quality regulatory submissions to regulatory agenciesEstablish relevant processes and procedures to support the Regulatory Affairs function activitiesInitiate and prepare regulatory agency correspondences to facilitate expedient and efficient product development and registration of assigned productsStay up-to-date on changes in regulatory guidelines and best practices that may impact Cogentâ??s product candidatesCreate plans to meet regulatory requirements, anticipate regulatory changes, build relationships with regulatory agencies, oversee regulatory submissions, and ensure compliance for Cogent's product candidates pre and post-approvalWhat You Will BringBachelorâ??s, Masterâ??s or PhD in a scientific or medical discipline with a minimum of 6 years in Regulatory Affairs in a pharmaceutical, biotechnology, contract research organization (CRO) or related industry is required.Experience with leading major submissions and health authority meetingsDemonstrated, hands-on experience, managing and preparing regulatory submissions especially Clinical Trial Applications outside of North America with a primary focus on European applications through the Clinical Trials Information System (CTIS).Strong competency in understanding global regulatory requirements and the emerging regulatory landscape.n$145,000 – $235,000 a yearDependent on level and experiencenPlease mention the word **IMPRESSIVELY** and tag RMzUuMjQ1LjkzLjIxMg== when applying to show you read the job post completely (#RMzUuMjQ1LjkzLjIxMg==). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

Contacts

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