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Regulatory Affairs Director-Drug Development

Hiring organization
BioLink 360

Employment Type
Full-time

Job Location
Denver, CO

Date posted
January 16, 2025

Description

Position Title: Regulatory Affairs Director-Drug Development
Location: Colorado
Position reports to: VP of Drug Safety
Salary Range: 195K-235K

This company is focused on transforming the treatment of disease with a novel integrated platform. The person hired for this position will develop and implement regulatory strategy leading to successful registration and life-cycle management and provide strategic guidance related to regulatory requirements for clinical trial and marketing applications for development projects. The incumbent will be accountable for delivering high quality strategies and processes that align with the company's strategic goals.

Responsibilities

- Responsible for content development, compilation, maintenance, and review of the Nonclinical and Clinical Modules for regulatory submissions
- Provide guidance to all appropriate departments to assure compliance with applicable regulations, remain knowledgeable of current regulations and guidance, provide thoughtful interpretation of same and notify appropriate personnel

- Serve as the sponsor point-of-contact to regulatory bodies and/or external regulatory consultants or CRO regulatory representatives.
- Devise and implement regulatory strategies for clinical trial applications/amendments, responses to health authority queries, and health authority interactions in partnership with cross-functional stakeholders.
- Analyze international (ICH) and country-specific guidelines, national regulations, and clinical trial / marketing application procedures, and translate complex scientific/technical information into concise written documents and presentations.

Qualifications

- BS/BA degree (or equivalent) in a relevant scientific field required; advanced degree (MS or PhD) is preferred.
- 10+ years of experience in regulatory affairs and lifecycle management within the pharmaceutical or biotechnology industry is a must,
- 3+ years of experience in management/leadership roles.
- Experience in Oncology, cell/gene therapy, combination products, or small molecules.