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Manager/Senior Manager US Regulatory Affairs - Global Development Projects

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Location: Florham Park

Category: other-general

Title: Manager/Senior Manager US Regulatory Affairs - Global Development Projects

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Start Date: ASAP

Leading Pharmaceutical Company located in NJ is hiring a Manager/Senior Manager US Regulatory Affairs - Global Development Projects with 5+ years industry experience. If you want to be a part of this groundbreaking work, please apply!

Responsibilities:

Provide regulatory strategy and tactical support for assigned projects.

Contribute to developing global/regional regulatory strategies for multiple clinical development projects at all stages (Pre-IND through NDA submission and approval).

Support and perform with limited oversight larger submissions, such as IND applications and NDAs, including organizing the submission development and review process and timeline, preparing sections, reviewing for completeness, accuracy, and appropriateness.

Minimum Requirements:

Bachelor's degree in science (e.g. Chemistry, Pharmacy, Biochemistry). Master's degree in science related field strongly preferred.

Minimum of 6 years of pharmaceutical industry experience with at least 4 of those years in Clinical Development Operations and Regulatory positions.

Working knowledge and experience in regulatory submissions and product life cycle management.

Broad range of experience to include Pre-IND and Phase I clinical development through NDA filing is sought (though not necessarily with same compound).

Knowledge of drug regulations and guidance's with ability to apply them to complex regulatory issues and requirements.

Ability to simultaneously plan, coordinate and lead activities on multiple projects.

Ability to self-direct workload, including reprioritizing and delivery under tight timelines.

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