

Investigator's Brochures and the pharmacology section of INDs and CTAs

Interact with regulatory agencies (US and ex-US) as needed.

You will be accountable for all clinical pharmacology aspects of compounds in the discovery to early development stage.

You will be responsible for oversight and interaction with consultants and CROs assigned to support clinical pharmacology tasks including preclinical PK, modeling, and clinical assay development.

Experience:

PhD or PharmD required.

>5 years of experience in Clinical Pharmacology supporting early development of biologics in a biotech or pharmaceutical organization.

clinical pharmacology experience with biologics in oncology is required.

with regulatory submissions and responses in early development is required.

with model-informed drug development preferred.

working on T-cell based therapeutics, particularly multi-specific T-cell engagers is preferred.

All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity/expression, national origin, disability, medical condition, age, marital status, status as a protected veteran, or any other legally protected characteristic.

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