# **United States Jobs Expertini®**

# **Clinical Pharmacology Leader**

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Company: Christine Mathews Consulting, a OneDigital Company

Location: Philadelphia

Category: other-general

\*\*Remote, Hybrid or onsite Philadelphia, PA\*\*

#### Company Background:

discovery and development of breakthrough biologics in Oncology and Immunology. This small but experienced team is currently expanding headcount to support the next phase of growth through IND submissions and clinical development.

#### **Position Summary**

with a responsibility for the ClinPharm package, connecting the project from discovery and preclinical PK into FIH studies. In this role, you will support IND preparation, work with the clinical team to set first in human dosing strategies, and continue with the teams into early development to support clinical PK/PD and optimal dose selection.

#### **Essential Functions:**

As part of the R&D development team, you will provide expertise to the overall preclinical and clinical development of novel biologics, in particular the design and oversight over clinical pharmacology.

Provide input into clinical development plans, clinical study protocols and reports,

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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## **Cross References and Citations:**

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