Amolyt Pharma is expert in therapeutic peptides development. The team's mission is to deliver life-changing treatments to patients suffering from rare endocrine and metabolic diseases.

We are looking for a highly motivated and innovative candidate for the role of

Non-Clinical Manager

The candidate will be responsible for the vendor management, the protocol development, the study implementation and the report writing. The right candidate will be a strategic thinker that brings a leadership presence and enthusiasm for the company along with a deep scientific knowledge.

This role reports to the director preclinical development and is based in Ecully, France.

Responsibilities:

- Prepare scope of work and solicitate proposals
- Assist in CRO selection
- Manage study contracts, budgets, purchase orders, invoices
- Ensure prioritization at CROs align with internal objectives and priorities
- Monitor established KPIs to ensure best practices for vendors
- Develop detailed study protocols
- Assess technical ability of CRO to meet study objectives and coordinate development of additional technical tools when deemed necessary
- Resolve scientific or logistical concerns with CRO regarding components of study protocols
- Ensure the protocol meets GLP expectations and protocol-related documentation is available to the CRO prior to study start
- Manage study achievements and metrics to ensure delivery study milestones
- Visit CRO during critical phases of the study to ensure technical capabilities are adequate and procedures match the protocol
- Interact with CRO as the first line of contact for any study-related issues. Make the initial determination of the impact of the issue on the integrity of the study
- Review and QC nonclinical toxicology, pathology, and DMPK data and reports
- Coordinate and monitor the internal review and interpretation of study data
- Prepare summaries and updates for internal communication to project team and management
- Compile all report comments and assure they are conveyed to the Study Director before finalization
- Integrate and assemble toxicology information for regulatory documents (CTA, IND/CTD, IB)

The candidate:

- PharmD, VetD, Master degree in Biology, Animal Sciences, Toxicology or a related field
- > 3 years of experience as a toxicology study director/monitor in pharma, biotech or CRO setting
- Understands the purpose, components and outcomes of drug development and safety assessment
- Expertise in management of nonclinical study conduct, including the fundamentals of Good Laboratory Practices (GLP) and data interpretation of nonclinical studies
- Understand the technical capabilities of individual CROs
- Fluent in oral and written English
- Excellent interpersonal and communication skills with ability to relate to both internal and external stakeholders

To apply, please check our website: https://amolytpharma.com/careers/