Job Title: Director/Senior Director Toxicology

Reports to: Vice President, Early Development & Program Management

FLSA /Pay Grade: Exempt

Why Artiva

Over the past decade we have seen stunning advances in the cellular immunotherapy therapy field in particular, with dramatic rates of clinical response in hematological malignancies, and rapid evolution of our understanding of factors that could extend this success to solid tumors. However, these transformative therapies are often accompanied by severe and potentially life-threatening toxicities, and patient access is limited by such factors as complex, time-consuming patient-specific manufacturing, variable product quality, and cost.

Our Mission

At Artiva, our mission is to deliver highly effective cell therapies that are also safe and immediately available and accessible to any patient who stands to benefit.

Position Summary

Reporting to the Vice President, Early Development & Program Management, the Director/Senior Director of Toxicology, is responsible for oversite of the design, analysis, interpretation, and reporting of Safety Pharmacology and Toxicology data for Early Development Programs.

Role & Responsibilities

- Collaborate with Research and Development to develop integrated Safety Pharmacology and Toxicology program strategies.
- Represent function on project teams and regularly interface with internal stakeholders to ensure timely and accurate dissemination of Safety Pharmacology & Toxicology findings.
- Lead the conduct, interpretation and reporting of Safety Pharmacology and Toxicology studies/data.
- Critically evaluate toxicology results and provide strategic guidance to project teams and senior management on the potential impact of toxicology results on Program and Clinical/Regulatory strategy.
- Develop experimental strategy to understand the mechanisms of toxicity as needed

- Responsible for risk assessment of new targets
- Responsible for the preparation of Safety Pharmacology and Toxicology sections of regulatory documents (IND, CTA, BLA, briefing books, Investigator brochures, etc.)
- Interface with regulatory agencies as required
- Responsible for the preparation of data summaries and presentations of results to internal and external stakeholders, as required.
- Responsible for building and maintaining effective CRO and consultant relationships that support the execution of non-GLP and GLP toxicology/biodistribution studies.
- Review study protocols and draft study reports, providing feedback as needed and responsible for report finalization.
- Develop and implement SOP's to guide functional activities.

Experience, Education and Specialized Knowledge and Skills

Must thrive working in a fast-paced innovative environment while remaining flexible, proactive, resourceful and efficient. Ability to manage complex research and development functions and timelines through outsourced or partnered workflows is a requirement. Excellent interpersonal skills, ability to develop important relationships with key stakeholders, conflict management and negotiation skills, ability to analyze complex issues to develop relevant and realistic plans and recommendations. Demonstrated ability to translate strategy into action. Excellent analytical skills, ability to communicate complex issues in a simple way, and ability to orchestrate plans to resolve issues and mitigate risks.

- PhD in Toxicology, Pharmacology or closely-related discipline
- Minimum of 10 years of experience advancing drug discovery projects into development within a biopharma environment.
- Experience in cell therapy or immuno-oncology product development is a requirement.
- Outstanding organizational and interpersonal skills, and outstanding ability to manage relationships and influence others.
- Proven experience in designing non-GLP and GLP safety studies.
- Demonstrated ability to work closely with CROs and provide close oversight of vendors, budget planning and coordination.
- Hands on experience in relevant laboratory techniques.
- Willingness to be both a strategic leader and hands-on problem solver.
- Experience allocating resources and managing budgets.
- Proven knowledge of FDA regulations.
- Superior oral and written communication skills are required, and the ability to work effectively with senior management. Strong analytical and scientific writing skills.
- Strong creativity, independent thinking and results orientation is required.
- Must have high ethical standards and impeccable integrity.

- Strong people leadership abilities, including inspiring and motivating a high performing team, setting clear direction, enabling cross-functional collaboration, empowering people, and developing and coaching talent.
- Ability to understand stakeholder concerns and frame issues/proposals to influence decision making.

Competencies

- Decision Making
- Time Management
- Strategic thinker
- Operations Management
- Finance
- Human Resources
- Risk Management
- Business Planning
- Implementing Plans
- Analysis & Reporting
- Negotiation
- Leadership & Team Development

Attributes

- Honesty/Integrity
- Self-starter
- Creative/imaginative
- Self-controlled
- Positive
- Ambitious/driven
- Collaborative
- Communications
- Forward thinking
- Confident
- Intuitive
- Committed
- Agile
- Transparent

We look for talented, entrepreneurial people who share our values.

We are called to put the **safety** of our patients and employees first, and to act with **integrity** and the highest ethical standards. To achieve our mission, we must collaborate across the Company at all levels, and we must hold ourselves and our teams **accountable** for delivering the progress we commit to, on the timelines we set. We embrace **diversity**, we include people and their ideas, and we aspire to **excellence** by listening, understanding, sharing and responding. We want you to be fully **engaged**, to develop personally and professionally through this chapter in your life, and to have **fun** along the way.

Artiva Biotherapeutics is an equal opportunity employer that is committed to providing a work environment free of harassment and discrimination based upon a protected category, as well as an environment free from retaliation for protected activity.

Benefits

- The opportunity to work with a team of highly experienced professionals from clinical to regulatory to CMC to research and early development
- To be part of building a company on the cutting edge of cell therapy that may be a game changer to patients in a culture that is entrepreneurial, highly collaborative and innovative
- Competitive compensation, including bonus
- Equity program
- Health and welfare benefits – Medical, Dental, Vision, Life, 401K, EAP

To apply, please send cover letter and resume/CV to: hr@artivabio.com.