Jesse M. Lueth

SENIOR SCIENTIST I

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Mr. Jesse Lueth has 12 years of experience designing, coordinating, conducting procedures for, and monitoring *in vivo* toxicology studies in the pharmaceutical field. In addition, he is a co-author and reviewer of multiple SOPs for operational groups at a contract research organization (CRO) and was a subject-matter expert for an electronic data collection system.

Mr. Lueth has experience with a variety of therapeutic modalities, including small molecules, biologics, and gene therapies, for various indications (e.g., neurological, ocular, and infectious diseases). In addition, he has experience with advanced therapeutic dose administration routes (i.e., intrathecal, intraarticular, intraocular dosing).

Mr. Lueth is certified by the American Association for Laboratory Animal Science as a Laboratory Animal Technologist and Laboratory Animal Technician and is also certified by the Project Management Leadership Group, Inc., as a Project Manager. He has expertise in the generation and review of preclinical data, protocols, reports, and proposals.

As a member of ToxStrategies' Pharmaceuticals practice, Mr. Lueth supports sponsors throughout the conduct of studies, including study monitoring. He ensures compliance with appropriate requirements outlined in SOPs, GLP regulations, stipulations required by Institutional Animal Care and Use Committees (IACUCs), the Guide for Care and Use of Laboratory Animals, and regulatory guidelines. As an experienced scientist in the pharmaceutical field, he collaborates with study directors, technical staff, and subject-matter experts to provide scientific and technical guidance during study design and execution. In addition, he advises sponsors in decision-making steps by reviewing available scientific literature and data and offers input on modification options.

EDUCATION AND DEGREES EARNED

2009 Bachelor of Science, Genetics
University of Wisconsin, Madison

2005 Associate of Applied Sciences, Ethnic Studies
University of Wisconsin—Wood County, Marshfield

SELECTED PROFESSIONAL EXPERIENCE

In Vivo Behavioral Assays

In a laboratory setting, maintained lines of *Drosophila melanogaster* for behavioral and genetic studies and analyzed mutagenized *D. melanogaster* for behavioral defects. Designed and modified an experimental procedure for testing the presence of *D. melanogaster* muscle defects, discussed various hypotheses and results with peers, and presented data at lab staff meetings.

In Vivo Toxicology

Conducted *in vivo* study procedures in both GLP and non-GLP settings for large and small animal species, including rats, mice, dogs, swine, rabbits, and non-human primates, and prepared associated documentation. Conducted clinical observations, body weights, vitals, husbandry tasks, and dosing (e.g., gavage, intravenous injection, subcutaneous injection, ocular instillation, intramuscular injection), and assisted with surgical procedures, and anesthetic administration and monitoring. Procedures were conducted in accordance with governing SOPs, policies, protocols, and regulatory agency requirements, and to ensure compliance with standards of the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

Reviewed protocols and adapted techniques to new procedures. Maintained study records, reviewed data in real time, and monitored data trends for ongoing studies to prevent downstream quality events.

Maintained and expanded knowledge of regulatory, protocol, SOP, and client requirements for *in vivo* pharmaceutical studies. Responded to Quality Assurance inspection reports and maintained discrepancy tracking data in support of departmental improvement efforts.

Designed and wrote protocols for *in vivo* toxicology safety assessment studies for both small animal (rodent) and large animal (non-rodent) species at a CRO. Study types included small- and large-molecule toxicology studies, cellular and gene therapy studies, and studies for neurological and ocular indications. Subcontracted with test sites on behalf of Sponsors when requested. Reviewed proposals and provided suggestions for study designs based on regulatory guidance documents and previous industry experience.

Acted as a representative subject-matter expert for the data collection system used by a CRO.

Conducted client tours and meetings during study conduct, and also trained, assisted, and instructed supporting staff.

Project Management

Served as acting project manager for a lab facility expansion designed to house and execute cell and gene therapy *in vivo* studies for a large CRO. Coordinated with multiple teams, including both internal and external stakeholders, to both identify and complete deliverables for the project. Presented to executives on progress of the project at regular intervals.

PRESENTATIONS

Wood M, Mease K, **Lueth J**. Study monitoring: Expert approaches for a successful nonclinical program. Exhibitor-Hosted Session, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025.