Comparative Bioscience, Inc.

A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH

A contract research organization by scientists, for scientists.
CBI was founded in 1996 with two scientists and a histology technician in Santa Clara, CA. We have grown each year steadily from 3 employees to 30 employees and increasing and expanding our capabilities and areas of expertise. In 2004, we moved into our new state-of-the-art purpose built facilities in Sunnyvale, CA. Our clients range from the smallest virtual company to pharmaceutical giants, academia, and government.

Comparative Biosciences, Inc., a premier preclinical contract research organization (CRO), is committed to providing expert high-quality contract research services to all sectors of the biomedical community. Extensive experience in the biotechnology and pharmaceutical industries provides our staff with a solid track record in preclinical research and drug development capabilities.

Experience

Due to CBI’s unique and extensive experience and state-of-the-art facilities, we have the skill and expertise to accelerate new drugs from discovery thru the drug development process to regulatory submission. We are committed and dedicated to providing advanced preclinical and translational research and offer a complete range of services to the biomedical industries.

- Toxicology
- Pharmacokinetics
- Pharmacology and Efficacy
- Histopathology and Pathology
- GLP-compliance
- Regulatory Consultation
Toxicology Services

Comparative Biosciences, Inc. offers a complete program of preclinical research services in toxicology to support a range of assessments. Beginning with early assessment of new molecules including single dose, multiple dose, and targeted studies, as well as directed or investigative toxicology, and finishing with complete IND enabling toxicology programs, CBI provides expertise, attention, and care on every study. Our study directors are experienced, communicative, and attentive, and we produce high-quality GLP reports in a very timely fashion.

ALL TOXICOLOGY SERVICES INCLUDE:

- Acute, subacute and chronic studies
- Regulatory
- Discovery
- Investigative, custom and special toxicology
- Conventional and unusual routes of administration
- Small, large molecules, vaccines, stem cells, biologics, ocular, otic

Pharmacokinetic Studies

CBI provides a complete range of research services in the area of pharmacokinetic, toxicokinetic, bioavailability, bioequivalence, and ADME studies. We feature rapid study initiation and report preparation to meet sponsor deadlines or milestones. Our capabilities in pharmacokinetics include early exploratory, investigative, or screening studies, cassette dosing studies, juvenile studies, disease model studies, and formal studies that support regulatory submission. We offer most animal species, routes of administration, including unusual routes, disease models, and animal colonies.

PHARMACOKINETIC CAPABILITIES:

- Quick “mini-PK” studies (compound sparing for rapid assessment of new molecules in rodents)
- Oral, ocular, dermal, intra-tracheal, IV, IM, SQ, IP, short infusion routes, and unusual routes of administration
- Pharmacodynamic endpoints
- Hypothesis-directed or investigational studies
- Small molecules, proteins, antibodies
- Radionuclide studies
- Rodents, small animals, dogs
Pharmacology

CBI provides a range of pharmacology capabilities across a spectrum of indications that ensure reliable results in the drug-discovery process. Assessment and analysis modalities are fine-tuned to meet the specific requirements demanded in each targeted area of scientific investigation.

OUR SPECIALITIES IN PHARMACOLOGY AND EFFICACY MODELING INCLUDE:

- Ocular
- Cardiovascular
- Inflammation
- Dermatology
- Arthritis and Immune-Mediated Disease
- Atherosclerosis
- Metabolic and Bone
- Fibrosis
- Anti-infective Models
- X-ray Radiation
- Botulinum Toxin
- CNS and Pain
- Specialized, Customized or Surgical Models
- Heymann Nephritis
- Coagulation
- Wound healing
- Otic-ototoxicity
- Veterinary

ALL PHARMACOLOGY STUDIES INCLUDE:

- Experienced, highly-trained study directors
- Complete and comprehensive documentation
- High-quality reports
- Rapid report preparation
- All histology, immunohistochemistry and pathology performed in house by a board-certified pathologist
- All clinical pathology reviewed and interpreted by a board-certified pathologist

"TEAMWORK... THAT IS THE ONLY WAY TO EXPLAIN WORKING TOGETHER WITH CBI. WE ARE PARTNERS IN RESEARCH."

- N.A. (BERT) MASSIE, PH.D., PHOENIX RESEARCH LABORATORIES
Ocular Toxicology and Pharmacokinetics

CBI is the premier ocular toxicology CRO, offering a wide range of ophthalmic toxicology, pharmacokinetics and pharmacology, from exploratory proof-of-concept toxicity and tolerability studies, to complete preclinical GLP Toxicology, Safety and Pharmacokinetic Studies suitable for regulatory submission for ophthalmic drugs, biologics, and devices. Test article administration routes include topical ocular application, and injection routes including intravitreal, subconjunctival, periocular, intracameral, subretinal, intrascleral, transscleral, intrastromal, subtenon, retrobulbar, ocular implants or ocular devices.

- Ocular irritation, tolerability and sensitization studies
- Single, multiple-dose acute, subacute and chronic ocular toxicity
- Contact lens, medicated contact lens, punctal plug, device ocular implant toxicology
- Custom ocular toxicology-efficacy and combination studies
- Ocular histology and immunohistochemistry

Ocular Pharmacology

Validated ocular pharmacology models at CBI include:

Neovascular and vascular models
- Laser induced macular degeneration induction in mice, rats and rabbits
- Oxygen induced retinopathy in neonatal mice and rats
- STZ induced retinopathy in diabetic rats
- Angiotensin II induced retinal vascular leakage
- Corneal pocket or suture model
- Vegf-induced retinal vascular leakage
- Lacrimation assessment

Inflammation
- LPS-induced acute uveitis in rodents and rabbits
- F40 80-induced acute uveitis in rabbits
- Albumin-induced conjunctivitis in rabbits

Immune-mediated inflammation
- Melanin associated antigen induced anterior uveitis in rats
- IRBP or S-Antigen induced posterior uveitis in mice and rats

Neurodegeneration
- Optic nerve ligation or severance
- Increased intraocular pressure
- Light damage

Cornel ulceration or injury
- Heptanol or chemically induced corneal ulceration in rabbits
- Corneal inflammation and neovascularization in rabbits
- Corneal transplant
- Corneal pocket
- Corneal infection

Dry eye models
- Scopolamine-induced dry eye in mice
- Botulinum-induced dry eye in mice
- ConA-induced model in rabbits
- Glycopyrrolate-induced model in rabbits
- Benzalkonium chloride-induced model in rabbits

Glaucoma and ocular hypertension
- Laser induced glaucoma in rodents
- Glaucoma in rabbits
- Corticosteroid induced
- Water loading
- Chymotrypsin
Specialized Histology

CBI has a GLP compliant contract histology laboratory providing routine, specialized and customized histology, immunohistochemistry and pathology services. We are staffed by highly skilled, dedicated personnel that are specially trained in research and toxicology tissue preparation. Utilizing state-of-art equipment, these professionals are experts in preparation of rodents, small and large animals, primate and human tissues.

ALL ACTIVITIES ARE OVERSEEN BY ACVP PATHOLOGIST.

Our histology lab is fully capable of supporting the smallest and largest of projects from pharmaceuticals, biotechs, contract research organizations (CROs), and universities, among others.

• Routine and special strains
• Tissue cross reactivity
• Paraffin, frozen and plastics
• Digital image analysis
• Immunohistochemistry
• Specialized and translational histology

Pathology Services

Skillful and accurate interpretation of histology and pathology specimens is critical to consistent success in efficacy, pharmacology, and toxicology studies. The oversight of a board-certified pathologist is essential to evaluate both research and GLP histology and pathology specimens. Whether evaluating studies that are generated in house, evaluating contract histopathology studies that are sent in, or conducting peer review, CBI’s ACVP Board Certified Veterinary pathologists provide the highest quality contract research pathology interpretation services and report preparation. Our pathology reports based upon FDA Part 11 compliant pathology data acquisition systems to collect and manage pathology data, thereby assuring the highest quality assessment and reporting of pathology data.

PATHOLOGY CAPABILITIES:

• GLP toxicology studies with all species
• Contract necropsy
• Pharmacology and efficacy studies
• Peer-review studies
• Image analysis and histomorphometry
• Digital photomicroscopy
• Expert reports
• Timely and cost effective report preparation
• IND report preparation
• Validated, Part 11 complaint pathology data acquisition program
Consultation

Assembling expert professionals, developing premiere scientific facilities, and creating cutting edge management systems represents the underlying infrastructure that supports CBI and facilitates our clients’ regulatory submissions.

The rewarding part of our work comes in utilizing our knowledge and experience for the benefit of our clients. Expert report preparation, IND submission services, and drug discovery and development planning are just a few of the consulting services CBI offers.

PRECLINICAL STUDIES:

Our modern vivarium, dedicated veterinary services, and quality assurance staff provide reliable Good Laboratory Practices (GLP) studies. With a team of specialists in surgical and efficacy models, ADME & toxicology/safety studies, CBI can meet a wide variety of preclinical needs.

INVESTIGATIONAL TOXICOLOGY:

Investigational Toxicology is one of our special areas of expertise. Our staff can assist the scientific investigator in avoiding common difficulties within a toxicology program. With thorough dose range-finding and early characterization of the drug safety profile, formal GLP toxicology studies and specialized hypothesis-driven investigative studies can be more reliably designed at significant cost and time saving for our clients.

CONSULTATIVE CAPABILITIES:

- IND and other regulatory document preparation
- Expert reports
- Development

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- CAROL MESCHTER, DVM, PHD, DACVP
CEO

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- JAMES CHRISTENSON, PHD
VICE PRESIDENT