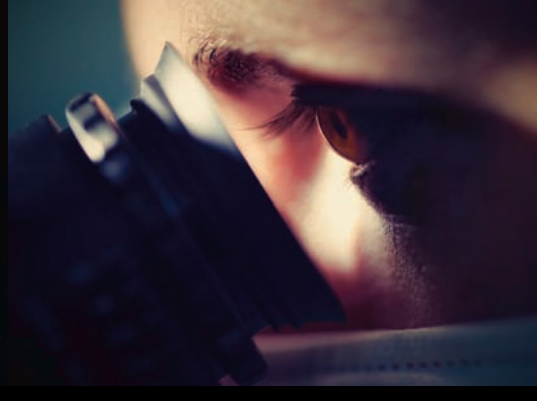

COMPARATIVE BIOSCIENCES, INC.

A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH

Technical Bulletin: OVERVIEW OF SERVICES

> "Scientists have become the bearers of the torch of discovery in our quest for knowledge."
>
> Stephen Hawking

A contract research organization by scientists, for scientists.

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.

Our particular areas of expertise include ocular, dermatology, fibrosis, ototoxicity, wound healing and burns, stem cells, oncology, renal, inflammation, immune-mediated, CNS, cardiovascular, infection models, and devices, as well as contract histopathology, immunohistochemistry and custom model development. Our clients range from the smallest virtual company to pharmaceutical giants, academia, defense, and government.

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 specialize in developing a custom study plan in order to best meet your preclinical research needs and prepare for regulatory submission.

We offer expertise in the following areas:

- Toxicology
- Pharmacokinetics
- Pharmacology
- Efficacy
- GLP and Non-GLP Studies
- In-house Histopathology and Immunohistochemistry

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Toxicology

We offer a complete program of preclinical research services to support a range of toxicology. Beginning with early assessment of new molecules including single dose, multiple dose, and targeted studies, as well as directed or investigative toxicology, complete IND enabling toxicology programs, and finishing with long term carcinogenicity studies, 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 manner.

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

Pharmacokinetics

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. We comply with FDA, OECD, and ICH guidelines. 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 specialize in unusual and customized studies.

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Pharmacology and Efficacy Studies

CBI provides a wide range of established and validated pharmacology and efficacy studies in all species in normal and in diseased animals, and with single, multiple or infusion/slow release dose administration with small molecules, biologics, stem cells, nanoparticles and devices. Our pharmacology capabilities ensure reliable results in the drug-discovery and translation process. Assessment and analysis modalities are fine-tuned to meet the specific requirements demanded in each targeted area of scientific investigation. CBI also offers custom studies and custom model development in all species.

OUR SPECIALITIES IN PHARMACOLOGY AND EFFICACY STUDIES INCLUDE:

- Pharmacology and efficacy modeling in multiple areas
- Custom model development
- Surgical modeling
- Investigative studies
- Combination GLP efficacy and toxicology studies

OUR PHARMACOLOGY AND EFFICACY STUDIES INCLUDE A WIDE RANGE OF MODELS INCLUDING:

- Ocular
- Dermal
- Otic
- Surgical
- Anti-infective
- Oncology
- Fibrosis and scarring
- Burns-thermal and UV
- Ischemia
- Renal
- Pulmonary and Cardiac
- Botulinum
- Wound Healing
- Inflammation
- Immune mediated
- Arthrosclerosis
- Arthritis
- Osteoporosis & osteogenesis imperfecta
- Metabolic
- Vascular
- Histology and immunohistochemistry
- Custom model development

ALL ACTIVITIES ARE OVERSEEN BY ACVP PATHOLOGIST.

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> "The rewarding part of our work comes in utilizing our knowledge and experience for the benefit of our clients."
>
> Carol Meschter, DVM, PHD, DACVP, CEO
>
> (click here to review Carol's Blogs)

Pathology

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 are 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.

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 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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