



COMPARATIVE BIOSCIENCES, INC.
A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH



Technical Bulletin: SURGICAL MODELS AND SERVICES



At CBI, our surgical models and services animal care program is AAALAC-accredited.

Rodent Surgery Models

We currently offer a variety of surgical models and services on multiple rodent species (rat, mouse, guinea pig, hamster, and gerbil) at several of our AAALAC-accredited production facilities in North America. Our surgical services are conducted by highly skilled surgeons with vast experience in veterinary medicine and animal science and range from simple procedures (e.g., soft tissue/organ extractions) to highly complex catheterizations and cannulations.

One of the unique and customized surgical services offered by **Comparative Biosciences, Inc.**

- All surgical procedures are performed by highly trained surgeons with oversight by ACLAM board-certified veterinary staff
- Surgical staff is certified through professional organizations including the AALAS and the Academy of Surgical Research
- Quality metrics are regularly monitored for each surgeon



Comparative Biosciences, Inc and GD3 have joined together to providing expert scientific resources and high quality contract research services to all sectors within the biomedical and pharmaceutical community.



SURGICAL MODELS

Rodent Surgery Preclinical Models at CBI

INTRODUCTION:

The number of potential surgical models in rodents are substantial and the applications of these models in biomedical research are broad. Surgical models we are able to provide include but are not limited to ocular surgery, intraocular artificial lens, ocular implants, dermal implants, ear drum surgery, renal ischemia, hysterectomy, cutaneous burns, surgical wound healing, bacterial infection. We also are able to develop unique and customized surgical models.

Comparative Biosciences, Inc. provides surgical models and services and resources can help get your research up and running by tailoring a research model to your specific needs.

State-of-the-Art Surgical Services Facilities

The surgical models and services suites at each site are composed of HEPA-filtered, positive-pressure barrier rooms with a series of entry locks. Each suite features individual functional areas used for surgical manipulations, animal husbandry support, preoperative holding, postoperative recovery, supply preparation, and clerical activities.

The entire animal surgery process (i.e., personnel training, animal anesthesia, analgesia, aseptic preparation, surgery, and postoperative care and holding prior to shipment) is reviewed and approved by our Institutional Animal Care and Use Committee.



Testing Preclinical Animal Surgery Models

The use of animal models in research resulted in the advancement of knowledge for how diseases affect animals and humans. Not only do we our research with rodents, but with large animals as well. There are a wide variety of animal models used in drug discovery including, a standing colony of healthy dogs, cats, and pigs for use in PK studies for our clients. Dedicated colonies assure the sponsor that PK studies can be scheduled and conducted very rapidly, usually with a 1-2 week turn around between scheduling and delivery of specimens for analytical assessment.

These species have been used to advance our knowledge of disease, to test new drugs, and to assure their safety before moving into the clinical phase with human subjects. Each model offers advantages and disadvantages, making them useful in certain types of studies or phases of drug discovery. Comparative Biosciences, Inc. can provide a table listing of the animals behind top drugs and a comprehensive summary of how animal testing and research has advanced human health.

MODELS BELOW INCLUDE MANY OF OUR SERVICES:

- . ANTI-INFECTIVE MODELS AT CBI
- . WOUND HEALING MODELS
- . COVID-ARDS ANIMAL MODELS
- . HYPEROXIA MODELS
- . DIABETIC AND METABOLIC MODELS
- . HYPEROXIA INJURY MODELS
- . CARDIOVASCULAR AND EFFICACY MODELS
- . OCULAR MODELS OF PHARMACOLOGY AND EFFICACY



SUMMARY: Animal Models

Animal models have greatly improved our understanding of the pathophysiology and have provided a valuable platform for testing potential therapeutic strategies. However, as with other preclinical disease models, no single animal model can mimic all clinical features at CBI. To contend with this drawback, investigators who perform translational studies increasingly use more than one model in their work. The most commonly used strategy is to use a combination of the collagenase and the blood injection models to confirm the major findings.

We have state of the art equipment and high quality detailed reports to support your research activities and FDA regulatory submissions.

THE FDA AND ANIMAL MODELS:

The FDA relies on data generated from animal models to assess efficacy and safety of new drug entities. The FDA Animal Rule states the FDA can rely on the evidence from animal studies to provide substantial evidence of the effectiveness of a drug only when all of the following four criteria are met:

- There is a reasonably well-understood pathophysiological mechanism of the toxicity of the substance and its prevention or substantial reduction by the product.

The effect is demonstrated in more than one animal species expected to react with a response predictive for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well-characterized animal model for predicting the response in humans.

The animal study endpoint is clearly related to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity. The data or information on the kinetics and pharmacodynamics of the product or other relevant data or information, in animals and humans, allows selection of an effective dose in humans.

