



# Preclinical Research Services

## Dermal/Transdermal/Wound Healing Evaluations in Miniature Swine

Sinclair personnel are experts in conducting GLP compliant dermal/transdermal toxicology/safety and DMPK studies in an FDA recommended model - miniature swine:

### Dermal Toxicology

- ☛ Acute, short-term (7- to 28-day), sub-chronic (90-Day), or chronic exposure durations
- ☛ Single or repeated dose (SID, BID, TID), occluded or unoccluded administration
- ☛ Passive and active (iontophoretic) dermal/transdermal patch administration
- ☛ Dermal evaluation (Draize scoring, etc.) and local tolerance
- ☛ Standard toxicology endpoints - clinical observations, clinical pathology, ECG, ophthalmology, histopathology
- ☛ Board Certified support personnel – veterinary ophthalmologists, veterinary cardiologists, and veterinary pathologists.

### Dermal DMPK

- ☛ Pharmacokinetics/toxicokinetics for dermal/transdermal routes of administration
- ☛ Cross-contamination prevention - custom equipment for dermal studies
- ☛ Custom large animal enclosures for dermal studies – stainless steel full barrier
- ☛ Radiolabelled and non-radiolabelled test articles
- ☛ Dose preparation
- ☛ Large capacity for chronic housing of large animals in a GLP compliant environment

### Dermal Wound Healing

- ☛ Incisional
- ☛ Excisional
  - Full Thickness
  - Partial Thickness
- ☛ Delayed Wound Healing Studies in Diabetic Pigs

Sinclair is proud to have assembled an exceptional combination of resources for pre-clinical in-vivo evaluation of transdermal or dermal drugs in miniature swine. Miniature swine are produced on site and are selected specifically to meet the research project requirements. Our staff is very experienced with the use of miniature swine in dermal/transdermal DMPK and toxicology studies.

Sinclair has produced miniature swine since 1964 and has been a privately owned preclinical CRO and animal model production corporation since 1994. Sinclair is AAALAC accredited and GLP compliant. Sinclair has experience with all conventional routes of compound administration, including transdermal and dermal applications.

Sinclair has developed a white, hairless Yucatan miniature swine for dermal absorption, irritation, and photosensitivity studies. The Hanford miniature swine, having white skin, is also an appropriate model for dermal studies.

Increasingly the scientific community has recognized the similar anatomy and physiology between swine and humans, with the swine dermal system being very comparable to humans with regards to the anatomical, physiological, metabolic, and histological features. Other organs and systems (cardiovascular, digestive, renal) are also analogous to human systems. Thus, the absorption, distribution, metabolism, and elimination of drugs in swine are generally very predictive of human metabolism, distribution, pharmaco/toxicokinetics. This has led to an increase in the use of miniature swine in preclinical research, including dermal toxicology and DMPK, and recognition by regulatory authorities that swine are an appropriate animal model for these evaluations.