



Pre-clinical Expertise
Efficient | Accurate | Responsive

Oct-Nov 2012

Message from the President



As the leaves begin to turn different colors we at CARE are reflecting on the kaleidoscope of exciting developments that we have witnessed this year.

In August, we had an extensive audit by the FDA that lasted a week. They complimented us on our thorough procedures and detailed SOPs. Needless to say no 483 was issued. In September we obtained an extension of our OLAW registration up to September 2016.

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An exciting event was the successful completion of several NDA enabling studies that involved long term oral gavage in rodents and dogs. The excellent results of these studies will allow our sponsor to continue conducting on-going pivotal clinical trials at multiple sites worldwide. Further we had several requests from numerous sponsors to respond to queries from the FDA involving both device and drug projects that we had conducted several years ago.

Our staff also continues to conduct studies using our rat kidney catheterization model to screen the pharmacokinetic behavior of diverse drugs and their metabolites. Finally, our team is here to continually serve our clients and meet their needs to develop the optimal strategy for presentation to the FDA.

Sincerely,

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Why CARE?



- Certifications: USDA, OLAW, EU ETS123
- Compliments on Documentation & Procedures
- Complete FDA audit - No 483 issued with accolades to documentation and procedures
- Expertise in DART studies (Developmental and Reproductive Toxicology)
- Exceptional team with proven integrity and accountability
- Expertise in protocol development and regulatory guidance

Surgical Tissue Adhesive Study

About CARE

22 Acre Facility

Acute & Chronic Toxicology

ADME Studies

Toxicology, Feed, Range
Finding

Multispecies TK & PK

Developmental & Reproductive
Toxicology



CARE surgical suite with C-ARM

CARE completed a study in pigs that demonstrated the equivalency of a novel tissue adhesive compared to the predicate material using our well equipped surgery suite.

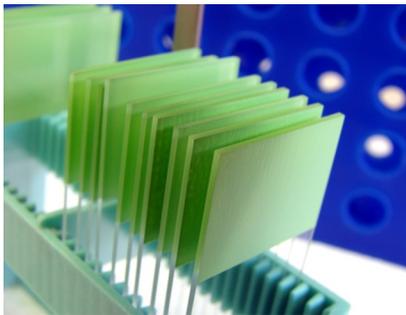
Kidney Catheterization



Custom built harnesses with attached cryovials that are used as receptacles for the urine from each individual rat ureter.

This model has been used to serve clients seeking to correlate the urine excretion rates of active drug and metabolites and relate them to concomitant drug plasma levels as a time sequence of PK. The model consists of individual ureter intubation of each kidney and quantitative collection of the urine volume and pH monitoring. The tubes are externalized through the rat's back muscle and each individual aliquot (time series) is collected in a small vial while the animals are engaged in normal activity (including overnight and well into the next day) after recovery from surgery.

In-House Clinical Services



Colorado Histo-Prep's seamless relationship with CARE ensures one point of project control not only of technical details but also complete timeline control (study director at CARE) responsibility for preclinical projects with histopathology endpoints to provide quality and timeliness of project completion.

- Hematology, Clinical Chemistry
- Complete, detailed Histopathology

www.histoprep.com