



YOUR DEDICATED PARTNER IN DRUG SAFETY

ITR Canada Overview

- Privately owned facility
- Purpose built for pre-clinical research
- 110,000 sq feet
- 50 animal rooms with anterooms, 11 inhalation exposure rooms
- Established in 1989. Expanded 8 times with the most recent in 2013
- 230 Employees
- Conducted over 3000 safety studies with over 2000 run GLP
- Has long-term Financial Stability, Debt-free
- FDA, EMA, OECD-GLP inspected and AAALAC, CCAC, DOD accredited



Preclinical Services

- **Toxicology Services** *(Covers all phases of preclinical drug development for IND and NDA)*
 - Mammalian Tox
 - Safety Pharmacology
 - Genetic Toxicology
 - Neurotox and bone research
 - Immunology
- **Drug Metabolism and Pharmacokinetics (non-radiolabelled)**
 - Toxicokinetics/Pharmacokinetics
 - In vitro assays
 - Surgical models
- **Laboratory Services**
 - Bio-analysis (LCMS, ELISA, etc)
 - Immunology (Biomarker analysis, flowcytometry, QPCR, cell based assays)
 - Formulation and analytical chemistry (HPLC, ELISA, etc)
- **On-Site Support Services**
 - Clinical pathology
 - Gross pathology and histopathology
 - 3 on-site pathologists – 1 is board certified
 - Cell culture
 - Toxicokinetic modeling
 - Separate TK/PK laboratory and group with a separate control area
 - QAU and on-site archiving
- **Toxicology Species** *(Commonly used Species)*
 - Mouse
 - Dog
 - Rat
 - Minipig
 - Rabbit
 - Primates
- **Dosing frequencies & Durations**
 - Acute, MTD & DRFs
 - Chronic (6-12 months)
 - 6 Month Tg.rasH2
 - Sub-chronic (14-90 day)
 - Carcinogenicity 2 Year Rodent
- **Routes of Administration** *(Common routes)*
 - Oral (gavage & capsules)
 - Topical (ocular and dermal)
 - Inhalation and intratracheal
 - Parenteral (IV bolus, IP, SC, intradermal, etc)
 - Infusion (continuous or intermittent)



**Come visit us at BioMed 2013, June 10th to 12th, at the David InterContinental Hotel, in Tel-Aviv, Israel
Booth No. 83!**

General Information on Specialty Areas

- **Infusion Overview** (Facility opened as an infusion lab)
 - Well equipped surgical suite, large inventory of infusion pumps (syringe & peristaltic mechanisms)
 - Jacket & tether systems
 - 500 + studies performed over 20 years
 - Durations from minutes up to 24 hours/day for 6 months in various animal species
 - Formulations can be administered:
 - Via implanted exteriorized catheter in a femoral vein
 - A disposable indwelling catheter in a peripheral vein (eg. tail vein, cephalic, etc.)
 - Implanted Vascular Access Port (VAP)
 - Other catheterized sites include subcutaneous, etc

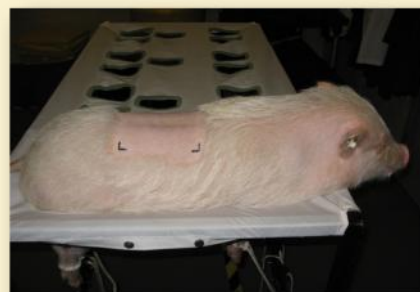


➤ Inhalation Overview

- Inhalation Unit, built in 2001, over 300 inhalation studies to date
- Durations ranging from single dose to two year carcinogenicity studies
- Modern inhalation unit using flow-past technology minimizing TA requirements
- Before commencing animal work, characterization of the aerosol in the exposure system is verified
- Supports all forms of aerosol (gas, powder, liquid or suspension)
- On-site analytical chemistry support
- Facility and work-flow designed to minimize cross contamination between groups, especially with control groups

➤ Dermal Overview

- Mini-pig is the most common species of choice
- Occluded vs. non-occluded
- From single application to chronic use
- Formulations experienced with: Gels, Creams (ointment), Sprays, Patches, Emulsions



➤ Safety Pharmacology

- Cardiovascular: Radiotelemetry (dog/primate using colony or naïve animals)
- CNS: Functional Observation Battery in rodents and non-rodents
- Respiratory: with head out in rodents and face mask in large animals

➤ Immunology Services

- Modern, purpose built labs:
 - Ligand binding lab
 - Tissue culture room
 - Molecular biology lab
- Support for biotechnology derived therapeutics:
 - Tox species selection
 - Bioanalysis
 - Immunogenicity: binding and neutralizing antibody assays
 - Biodistribution and persistence; genomic integration
 - Pharmacodynamics
- Specific assays for immunotoxicology studies:
 - Standard format Rat KLH TDAR; NK; ALC are commercialized, cyno assays in progress
 - Custom endpoints; Surface and intercellular flow phenotyping, including phospho flow, ex vivo lymphocyte, pDC, neutrophil and macrophage responses

