18 YEARS OF EXCELLENCE IN RESEARCH

cliantha® research

Delivering Excellence

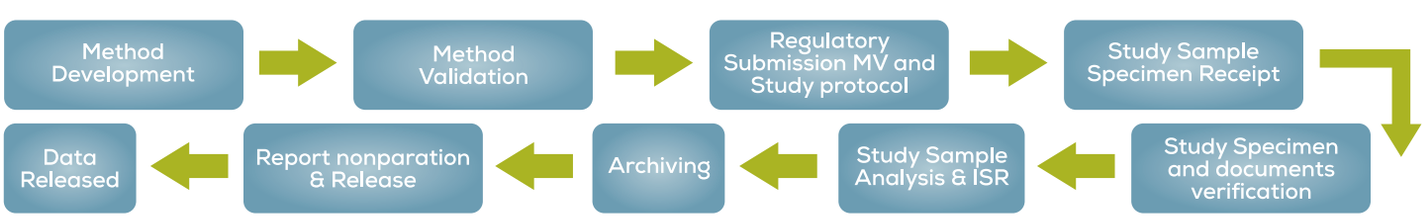
An Insight into Good Laboratory Practices (GLP) for Preclinical Studies

To accelerate the development of new drugs into clinical trials, our high quality preclinical bioanalysis program helps you unlock regulatory challenges. Having Cliantha Research (Toronto, Canada) as your drug development partner, we provide you with the regulated preclinical bioanalytical support for IND submission. Our preclinical bioanalytical services support toxicology activities for small molecule drugs with global Good Laboratory Practice (GLP) regulatory compliance.

Cliantha GLP (Animal) Bioanalytical Overview

- Cliantha set up GLP Bioanalytical laboratory operation to conduct human BA/BE studies and GLP Non-clinical animal studies
- State-of-the-art 12,000 sq. ft. facility
- Operated by a team of scientists with many years of direct hands-on experience in
  - Bioanalytical Method Development & Validation
  - Sample Analysis to support Human BA/BE studies
  - GLP and Non-GLP non-Clinical Animal Studies (dogs, cats, horses, rats, etc.,)
  - Simple to Complex drugs and metabolites including Endogenous Substances
- The team has significant and extensive industry experience in managing FDA, EMA, TPD, and AEMPS regulatory inspections and sponsor audits

Flow Chart of a Typical GLP Study



GLP (Animal) Bioanalytical Studies - EXPERIENCE & EXPERTISE

Method Validation

- Completed more than 15 validations in compliance with FDA and OECD GLPs
- Have 13 approved MV Reports submitted to FDA CVM
- Conducted approximately 10 Pivotal and 20 Pilot GLP Animal Studies
- Regulatory Query Management with a turnaround time of one week or less

Biological Species	Matrix	Compound
Dog	Plasma	Carprofen, Marbofloxacin,
Cat	Plasma	Enrofloxacin, Cefpodoxime, Deracoxib, Meloxicam, Pimobendan, Cyclosporine, Amoxicillin/Clavulanate, Milbemycin Oxime, Furosemide, Firocoxib, Maropitant, Praziquantel
Dog	Serum	Levothyroxine
Horse	Plasma	Omeprazole

Non-GLP Non-Clinical Animal Studies - EXPERIENCE & EXPERTISE

- Fit-To-Purpose Method Development: 3
- Fit-To-Purpose Pilot Study Sample Analysis: 2
- Client Query Management: Within 24 hours
- Biological Species: Dog, Cat and Horse
- Examples: Rapamycin in Dog and Cat whole blood and Omeprazole in Horse Plasma

Quality Systems

- Strict adherence to SOPs and Regulatory Guidance
- Quality and compliance training programs (GCP, GLP, Safety)
- Sample Integrity – 'Beginning to End'
- Process and review data in real time
- Management and Bioanalytical Investigator direct involvement in day-to-day operation
- QA team independently monitors all activities ensuring compliance to Protocol, SOPs, GCP, GLP and applicable regulations

Regulatory History - Toronto Lab

Year of Inspections	Agency
August 12 - 16, 2019	**Food and Drug Administration, USA** (Facility, systems and studies) Successful inspection resulted in No 483
June 12, 2019	**Controlled Substances Program, Health Canada** (Security & System Requirements for Controlled Substances) Successful inspection; Security Level 1 maintained
November 16, 17, and 20, 2017	**Spanish Agency of Medicines and Medical Devices** (Facility, systems and studies)
June 15, 2017	**Controlled Substances Program, Health Canada** (Security & System Requirements for Controlled Substances) Successful inspection; Security Level 1 licence issued
May 15 - 19, 2017	**Food and Drug Administration, USA** (Facility, systems and studies) Successful inspection resulted in No 483
April 27 - 28, 2016	**Standards Council of Canada, Health Canada** (GLP)-Successful Facility inspection
March 02, 2016	**Ministry of the Environment and Climate Change, Toronto District Office inspection** (Environmental and Laboratory safety)

Contact Cliantha for more information about
how we can enable you to make research decisions faster.

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