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Newsletter - Oct'19

USFDA



Cliantha Research successfully concluded two USFDA inspections in September at two different clinical sites for the late phase studies.

CAP



Cliantha research concluded a successful College of American Pathologists (CAP) inspection at the Ahmedabad and Vadodara clinical labs. Delhi (NCR) facility CAP inspection shall be conducted in the month of November.

Large Molecule Lab



Cliantha is currently working on numerous flow cytometry biomarkers viz. CD 19, innovative markers like PAC-1, interleukins and other cytokines. We have the capability of testing NK cell activity and other biomarkers on flow cytometry.

Mr. Arnab Sinha Roy, our Scientist from Large Molecule Lab participated in the 'National Hands-on Workshop on 'Applications of Flow Cytometry in Pharmacology and Drug Discovery' at PGI Chandigarh.

Microbiology Lab



We offer antimicrobial agent screening against bacteria, fungi and biofilms. (Viruses and mycobacteria excluded). We test against a wide variety of standard and non-standard (culture collection sourced) microbial strains.

1. Disinfectant validation studies against a variety of microorganisms including bacteria, fungi and bacterial endospores.

2. Supporting home and personal care products with laboratory testing, evaluation, consulting and research activities.

3. Microbiology testing for cosmetics

- 4. Packaging testing
- 5. Consumer healthcare trials

Operational Excellence in Clinical Trials (OECT) Summit, Toronto, Canada

At this conference Cliantha shared its late phase capabilities in Oncology and in the Biosimilars Realm. The conference was participated by Ms. Anjali Chudasama (Senior Director - Business Development), Kunal Sehra (Associate Director - Clinical Operations, USA), Natalia Najera (Associate Director - Clinical Operations, Canada) and Vesna Spudic (Manager - Marketing and Subject Recruitment, Canada)



Meet us at CPhI Frankfurt (Booth 90H23)

This year Cliantha Research will have a large presence at the CPhI Worldwide in Frankfurt, Germany. Cliantha Research booth shall be represented by Mr. Vijay Patel (CEO), Mr. Naveen Sharma (President), Dr. Anne Marie Salapate (Executive VP & Chief Scientific Officer), Dr. Chirag Shah (Sr. Director - Business Strategy), Mr. Rahul Nijhawan (Sr. Director - Early Phase), Mr. Abhishek Patel (General Manager - BD, Early Phase) and Mr. Pedro Pedroso (Sr. Project Manager, Europe)







Bioanalytical Lab, Toronto

On September 13th Cliantha Toronto Analytical Lab celebrates six successful years under the leadership of Dr. Chinna Pamidi. Toronto lab has had successful USFDA, EMEA and Health Canada audits. Toronto Lab provides bio analytical, IVRT and IVPT services. Recently lab has completed two IVRT methods in Dapsone USP 5% cream and Hydrocortisone USP 1% cream.



Lab, Toronto Bioanalytical completed sample analysis for the following studies:

- Rifaximin 200 mg
- Dapsone 7.5% Gel
- 15-OH Lubiprostone 24 μ g
- Scopolamine 1.5 mg Transdermal
- Isotretinoin 40 mg
- Furosemide 50 mg in Dog

Bio Lab also completed following method validation:

Molecule	Dose	LLOQ
Atovaquone	750 mg/5mL	25 ng/mL
Isosorbide Dinitrate and its metabolite Isosorbide-2-Mononitrate and Isosorbide-5-Mononitrate	40 mg tablet	0.500/1.00/2.00 ng/mL
Furosemide	50 mg tablet	5.000 ng/mL

The complete list is available on cliantha.com

Bioanalytical Lab, India

Cliantha India Analytical Lab has successfully completed Method validation followed by study sample analysis of Protein-Bound Particles for Injectable Suspension (albumin-bound) 100 mg/vial at a dose of 260 mg/m2 of Unbound Paclitaxel (LOQ 5 ng/mL)and Total Paclitaxel (LOQ 0.1 mcg/mL).

Lab has also completed following new method validations:

Molecule	Dose	LLOQ
Crisaborole	750 mg/5mL	0.5000 ng/mL
Haloperidol	40 mg tablet	0.01000 ng/mL
Furosemide	50 mg tablet	0.5000 ng/mL
17-Desacetyl Norgestimate	0.15 mg/24 hr Film extended release (Patch),0.250 mg Tablet	0.02000 ng/mL

The complete list is available on cliantha.com

Consumer Research India

- Hundred + female subjects enrolled in less than 12 days for a successful completion of facial skin glow cream.
- Successfully completed double blinded organoleptic studies for Cholestyramine Suspension
- Safety and efficacy studies for Anti-dandruff products, Make-up removal products, Anti-hair fall products, and Hair growth products.
- Acquired new Fibra One instrument from DiaStron for Hair Fibre Testing. This Instrument Is used for claims supports i.e. Hair Tresses, Anti breaking/strength claims, Damage prevention, Heat Protection, Elasticity claims, Depilatory cream claims, Volume, softness, suppleness, and Manageability claims
- Facility expansion and systems in place to execute PIPT/HRIPT studies as per BIS (EU) and USFDA norms.

Training, India



• Mr. Nayan Prajapati head of training department was certified among the top training and development leader at the World HRD Congress conclave.

