Mithra Biotechnology Inc.

Always developing with you

Mithra

Founded in 1988 as The First CRO in Taiwan

About Mithra

Company Introduction

Mithra, the first Contract Research Organization (CRO) Company in Taiwan, was founded in 1988 which provides analytical method development, validation and Quality Assurance services at the time. In 2011, Mithra merged the proteomics laboratory from Mass solutions Technology (founded in 2005) and started our dedication to assisting biopharmaceutical development from the preliminary discovery to manufacturing.

Milestones

1988 Mithra is the first Contract Research Organization (CRO) established in Taiwan and focused on providing bioavailability and bioequivalence (BA/BE) study services.

1997 Expansion of organization, set up of a new laboratory, procurement of new LC-MS/MS and GC/MS systems to enhance analytical capabilities.

2004 Successfully passed the College of American Pathologists (CAP) single-blinded proficiency test using LC-MS/MS analysis for 4 consecutive years.

Launched the pre-clinical bioanalytical services for animal blood samples.

2005 Established the Clinical Trial Department for Investigational New Drugs and Medical Devices in order to cope with the demands from Taiwan pharmaceutical industries and to provide Phase I to IV clinical study services.

2006 Implemented the Electronic Clinical Study System to enhance quality of clinical study services.

2009 Acquired the ISO/IEC 17025 accreditation and provided small molecule drugs bioanalytical services.

Obtained the contracts for the bioanalysis of Phase I clinical study samples from U.S., North Africa and Canada.

2010 Jointly acquired by Ruentex Group Taiwan and Dr. Allen Chao, the founder of Watson Pharmaceutical U.S., Mithra aggressively progressed to further enhancing service quality and expanding service scopes.

2011 Combine with Mass Solution Technology, become the only CRO company that can entrust small molecular drug and protein drug services.

2012 Passed the inspection of Good Laboratory practice (GLP) for protein drug analysis by TFDA.

2014 Attained the GLP compliance recognition by Organization for Economic Co-operation and Development (OECD), Taiwan.

2015 Acquired the Compliance Programme for BE Centre of NPCB, Malaysia.

Services

Mithra provides multi-services through each stage of drug development. Mithra provide services include BA/BE/PK/PD, clinical trial and protein drug characterization as either total solution or partial service to your research needs. As for animal test we also have a co-operate company to work with.

For over the decades, Mithra has breakthrough on bioanalytical methods and providing sample analysis for pharmaceutical industrial clients. Mithra's laboratory specializes in liquid chromatography – tandem mass spectrometry (LC-MS/MS) services, with industry recognized expertise in bioanalytical method development. We conduct bioavailability, bioequivalence and pharmacokinetic study, fasting studies, food effect study, multiple dose and steady state studies.

We have the only GLP proteomic laboratory in Taiwan, which provides protein analysis serviced based on mass spectrometry techniques, such as protein identification, post translational modification analysis, relative protein quantitation for various biological samples. We also provide full characterization plans for biological products include full sequence analysis, modification determination, peptide mapping and degradation/impurities profiling.

Our Clinical Trial Department provided service though on each clinical trial phase of drugs, medical devices and biotechnology products. Each study, start with protocol development, site selection, regulatory submissions, study set up, study monitoring, data management, statistical analysis, writing clinical study report, site close out, and investigational product management.

Services List

Protein Analysis

- Protein Primary Structure
- Post-Translational Modification
- Glycosylation
- Protein Identification
- Protein Quantification
- Protein Drug Analysis

Bioanalytical Services

- Bioanalytical for Clinical Trial
- Bioanalytical for Animal Study
- Bioanalytical for *in vitro* (cell lines) Study

Pharmaceutical Analytical Services

- Active Pharmaceutical Ingredient (API) Analysis
- Pharmaceutical Impurities Analytical

Pharmacokinetics and Metabolism Studies

- Bioavailability and Bioequivalence Studies
- Clinical Pharmacokinetic Study
- Bridging Study Evaluation (BSE)
- Post-Marketing Pharmacokinetic Studies
- Pre-Clinical Pharmacokinetic and Toxicokinetic Studies
- In Vivo and In Vitro Metabolism Studies
- Pharmacokinetic Study Design, Evaluation and Consultation
- Animal Studies

Clinical Trial

Study Set-up

- Investigator Selection and Qualification
- Protocol / Clinical Study Report / Case Report Form / Informed Consent Form Development
- Regulatory Authority Consulting
- Regulatory Authority and IRB / IEC Submissions/Report

Study Periods

- Site Initiation Visit
- Routine Monitoring Visits
- Study Closeout Visit

Data Management & Statistical Analysis

- Database Development
- Data Validation
- Data Entry
- Data Cleaning
- Data Tracking
- Data Coding
- SAE Reconciliation
- Database Locking
- Randomization and Blinding
- Statistical Report Writing
- Statistical Analysis

Quality Assurance Activity

- Quality Assurance Audits
- Regulatory Authority Inspections

Clinical Trial Experiences

Mithra have excellent experience not only on the BA/BE Study of healthy subject but also on the Clinical Study:

Indication	Category	Study Type	Site No.	Subjects No.
Pain	New Drug	Phase I	1	12
Dizziness	New Drug	Phase I	1	24
Pain	New Drug	Phase I	1	24
Pain	New Drug	Phase I	1	28
Putamen Hemorrhage	New Botanical Drug	Phase I	1	48
Depressive Disorders	New Drug	Phase I/IIa	1	32
Nasal Symptoms	New Drug	Phase II	2	60
Back Pain	New Botanical Drug	Phase II	1	90
Pulmonary Tuberculosis	New Drug	Phase II	7	260
Diagnosis of Carcinoembryonic Antigen	Medical Devices	Phase II/III	3	600
Pain	New Drug	Phase II/III	4	200
Pain	New Drug	Phase II/III	4	130
Myopia	Medical Devices	Phase III	2	30
Back Pain	New Botanical Drug	Phase III	3	360
Pulmonary Tuberculosis	New Drug	Phase III	8	320
Diagnosis of Alzheimer's Disease	Medical Devices	Phase III	4	240
Post-Operative Wound Healing	Medical Devices	PMS	1	150
Post-Operative Sever Pain Morphine Indicated	Control Drug	PMS	3	60
Cough	New Botanical Drug	Phase I/IIa	1	40





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