The Right Dose of
Intelligent Toxicology

Vanta Bioscience Limited
a contract research organization

About Us

Vanta Bioscience Limited (VBS) is a full-service preclinical contract research organization located in Chennai (Tamil Nadu), India. VBS is a center of excellence for preclinical research. VBS operates in full compliance with OECD, ISO, ScheduleY, EMEA, ICH, EPA, and USFDA GLP regulatory guidelines. We offer services to clientele from diverse field including pharmaceutical, agrochemical, biotech, medical device, cosmetics, agro-foods, food supplements, feed additives and chemical industries.

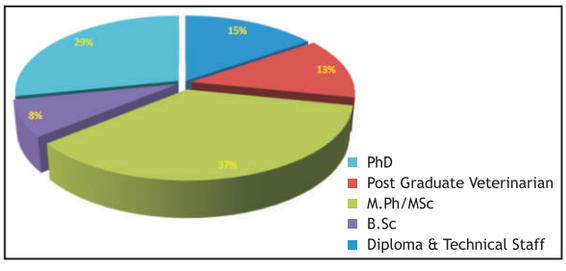
VBS is GLP certified test facility approved by the National GLP Compliance Monitoring Authority (NGCMA) of India, Department of Science and Technology, Govt. of India and registered with the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) as a Ministry of Environment & Forests, Govt. of India approved Animal Testing Facility. In addition, VBS is also one of the few facilities in the country to be certified by AAALAC for its highest standards and practices concerning the care, use and humane treatment of laboratory animals in the research.

Team

The scientific team of VBS consists of highly qualified and board certified toxicologists, pathologists and other scientists with the vast experience in conduct of variety of preclinical toxicology studies including early discovery toxicology and efficacy studies in different animal models. All the Study Directors, Study Personnel and Technicians possess in depth understanding and knowledge of GLP and other quality systems and consistently demonstrate commitment for maintaining high compliance level. The team is a perfect blend of scientists with diversified educational background and experience in toxicology, veterinary pathology, biochemistry, pharmacology, microbiology, biotechnology and biostatistics etc. Collectively, the team has more than 100 years of experience in the regulatory toxicology, quality assurance and allied fields.

The team is a pool of both technical and regulatory knowledge and expertise in safety evaluations of New Chemical entities (NCEs), Biologics, Biosimilars, Medical devices, Value added generics (505b2 & 505b1), herbals, Nutraceuticals and Agrochemicals. It excels in its ability to conduct regulatory studies and deliver study reports in precise turnaround times striving to meet time lines and prompt in responding to client and regulatory queries backed by highly efficient project management team.

Experienced Staff



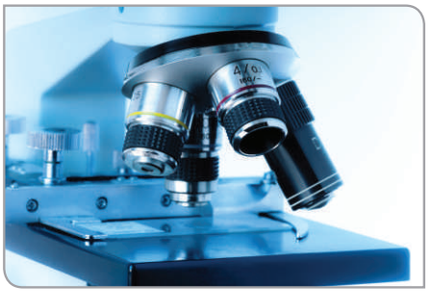
Services

VBS offers complete and full range of preclinical toxicology studies including In Vitro and In Vivo Genotoxicity studies. We also undertake a variety of other in vitro assays and tests to support cosmetics and other products testing. The state of the art analytical, bioanalytical and formulation laboratories offer consistent support to toxicology besides providing exclusive services in the field of Analytical and Bioanalytical sciences. Our well qualified and experienced pharmacologists and pathologists have hands on experience in the standardization and validation of several animal models of human diseases to establish Preclinical Proof of Concept (PoC) for variety of therapeutics including NCEs, biologics, bio-similars, new formulations, new indications and change in the route etc.

VBS has expanded its portfolio to include preclinical testing using beagle dog and porcine. Presently these studies are undertaken with our associates located in UK & USA.

VBS works closely with the clients to design the most appropriate study protocols in accordance to the product under development and ensures high level of commitment and compliance through completion of studies as per stringent global standards and adhering to committed time lines to meet the goal of clients.

Service Portfolio



- Biocompatibility studies on Medical Devices as per ISO 10993 guidelines
  1. Cytotoxicity
  2. Dermal Sensitization
  3. Intra-cutaneous
  4. Mucous Membrane Irritation
  5. Acute Systemic Toxicity
  6. Mutagenicity Assays
  7. Implantation studies
- Preclinical and Non-Clinical Toxicity studies (Rodents & Non-Rodents*)
  1. Single Dose Toxicity Study
     a. Acute Toxicity Studies
     b. Maximum Tolerated Dose
  2. Repeated dose Short term and Long term studies
     a. Sub Acute Studies
     b. Sub Chronic Studies
     c. Chronic Studies
     d. Carcinogenicity Studies
  3. Pharmacokinetic Studies
  4. Safety Pharmacology Studies
  5. Reproductive Toxicology Studies
  6. Local toxicity (including reconstructed human epidermis model [EpiSkin™] for *in vitro skin* irritation/corrosion testing)
  7. Cytotoxicity and Genotoxicity Assays
  8. Ecotoxicity Studies & Inhalation Studies
- Exploratory Toxicology
- Efficacy studies to establish Proof of Concept (PoC)
- Bio-Analytical and Formulation Analysis Services
- Stem cell potency assessment
- Pyrogen Testing and Toxicity Studies for Vaccines
- ICCVAM/ECVAM/OECD Approved Alternative Methods

*Currently these studies are undertaken with our associates (GLP CROs) located in UK & USA

Routes of Administration

All standard routes of administration are supported. Other routes of administration are supported for custom protocols and depend on the study requirements.

- Intravenous
- Intramuscular
- Intra-peritoneal
- Subcutaneous
- Topical
- Oral
- Inhalation

Quality Assurance

Independently reporting to senior management, the Quality Assurance Unit ensures data quality and integrity through a comprehensive OECD GLP compliant auditing program.

IT Systems and Confidentiality

Industry best practices for IT and data management are institutionalized with secure systems for data storage and secondary backup, ensuring utmost data security and confidentiality, including audit trail.

> Vanta Bioscience Limited believes that confidentiality is central to a customer's service excellence and the vital interests of our clients. Compliance with a rigorous corporate policy and all approved SOPs is a key parameter for building trust and credibility with our clients.

Sponsor specific secure access electronic repositories are provisioned for project status updates and study reporting, including draft and final reports.

Facilities

Vanta Bioscience Limited is spread over 56,000 sq.ft state-of-art research facility:

- Class 100,000 facility with efficient HVAC control at 15 air changes per hour
- Individual AHUs for each animal room to avoid cross contamination
- Equipped with “Individually Ventilated Cages (IVC)” for animal holding and experimentation
- Dedicated service floor to ensure integrity of the core procedural areas
- Three level pressure gradient system with supply and return corridors
- Isolated procedure rooms designed to support holding rooms for dosing, sample collection, cage change and animal weighing and observations
- 24/7 operations with monitoring and control of fire alarm, public address and access control systems
- Intelligent Building Management System (iBMS) with dual backup and UPS and DG power
- The fire proof archival facility for dry and wet archives is designed for adequate records retention and efficient retrieval during audits and to with stand any force majeure.

Client Engagement

We have built a client engagement framework where we work closely with clients and build protocols tailor made to suit the product registration requirements for regulatory submission. We ensure that any new studies proposed and initiated based on the client need are first validated in-house and take up the client prompted studies as per the principles of GLP. Vanta Bioscience Limited believes that our success is based on our client success.

Vanta Bioscience Limited

To learn more about Vanta Bioscience Limited
please visit
http://www.vantabio.com

Accredited by :

National GLP Compliance Monitoring Authority

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