



Digitization at Veeda

- Bureau Veritas certifies Veeda with ISO 27001:2013 and validates its quality compliance of its Information Security Management System (ISMS) at par with international standards
- E-Registration of volunteers using Cronos - completion of clinical module is expected by March 2020

Regulatory Audit in 2018-19

- Total number of audits by FDA at our Clinical trial Investigators' sites: 17
- Successful in-house and site auditing by independent external auditor
- Cleared 2 patient trial inspection with No 483 by USFDA since Aug 2018.
- Zero FDA 483 observations by any of the 3 USFDA inspections in August 2019
- Successful Inspection by NPRA and WHO with closure letters
- ANVISA inspection in 2019 concluded with no observations
- Approval of a new clinical facility at Mehsana with validity until 2024 by CDSCO

Special studies conducted since Aug 2018

- 4 Inhalation studies
- Performed 2 Patch studies
- 4 BE study with Long housing of volunteers (>1 week)
- 1 Long acting injection BE study with high sample size
- 3 Geriatric studies
- 1 Post-menopausal women study

Average patient dropout ratio has been around 2%, the main reason being subjects not reporting to the facility.

Expansion of clinical infrastructure

New state-of-art clinical facility at Mehsana, Gujarat comprising of four clinics, a pharmacy and archive facilities.

Patient studies - Updates

- Database of Investigators: Over 1100 investigators with expertise in varied therapeutic areas
- Enrollment of more than 200 patients during Aug 2018 to Sep 2019
- Completion of two liposomal doxorubicin studies, one long-acting injection study for risperidone, and one capecitabine oral product study
- 8 ongoing studies in different trial phases in therapeutic areas such as oncology, psychiatry, cardiology, and gynecology

Development of complex assays in Veeda's bioanalytical laboratories

- Incurred Sample Reanalysis (ISR) passing ratio of 98.1% for 245 projects from September 2018 to August 2019
- Developed methods for Salmeterol, Amphotericin (Free and Liposomal), Levosalbutamol, Ipratropium, Thiamine, Doxorubicin (Free and Liposomal)

Training & Development Programs

- Workshop on "Scientific and Medical Writing" that includes honing of technical/scientific writing skills and basic grammar skills for all medical writers
- Development of an in-house application called 350 interactive e-Module using in-house standard operating procedures (SOPs) to enable online e-learning/training through LMS
- Interactive workshop on "Root Cause Analysis" by external industry experts to bolster qualitative research, brainstorming, and problem solving

Institutionalizing the "Quality First" mindset at Veeda

Monthly Quality Review Meetings

(QRMs) that focus on:

- QA audit observations and trend analysis for compliance evaluation
- Corrective and Preventive Actions (CAPA) and assessment of effectiveness
- Identification of additional improvement areas

Open and transparent reporting of any issues, deviations, or errors from all levels of the organization is encouraged irrespective of hierarchy.

Veeda's Vision Ahead

- Augmenting our scientific skills in conducting complex studies
- Pursuing inorganic growth opportunities in core markets to expand our range of services to cover drug development programs of existing clients

**Frost & Sullivan Recognized Veeda Clinical Research as
"The Clinical Research Organisation of the year 2019"**

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