Veeda Updates

Clinical

We successfully completed the 1st USFDA audit of our new "Vedant "facility with zero 483's

- In the last 1 year we have performed studies in different therapeutic segments like Inhalation, Nasal Spray, Suppositories, Biosimilars – GCSF, Glucose Clamp and Patches.
- We have conducted Inhalation studies for molecules like Albuterol Sulfate HFA Inhalation Aerosol, Fluticasone Propionate and Salmeterol inhalation powder (100/250/500 & 50 mcg) Beclomethasonedipropionate Aerosol & Budesonide + Formoterol MDI
- Nasal Spray: Fluticasone Nasal Spray
- Suppositories: Artesunate rectal capsules, Mesalamine Rectal Suppository, 1000 mg
- Biosimilars/Glucose Clamp: GRANULOCYTE COLONY STIMULATING FACTOR STUDY, Wosulin N 200IU/ml, Insulin Glargine, Wosulin 30/70 (E.Coli, 100 IU/ml), ISOPHANE INSULIN INJECTION 200 IU, Wosulin 30/70 (100 IU/mL)
- Patch Studies: Estradiol Transdermal System USP, 0.1 mg/day, Rivastigmine Transdermal System

Analytical

- In the last 1 year we have developed methods for complex molecules like Pencillamine , N,N Diethyldithocarb amate, S-Methyl N N Diethyl Dithiocarbamate, S-Methyl N N Diethyl Dithiocarbamate, Chlorpheniramine + Phenylephrine, Prasugrel and its metabolite, Unbound paclitaxel, R and S Nebivolol, R and S Ibuprofen, Butyl Scopolamine, Budesonide, Alverine and its metabolite, Simvastatin acid, Tetrabenazine and Methylergonovine
- In spite of the challenges in reproducibility and optimization of methods we have 97.20% pass rate for ISR in 2016 2017
- We have even added aultra sensitive machine like Shimadzu 8060 to achieve lower levels of quantification for sensitive molecules. We have developed methods for Formoterol and Ketotifen with a linearity range of 0.4 to 200pg/ml & 2 to 1000pg/ml respectively

Regulatory

- In the year 2017, we have completed 8 US FDA inspections at hospital sites for patient based studies with zero 483s. These inspections were conducted for oncology patient based studies. Overall in last 1.5 years, we have faced 14 US FDA inspections at hospital sites and all were cleared with zero 483s except one which required no action.
- For Healthy subject BE studies, we faced a data integrity inspection in the month of March 2017 and the same was cleared with zero 483s in addition to the 2 recent audits in September 2017 with zero 483s and till date we have completed 11 US FDA inspections at Veeda.
- We have successfully cleared an UK MHRA audit in December 2016 and have received the closure letter.

Training and Development

- Veeda's training and development team is developing an e-learning system and working on around 400 modules for the SOP training. Among this, we have already developed around 67 modules and target to complete the other modules by mid of next year. E-learning is a new training strategy which improves the performance and productivity.
- Apart from this we have the annual training for GCP & GLP for all our staff in addition to the training on BLS & ACLS for our medical and para medical staff every quarter.

Awards

For the good work done by the company we have received the below mentioned awards in the last 18 months.

Year	Organization	Award Category
2016	Novartis	Certificate of Appreciation
2016	Dr. Reddy's	Business Partner Excellence Award
2016	Pharmaceutical Leadership Summit	Clinical leader of the Year
2017	Praxis Media	National Excellence Award
2017	AI Global Media	Best Pharmaceutical CRO
2017	Health & Safety Awards	Best Clinical Research- India
2017	Times Network- National Awards for Marketing Excellence	Best Clinical Research- India
2017	Gujarat Best Employer Brand Awards	Mark of Excellence
2017	Frost & Sullivan	Indian Clinical Research company of the year

Patient based studies

We have further added to our experience in patient based studies .

- Till date we have completed 4 global multi-centric phase II clinical trials in Oncology , 2 phase 111 studies of injectable implants and 18 patient based PK trials.
- We have another 8 patient based PK trails in different level of execution in addition to 1 phase 11 study in oncology
- We have worked with more than 125 sites and recruited 890 patients in the different trails

Our preparation to face the continuous regulatory audits

Inspections can occur at any time and we need to be ready to act during any such event. We, at Veeda, believe that Inspection readiness is more than a "one time" event. We ensure following to meet this goal:

1. Adequately trained Staff are available to perform study related activities. Training is ensured by seniors before delegating any study related activities.
2. All study related documents are promptly filed in the Trial Master files and ensured that all these documents are complete with all relevant details.
3. Facility readiness is ensured by continuous verification of the systems and documents.
4. In-house quality monitors team conduct review of processes and documents during study conduct thereby ensure the compliance to study protocol requirements.
5. In-house Quality assurance team conduct system/facility and equipment based audits periodically to check the compliance with in house procedures and Study audits to verify the compliance with study protocol.
6. Senior Management continuously monitors the quality systems of various departments to ensure that all standard processes and practices are implemented, thereby ensuring all time audit readiness of various facilities.

Frequent quality meetings in Veeda

Veeda is committed to becoming the leader in the CRO industry and to deliver quality research solutions that meet and exceed our customers' and in-house requirements while maintaining compliance with GCP, GLP requirements as well as applicable regulatory, national and international standards.

To meet this quality objective, senior management ensures that all departments plan and implement the quality systems to meet company's quality objective and continually improve them. **We are trying to institutionalize quality.**

Senior Management conducts bi monthly quality review meetings with an objective to assess compliance of systems and processes focused on following different areas:

1. Audit Results and Compliance Evaluations
2. Adequacy of Resources
3. Vendor performance
4. Corrective / Preventive Actions and its progress including effectiveness assessment.
5. Identification of any addition improvement opportunities

Digitalization / Paperless environment

- Veeda is in the process of implementing electronic modules in a phase wise manner for electronic capturing of various activities from volunteer screening till report finalization to ensure better quality and regulatory compliance.
- Registration module is being effectively implemented at Veeda currently.