The Veeda Newsletter

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VEEDA NEWS

United States Food and Drug Administration (USFDA) conducted 8 site Inspection of Patient based PK studies managed by Veeda Clinical Research in 2016-17

Veeda CR is glad to share the successful completion of 8 USFDA Inspection at Clinical trial sites for various studies managed by Veeda CR in last financial year -2016-17. The studies were conducted in various indications like Chronic Myeloid Leukemia / GIST, Psoriasis, Rheumatoid arthritis, Advanced Rental cell Carcinoma and Breast Cancer.
The Outcome of all the 8 USFDA Inspection in a year was -No 483s,which accounts for a total of 10 out of 11 USFDA Inspections at clinical trials sites with No 483s.

Veeda CR team demonstrated excellent overall preparedness for the Inspection with Right First time approach, thorough preparedness for Regulatory inspections at sites and a good process control for study execution. The process control by Clinical Operations team can be demonstrated through the exemplary track record of having completed all the studies within Budget and timelines and in compliance with the applicable Regulatory Requirements.

Such a consistent and remarkable feat of 'No 483s' in sequential USFDA Inspections could only be achieved with dedicated and motivated staff geared up to do the right things at the right time in the right method. It is a humbling milestone for Veeda Clinical Operations and Quality Assurance. This was possible due to a highly supportive, passionate and visionary management of Veeda CR who are sensitive to Quality and Regulatory Compliance.

Achievement of VEEDA on D-Penicillamine – The lifesaving drug.

FDA some time back released a list which includes drug for' Wilson's disease treatment named penicillamine which lacks the generic competition. The availability of the drug is very important as there are no alternatives for the treatment of Wilson's disease.

A brief update on the drug property

Penicillamine has a tendency to dimerised with own (dimer of Penicillamine) molecules in aqueous media as well as biological matrix. Also Penicillamine binds to cysteine in biological matrix. In body, Penicillamine converted in to Penicillamine-cysteine and Penicillamine disulfide. In body, major part of Penicillamine converted in to its metabolites and small portion remains as a free Penicillamine.

Challenges faced by the Industry to develop method for penicllamine.

A very important step in developing the method is to prevent dimerization of Penicillamine in solution as well as in biological matrix (used to prepare calibrators and QCs). The reason is Penicillamine is not stable at ambient temperature. It is required to add such buffer which can prevent dimerization of Penicillamine as well as it can prevent back conversion from Penicillamine metabolites to Penicillamine. The major challenge faced in the development of the method is its reproducibility an optimization.

The breakthrough to achieve precise and accurate method

Veeda team worked on the development to prevent dimerization and metabolism of Penicillamine.During re-optimization, different trials were taken to select such a buffer which would prevent dimerization of Penicillamine as well as prevent the back conversion of penicillamine disulfide and penicillamine-cysteine. After selecting a proper buffer for plasma samples, different experiments were done to check the both issue and no further problem was observed.

Using this new method, study sample analysis was carried out and 97.17% ISR samples were found within acceptance criteria. The new validated method for the estimation of penicillamine is suitable for assay of free penicillamine without causing dimerization of free penicillamine as well as without causing breakage of penicillamine metabolites to penicillamine with excellent incurred samples reanalysis reproducibility.

With the excellence and dedication of the team, Veeda have now in it's basket of method library – a robust, scientific and regulatory compliant method with a proven ISR reproducibility of more than 95%. We are glad to share the above success story with our clients and always welcome to get associated to with the industry on such developments in future.