Automating Bioanalytical Workflows at Veeda Clinical Research

Veeda Clinical Research® (Veeda CR) is a full service early phase global CRO with over 20 years of experience in phase I and IIa clinical research. With state-of-the-art facilities in the UK, India and Belgium, we provide a full range of services in phase I and IIa clinical research, delivering expert, cost-effective research solutions to the pharmaceutical and biotechnology industries worldwide.

About Veeda

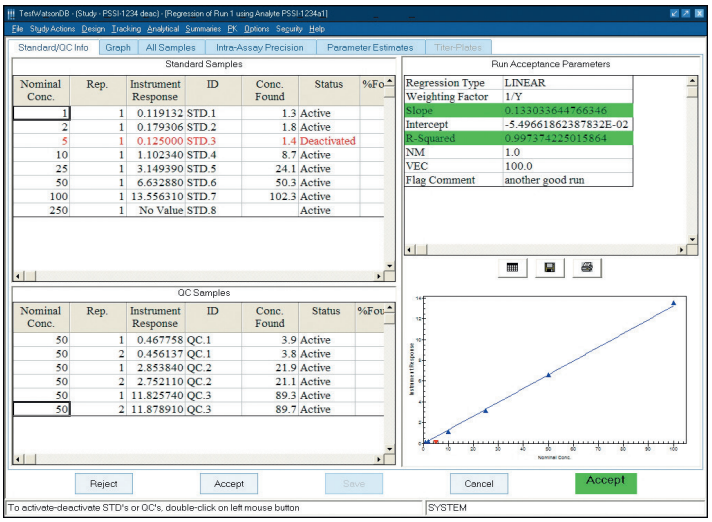
Veeda CR Laboratory located in Ahmedabad, India is a premier bioanalytical facility offering bioanalytical services to the pharmaceutical sector. Veeda's analytical services encompass development, transfer, validation and application of bioanalytical methods for small molecule bioanalysis for both NCEs and generic pharmaceuticals. Laboratory analyses may be either standalone whereby we assay samples generated by third party clinics or else in support of studies conducted at one of Veeda's experienced clinical facilities.

Requirements

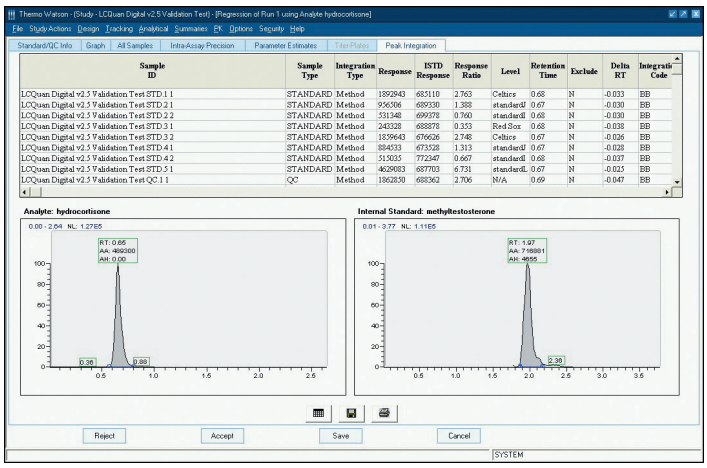
The Bioanalytical Research facility in Ahmedabad, India, tests 200 samples of plasma, blood, serum and urine per instrument per day and the three laboratories that Veeda CR currently operates around the world handle more than 4.5 million samples per year – a figure which is expected to double.

In this existing facility, the company has traditionally deployed manual sampling and monitoring systems with physical documentation and paperwork.

The organization of documents has been a large and time consuming job which employed vital staff in essential yet unproductive work. This underutilization of manpower represented a significant loss in terms of productivity and personnel costs and space. Veeda CR required a system that would automate the paper-based documentation processes in order to reduce the paper trail and the considerable expenditure in man hours devoted to the management of manual data, thus increasing the capacity of its laboratories.



Watson LIMS software analyzes calibration curves from standards and back-calculates concentrations for QCs and unknowns. Configurable parameter flags alert the user to acceptability criteria. Color-coding enhances visual inspection of results.



The advanced, bi-directional digital interface between Watson LIMS software and LCQUAN, the data acquisition system for the Thermo Scientific™ TSQ Quantum™ mass spectrometer series, enables the secure transfer of worklist information and results data, together with integrated peak viewing in the LISMS.

In addition, different software solutions were being used to manage the vast workload, resulting in significant irregularity in data display. With each software platform incorporating different algorithms, there were too many discrepancies noted in values and results. As a consequence, there was a prominent need for a system that would enable consistent presentation of data while also ensuring strict compliance with 21 CFR Part 11. Harmonization and uniform presentation of protocols, reports and other data formats was a critical requirement to maintain the consistency and error-proof compilation and presentation of generated data. Reporting of results also needed to be accelerated without compromising quality.

Apurva Shah

In 2007, Veeda CR selected Thermo Scientific™ Watson LIMS™ software to automate its laboratory processes. The LIMS has been deployed for the analysis of drugs and metabolites for small molecules to significantly increase throughput in the laboratory.

"We were familiar with the advantages of Watson LIMS software and recognized that this is a compatible system for the automation of our bioanalytical data processes. We knew that Watson LIMS software was the most comprehensive system for us, capable to meet our business requirements and enable us to offer a world-class service from our facility," says Apurva Shah, Co-group Managing Director and Co-founder of Veeda.

"The whole purpose of buying this LIMS from Thermo Fisher is to handle the projects as efficiently and quickly as possible. It is also a selling point to attract Western pharmaceutical organizations, who see systems in place that they are all used to."

Implementation

Watson LIMS software has been installed to run on an IBM™ Series 3400™ Server using the Windows™ server 2003 operating system. Oracle™ 10 G is used as the database server with MS Office™ 2003 and the LIMS. The installation has been undertaken jointly by Thermo Fisher Scientific and Veeda CR.

Prior to implementation, training on the basic operation of the LIMS was organized by Thermo Fisher. Staff have indicated complete acceptance of the new system and are fully conversant with its operational requirements. Further post-implementation, follow-up training has ensured that the system is used to its full capacity.

Now that projects are entered into Watson LIMS software, Shah confirms, "All our Western clients expect their projects to run on the same LIMS, they require it and it enhances their data transfer. We recognize that Watson LIMS software is the requirement of the day in our industry. Many of our customers already have Watson LIMS software themselves – by default the LIMS is a necessity for us. They send us a copy of their project database, which allows us to collect and store the data in exactly the same format and we can seamlessly upload our data file back into their server. The seamless uploads take place either via FTP or using Citrix™."

Benefits

Since its implementation, Watson LIMS software has significantly increased throughput of the laboratory services. The entire laboratory operations and enterprise systems are now fully integrated with the LIMS, eliminating manual and disparate processes to improve productivity and quality. Automation of data management has freed up the laboratory's highly trained technicians and analysts and allowed them to focus on the core competencies of the business.

By harmonizing and unifying its process onto an integrated enterprise software system, Veeda CR has adopted a similar world-class operating environment to that found in its pharmaceutical sponsors' facilities. Watson LIMS software is installed in all of the top 20 global pharmaceutical organizations, and is widely used in leading biotechnology and contract research organizations worldwide. The universality of the system means that both sponsors and Veeda CR can view the study results in the same format. In that way, communication and data transfer between them is totally seamless. Further to ensuring seamless transfer of data between Veeda CR and its sponsors, Watson LIMS software has facilitated timely, flawless and secure communication between the company's Indian and UK facilities.

Apurva adds, "Many of Veeda CR's clients in India manufacture generics. With bioavailability/bioequivalence studies in India, projects may remain manual if clients want to keep costs low. The option will remain."

Manish Yadav, head of bioanalytical research in Ahmedabad comments, "The Indian pharmaceutical industry, with its qualified and experienced scientists and growing research capabilities is well set to develop a strong position in the international market in the near future. Watson LIMS software represents a big investment for Veeda CR that allows us to remain at the forefront of innovation and reap the benefits of this growth. The system enables us to offer our sponsors a service from India that matches what they can buy in the West."

Watson LIMS software has also been able to ensure that the facilities operate in compliance with the strict regulatory environment of the pharmaceutical industry and with FDA 21 CFR Part 11. Sample management and the online data transfer and monitoring of activities have become easier, backed up by extensive training and a substantial support service from Thermo Fisher. Because Watson LIMS software is a purpose-built LIMS, designed specifically for the bioanalytical laboratory workflow, the solution did not require Veeda CR to undertake any customization, allowing

for much quicker implementation, validation and upgrade of the system compared with generic LIMS.

Designed to fit the bioanalytical workflow, Watson LIMS software has accelerated sample turnaround, thereby reducing sample management costs. The LIMS tracks shipments and sample storage and includes more than 150 pre-configured reports as well as ad hoc reporting capabilities, facilitating data review and analysis. This organizational ability has been fundamental to the smooth operation of the laboratory, enabling Veeda CR to benefit from improved operational efficiency and expand the operations of its business.

Watson LIMS software incorporates key functionality specific to DMPK/Bioanalytical studies in drug development, including flexible protocol-based study design, assay/method standardization and management, integrated sample management and a configurable re-assay decision tree. The solution includes more than five in-built interfaces to LC/MS, HPLC, plate readers, counters and ICP-MS instruments while also supporting a wide range of pharmacokinetics and toxicokinetics calculations.

Future developments

"With a platform like Watson LIMS software, there are so many things that the system can do." Manish explains, "We have currently validated the parts of the system that we will use regularly. This process took more than 12 months and Veeda CR needs to recoup the investment. Veeda CR has invested not only in the LIMS but also has a large investment in laboratory automation which means that Veeda CR is unique in India with the ability to now automate the whole process (which is necessary for some compounds)."

Veeda CR is also in the process of obtaining more licenses to ensure optimum utilization of Watson LIMS software on a growing number of projects. Additionally, the Oxford facility intends to interface instruments into the LIMS. This interface will commence with the Gyrolab, and Manish explains that the most significant instrument platforms will be selected in terms of what they process, for interface into Watson LIMS software. He explains, "By extracting the raw data directly into the LIMS, the data reduction can be undertaken within the same system. This gives full audit control for the data, within Watson LIMS software."

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Conclusion

"In a typical laboratory, you expect LIMS to be menu-driven, to manage laboratory workflow. In my view, because it is so uniquely built-for-purpose, Watson LIMS software is the most suitable data management tool for Veeda CR."

Veeda CR is the largest phase 1 CRO in India and as part of its ambitious plan, has implemented Thermo Fisher Watson LIMS software. Since its implementation, the LIMS has improved the data management processes and overall laboratory efficiency at Veeda CR, increasing productivity and ensuring regulatory compliance, all in a single server application.

Shah concludes, "What Watson LIMS software does bring is a very structured way of managing the department. There are many opportunities for us to use its overall capabilities, which Veeda CR will realize in the future from this investment. It also represents to customers that Veeda CR is an international organization that works compatibly with pharmaceutical sponsors."

Partnering with Thermo Fisher

Thermo Fisher is the worldwide leader in laboratory software and services, providing enterprise-wide, multi-laboratory solutions that are relied on at all of the top 20 global pharmaceutical companies, and bioanalytical laboratories around the world, including Nerviano MS (Italy), Covance, Advion BioServices, Inc. (USA), and many others. To support our installations, we provide implementation, validation, training, maintenance and support from the industry's largest worldwide informatics services network.

Find out more at **thermofisher.com/digitalscience**

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