

Standardizing bioanalytical workflows at Nerviano Medical Sciences

Nerviano Medical Sciences (NervianoMS) is the largest pharmaceutical research and development facility in Italy, and one of the largest oncology-focused, integrated discovery and development companies in Europe. In 2006, the pre-clinical development unit of NervianoMS, Accelera, began using Thermo Scientific™ Watson™ LIMS (Laboratory Information Management System) software in order to manage and process statistical data related to ELISA (Enzyme-Linked ImmunoSorbent Assay) experiments in line with GLP regulations. (Watson LIMS software was implemented in 2001 for all the PK study support.)

Nerviano Medical Sciences and Accelera

NervianoMS is a private company owned by the Congregazione dei Figli dell'Immacolata Concezione (CFIC) and was incorporated in 2004 following a company re-organization by Pfizer. A total of almost 700 highly skilled



and experienced scientists, technicians and managers are involved in oncology R&D projects at NervianoMS, from target validation to clinical phase IIa. NervianoMS aims to discover and develop innovative medicines for the treatment of cancer, and to establish partnerships with the biopharmaceutical industry and the scientific community.

The preclinical development unit (PCD) of NervianoMS, Accelera, is committed to predicting and managing potential toxic, pharmacokinetic and metabolic issues of new compounds and to supporting all stages of drug discovery and development. Based outside Milan, Italy, Accelera has successfully developed and applied state-of-the-art technologies and ad hoc approaches to "pick the winner" among potential drug candidates for all therapeutic areas.



Currently employing approximately 120 scientists, Accelera provides a range of PCD services including preclinical discovery and profiling, development services and consultancy, clinical and preclinical bioanalysis and oncology drugs research services. Beyond the specific expertise in the design and execution of PCD programs for oncology drugs, Accelera has strong competencies to support projects across a range of therapeutic areas.



The challenge

The IT group of NervianoMS manages and maintains complex IT infrastructure architectures, information system networks and software applications and supports more than 1000 workstations across the organization. The group must also maintain processes in line with GLP and FDA Computer Validation Guidelines, as well as other regulations relevant to the pharmaceutical environment.

Both GLP and FDA guidelines require drug makers, medical device manufacturers, biotechnology companies and other regulated industries to implement control processes including regular audits, validation programs and full documentation of products and systems. GLP guidelines help to assure regulatory bodies that data submitted by manufacturing companies are a true reflection of the results obtained and can therefore be relied upon. In order to comply with this wide range of regulatory requirements, it is essential that companies undertaking sample analysis implement carefully validated software systems.

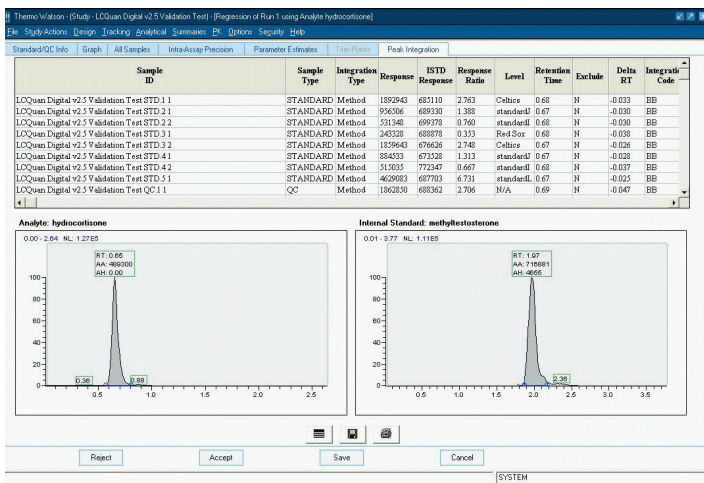
As part of its R&D activity, Accelera carries out ELISA experiments with a large focus on GLP compliance. In the end of 2005 the company began to receive both internal and external requests for bioanalytical support for ELISA data in preclinical and clinical regulated studies. The main business requirements for such a support system were a validated process to generate and manage

ELISA data, a validated statistical tool for ELISA data, the capacity to electronically manage study information and an electronic repository for ELISA data that was compliant with regulatory guidelines such as GLP. In order to meet these requirements, the company began to look for a LIMS (Laboratory Information Management System).

Implementation

Accelera traditionally used vendor-specific instrument analysis software for the management of ELISA data, as well as Microsoft Excel and paper-based procedures, but in 2006 the unit began to investigate the installation of a LIMS. NervianoMS looked at several alternative systems for Accelera, but found that none matched the capabilities of Watson LIMS software in terms of integration, development for the analytical field and guaranteed GLP compliance.

Watson LIMS software is a highly specialized protocol-driven system which has been specifically developed to support DMPK and bioanalytical studies in drug development. The system was developed with input from major pharmaceutical companies and its success is a direct result of its ease of use and the high level of service offered to assist in implementation. Watson LIMS software is installed in the top 20 global pharmaceutical organizations and is widely used in leading biotechnology and contract research organizations worldwide.

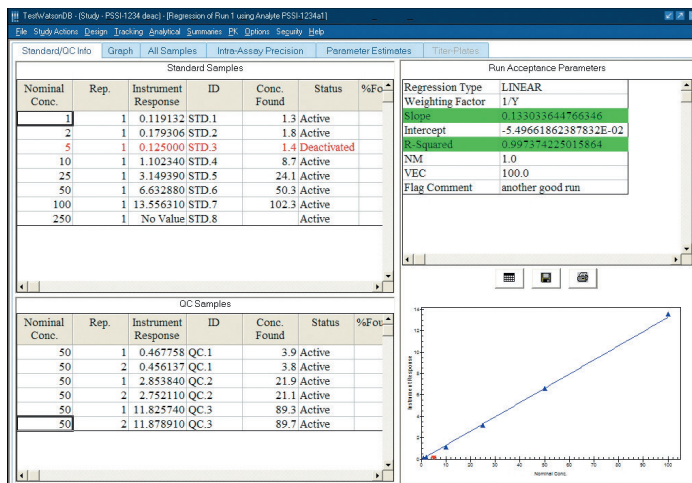


The advanced, bi-directional digital interface between Watson LIMS software and LCQUAN™, the data acquisition system for the Thermo Scientific™ TSQ™ Quantum mass spectrometer series, enables the secure transfer of worklist information and results data, together with integrated peak viewing in the Watson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

NervianoMS already had an established relationship with Thermo Fisher Scientific as the organization uses a range of Thermo Scientific branded instruments. Thermo Fisher's proven track record of support for Watson LIMS software attracted NervianoMS, as well as the company's ongoing dedication to developing and integrating its systems in the analytical field. Additionally, the LIMS has been expressly built to promote compliance with GLP regulations and the 21 CFR Part 11 guidance, a significant consideration for Accelera when choosing a LIMS.

During the Accelera implementation, Watson LIMS software was configured to use a central Oracle™ 92 database on a Linux operating system. The LIMS offers a simple, point-and-click graphical interface that resulted in minimal training for the 50 LIMS users at Accelera. To aid GLP compliance at Accelera, the system security and audit trail are designed to provide maximum flexibility and configurability while preserving data integrity. Watson LIMS software is the ideal system for Accelera as it is capable of handling and storing complex study protocols and tracking deviations to each study.

Since its installation, Watson LIMS software has become a key driver for all GLP activities at Accelera, and as a result almost all experimental data must be organized and managed by the LIMS. In addition to implementing the LIMS, Accelera required a method to import ELISA data files directly from its PerkinElmer™ Victor2™ fluorometer into the LIMS. As a result, Accelera uses ELY4, a program compiler, to interface Watson LIMS software with the



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.

Wallac 1420 software for the Victor2 microplate reader, thus guaranteeing full LIMS support for the determination of large molecules. By interfacing with ELY4, Watson LIMS software represents the full driver for a range of activity, from study information and sequence plans to the final results reports in Accelera's fully compliant environment. The ELISA experiments constitute 10-15% of the studies managed by the LIMS.

Key benefits

Since the implementation of Watson LIMS software in 2001, Accelera has experienced considerable benefits including guaranteed regulatory compliance as well as increased laboratory productivity and accelerated sample turnaround.

As the LIMS fully supports unit management and allows data consolidation across studies and projects, it has been quickly accepted by Accelera's analytical community. By expanding the use of the electronic format across Accelera's traditionally paper-oriented environment, Watson LIMS software has had a significant impact on laboratory productivity, and enables laboratory analysts and ELISA study directors to easily consolidate sample and instrument data.

Watson LIMS software has also had a significant impact on the level of compliance of Accelera's laboratories. The system provides a clear audit trail for Accelera which guarantees GLP compliance for the execution of regulated studies.

Conclusion

In a global pharmaceutical manufacturing company such as NervianoMS it is essential that processes and practices be compliant with strict regulations such as GLP and FDA. However, newly implemented systems must be flexible in order to interface with Accelerera's wide range of instruments and data used at Accelerera. By using Watson LIMS software, Accelerera has put in place an easy-to-use system which improves laboratory productivity and turnaround time as well as guaranteeing simple regulatory compliance in a cost-effective way.

The LIMS has fulfilled the initial requirements of Accelerera and through its security control and server qualification provides a fully compliant system for the management of ELISA data. With the capability to support a validated statistical tool for ELISA data as well as being the driver of automated data processes, the LIMS is an electronic repository for ELISA data across multiple studies and projects for Accelerera.

Stefano Cavanus, Watson LIMS software System Manager at NervianoMS, comments, "We initially chose the LIMS because of the development of the system within the analytical field, into which Watson LIMS software is perfectly integrated. We were also impressed by Thermo Fisher Scientific's efficient group dedicated to solving problems. Watson LIMS software is extremely easy to use and was quickly accepted by our 50 users, and we continue to devote significant time to train these users according to their roles and activity with the LIMS."

"Watson LIMS software has met all of our requirements and was easily configurable to enable interface with our instruments. Since implementing the LIMS, all of our processes have been validated and all points of the NMS Computer Validation Policies have been applied, in agreement with the FDA Computer Validation Guidelines. As a result of the increased productivity of our laboratories and the guaranteed compliance of the LIMS, we cannot do without it."

Watson LIMS software is now used as the standard LIMS across Accelerera's PCD laboratories, including the development of LIMS interfaces for its key instruments.

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