

# Creating an environment for bioanalytical excellence

PRA International Bioanalytical Laboratory serves global pharmaceutical and biotech companies, offering method development, implementation and validation, bioanalytical protocol design, in addition to a range of other services tailored to early stage bioanalytical development studies. The laboratory has standardized on Thermo Scientific™ Watson LIMS™ software (Laboratory Information Management System) software for operational excellence in the management of 150,000 samples per annum.

## Profile

Headquartered in Raleigh, North Carolina, PRA International is one of the world's leading clinical development organizations delivering a broad array of services, from filing of Investigational New Drug (IND) to product registration and post-marketing studies. The company's core services include drug development and regulatory strategy plans, Phase I clinical trials, Phase II through IV multi-center clinical trials, development and analysis of integrated global clinical databases, preparation and submission of regulatory filings in North America and Europe, long-term drug safety programs and late phase (IV) programs. Since 1984, PRA International has conducted studies for almost every major pharmaceutical company in Europe, the United States and Japan while also providing supporting services including data management, pharmacy services and manufacturing.



PRA International operates a state-of-the-art, GLP-compliant Bioanalytical Laboratory, located in Assen, the Netherlands, which provides pharmacokinetic/pharmacodynamic analyses, including endogenous compounds and biomarkers. The laboratory has an excellent 24-year record in bioanalytical activities, with over 2,400 studies executed. It includes facilities for mass spectrometry, high/ultra high performance liquid chromatography, biochemistry and immunochemistry, genotyping, radioisotope analysis and handling of biohazard samples.

## Requirements

In 2008, PRA International selected Watson LIMS software to manage the vast workload of 150,000 samples per year at the Netherlands-based Bioanalytical Laboratory and to provide a platform to support growth. The company required a powerful, fully integrated LIMS to help them achieve their ambitious objective for optimum operational excellence. PRA International was looking for improvements in sample throughput, more efficient use of its laboratory equipment and limited downtime for its instruments.

The decision to invest in a new state-of-the-art LIMS to manage the primary production process from sample receipt through to sample report was imperative for the Bioanalytical Laboratory. Peter Ketelaar, Vice President of PRA International Bioanalytical Laboratory explains, "The decision-makers represented both the business and the practical application, including laboratory, IT and management functions. Thermo Scientific Watson LIMS software is the industry-standard LIMS, used by the majority of our pharmaceutical sponsors. As a result of its market universality, we selected Watson LIMS software for our Bioanalytical Laboratory."

## Industry leading solution

The laboratory operates within GLP/OECD compliant protocols, and manages the process from start to finish: from managing the trials and analyzing the samples, to managing the data for the company's pharmaceutical sponsors.

Watson LIMS software was selected for its standardized, out-of-the-box functionality, which is specifically suited for the demanding applications undertaken in the Bioanalytical Laboratory. A little over 100 scientists and staff use the LIMS to help service their clients and manage data from the facility's state-of-the-art equipment, including sixteen LCMS, two UPLC systems and five HPLC systems. Watson LIMS software is tasked with storing and tracking data processed in the laboratory, from sample receipt through to sample report. All existing instruments of the laboratory are integrated with the LIMS.

To invest in the new LIMS, PRA's team undertook an investment proposal, seeking to ensure excellent Return on Investment (ROI). Based on net present value, the calculation assumed savings and cost reductions from the use of Watson LIMS software. The implementation of the LIMS has been phased, it is managed by PRA International and supported by Thermo Fisher Scientific.

Peter Ketelaar clarifies, "At PRA we make it a policy to adopt industry-standard technology. Our pursuit of excellence means that we select the best in breed products. Seventy-five percent of the LIMS in use in our pharmaceutical sponsors' own working laboratories are Watson LIMS software. 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. So, we just follow the industry trend."

## Benefits

Since its implementation, Watson LIMS software has been able to bring to the Bioanalytical Laboratory a set of flexible reporting tools, which allow scientists to fulfill their customers' requirement for reports that follow the same format as the one implemented in-house. Watson LIMS software ensures that PRA's reports are identical to the pharmaceutical sponsors' reports. Pharmaceutical sponsors design their studies in the LIMS, PRA opens the studies, fills in the data and sends the studies back to the sponsors. Communication and data transfer between PRA International and its pharmaceutical sponsors is totally seamless.

Further major benefits realized at the Bioanalytical Laboratory since the installation of the LIMS are the accelerated sample turnaround, reduced costs associated with sample management and improved operational efficiency. The system also meets the laboratory's need for GLP and 21 CFR Part 11 compliance. Watson LIMS software has built-in security and audit trail to provide maximum flexibility and configurability while preserving data integrity. The solution has been capable of handling standard and complex study protocols, providing audit trails to track deviations and amendments to each study.

Watson LIMS software uses a central Oracle database and offers a simple, point-and-click graphical interface that has been quick to learn and easy to use. It has benefited PRA International with its full bi-directional interface capability to analytical instruments while also being able to track shipments and samples through user-designed barcode labels. It has been supporting a wide range of PK/TK analyses and organizing study results in a unique document management system. Watson LIMS software also fully supports unit management, allowing true data consolidation across studies and projects. The system's exceptional ease-of-use and the high level of service offered by Thermo Fisher to assist in implementation are added advantages offered to the Bioanalytical Laboratory.

## Conclusion

PRA International works with a wide range of pharmaceutical sponsors worldwide, on multiple projects across its European facilities. Being both scientifically driven and client-oriented, PRA International has always been equipped with the technologies and infrastructure that allow it to deliver high quality, efficient studies on a wide range of drugs and indications. As part of its ambitious plan to implement technological innovations that promote operational excellence and regulatory compliance, PRA International has standardized on Watson LIMS software in its state-of-the-art Bioanalytical Laboratory. Since its implementation, the system has enabled flawless transmission of data between the company and the multiple pharmaceutical sponsors it serves. It has improved laboratory productivity and minimized costs.

## Partnering with Thermo Fisher Scientific

Thermo Fisher Scientific is the worldwide leader in laboratory software and services, providing enterprise-wide, multi-laboratory solutions that are relied upon at all of the top 20 pharmaceutical companies, and bioanalytical laboratories around the world, including NervianoMS (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.

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