

LabSystems Case Study: HFL's involvement in the development of Nautilus

Company:
HFL
Industry Sector:
Forensic Science
Environment:
Forensic and Drug Testing
Software Used:
Nautilus
Platform:
Windows® 95 & Windows NT®
Database:
Oracle®

HFL is a research-based company, owned by the Horserace Betting Levy Board. Located in Newmarket, the laboratory is responsible for drug detection procedures, and analytical chemistry for racing and equestrian authorities, including the Jockey Club of Great Britain. The services offered at HFL extends to greyhounds, pigeons, and even camels. Its forensic services are used for routine screening and counter analysis by racing authorities and equestrian federations worldwide. HFL is the designated laboratory for the Federation Equestre Internationale's (FEI) medication control programme in Europe.

HFL, with a staff of more than 60 scientists, specializes in separation science, analytical chemistry (especially mass spectrometry) and drug metabolism and immunoassay techniques. Services include comprehensive screening for drugs prohibited by sporting authorities, analysis of medicines, testing meat for veterinary drug residues, pharmacokinetics and metabolism studies, stability studies, GCMS, LCMS and LCMSMS services. The varied workload of the scientists adds to HFL's ability to recognize new drugs, and track doping trends worldwide. HFL's experience of prohibited substances has led to the development of a unique library of chromatographic and mass spectral characteristics of drug metabolites.



Random drug testing is carried out in most sports, and horse-racing and greyhound-racing are no different. Samples are taken at random from about 8 horses participating in every race meeting across the UK. During 1997, HFL analyzed more than 19,000 samples for racing and equestrian sports authorities. From the samples screened for illegal substances, 313 reported positive during 1997 which included approximately 60 different drugs and metabolites from the List of Prohibited Substances*. HFL aims to provide results from tests in less than 10 days; however the average time between sample receipt and reporting of results for a full screening analysis of a regular sample is about five working days. Any samples with unusual results or irregularities are tested further so that positive findings can be confirmed, resulting in disciplinary action by the authority concerned.

As a forensic laboratory the results of HFL's work are likely to be subjected to legal scrutiny. It is therefore of paramount importance that all the analytical procedures and working practises employed at HFL are carried out with a high level of control. Samples are collected at the racetrack under controlled conditions and delivered to the laboratory in tamper-evident collection bottles. Following inspection on arrival the bar-coded samples are processed through the highly automated laboratory. It is essential to maintain rigorous sample tracking procedures. To support its chain of custody** requirement HFL must integrate state of the art laboratory technology with stringent internal auditing practices in addition to the requirements of UKAS (150-25) and GLP.

For management and collation of its sample information and data, HFL specified its first LIMS over 10 years ago, and the system went live in 1990. The LIMS was originally commissioned to replace the laboratory's manual systems, to reduce the 'paper mountains' as well as improving efficiency of working, eliminate human and other transcription errors, and improve both the quality and the integrity of data.

Requirements for the LIMS included: utilization of barcodes, automatic data transfer and result entry, as well as meeting the constraints of the forensic environment (such as chain of custody and multi-level result review).

Having projected a five-year lifetime for the original LIMS, in June 1994, an internal group was formed to assess the requirements for a new system. There was a need to justify the replacement of the LIMS, and to identify the options for replacement. Having run a LIMS for



more than 10 years, HFL is an "experienced" LIMS user, and took the opportunity to consider the longer term needs of its replacement system. HFL's new LIMS had to be flexible so that the business rules could be changed easily without needing to re-customize the system. The LIMS had to meet all previous requirements, as well as new definitions laid out for flexibility, integration, new technology and usability.

In terms of product functionality, several companies can provide a system to meet today's needs, but HFL's concerns were 'what about tomorrow?'. As such, the LIMS team decided to look beyond the product for criteria which would add value to the LIMS use, such as:

- Customer Services
- Future Development
- Company Stability

These factors influenced the team's decision when considering the vendor for the new LIMS system. Two LIMS vendors were finally shortlisted, both with systems which seemed to meet the needs. Of those, LabSystems was selected, because it addressed both HFL's product and corporate considerations.

HFL signed a contract with LabSystems to contribute to the development of NAUTILUS, a new generation of LIMS. Nautilus has been developed by LabSystems, with real users such as HFL intimately involved throughout the development process. This process is known as Joint Application Development (JAD) and HFL (plus other users who participated in the programme) were known as JAD partners.



Case Study: HFL

Nautilus was designed in an auditable development environment, as a "whole product". Software, documentation, validation material, training collateral etc were produced simultaneously.

As a JAD partner, HFL had to provide at least one Ambassador user together with a number of Advisor users for nearly two years of development. Each Ambassador user has to be committed to the Nautilus JAD project for at least 60% of their job.

The role of the Ambassador users has been:-

- Providing key input to requirements and design sessions
- Acting as conduits between LabSystems and the Advisor users, co-ordinating the activities of the Advisor Users and communication between them and LabSystems
- Getting agreement from Advisor Users on requirements and design specifications
- Providing input to prototyping sessions
- Reviewing documentation
- Providing user documentation
- Ensuring user training is adequately carried out
- Organizing and controlling user testing

Advisor users are committed to the JAD project on a part-time basis, typically around 10%-15% of their time. They are usually laboratory operators or their managers who would be end users of Nautilus. In outline their roles would be:-

- Participating on the prototyping and review process
- Approval of designs and prototypes as acceptable for use
- Assisting with functional and usability testing

Trevor De Silva and later Paul Bassett were the 'Ambassador' users at HFL. Trevor De Silva is Facilities Manager with full responsibility for the IT Group. He oversaw the development of Nautilus, its installation into HFL in December 1997, subsequent validation and then going live in March 1998. Now Paul supports the 25 users as they adapt to a totally new LIMS system, which HFL is the first company in the world to run.

Trevor states, "Nautilus has some built-in features which are unique in the LIMS market. These are already revolutionizing our ways of working."

He explains that the Explorer-type interface of Nautilus means that his staff find using it very easy. "Nautilus is just like using Windows® 95; the laboratory team are already familiar with Windows 95 and therefore find using the LIMS very straightforward. For example, where in the past we needed dedicated reports to access the information, with Nautilus they can now just create a new folder, sort data, then later go into the folder to filter and sort through the information."

"Some new innovations were built into Nautilus specifically at our request, and now feature in the final product. One of these is a 'rack' system which mimics our sample handling racks and autosampler trays. This new feature of LIMS works very well for us, and really mirrors the way we work. The new technology that LabSystems has produced with *workflows* is a definite development for LIMS - it gives total flexibility to the laboratory and there is nothing like it available in the world. You can change the business rules in the laboratory, and be up and running with the LIMS in a very short time, *without needing to customize.*"

As well as being designed with a Microsoft® Office user interface, Nautilus also has instrument integration incorporated into the heart of the LIMS, so it can connect and extract laboratory data directly and straightforwardly from most instruments located in the laboratory.

Morgan Skinner, Project Leader at LabSystems for Nautilus, confirms that the pre-release version of Nautilus had some performance issues. "Efficiency in the laboratory is a major consideration for customers so numerous enhancements have been made to Nautilus since the initial installation at HFL, who went live on a January beta release.

These enhancements address usability, functionality, and performance features of the application."

*** List of Prohibited Substances.** *For more information please refer to the International Agreement of Racing Authorities, which will provide types of substances and their threshold levels.*

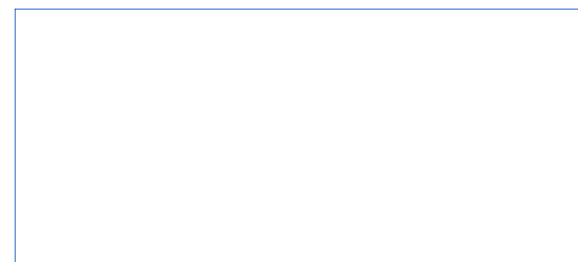
****Chain of Custody:** *the need to provide sample integrity starts from the moment the sample is collected from the animal. Samples are delivered to, processed, analyzed and stored in a secure area, only accessible to authorized personnel using electronic passes. Samples are only identified by coded sample numbers, so there is no possibility that the animal can be identified with the sample (to prevent sample mix-up or deliberate tampering.)*

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