

SampleManager LIMS™

Implementation of a SampleManager LIMS at Helsinn



Profile

Helsinn is a Swiss based group of companies engaged in the licensing, development, manufacture and distribution of pharmaceutical products worldwide. Its headquarters are based in Lugano, and it has manufacturing facilities in Switzerland and Ireland. The group employs 380 people worldwide and in 2004 had net revenues of €€30million.

Two of these facilities are located in Mulhuddart in Dublin 15. Helsinn Birex Pharmaceuticals Ltd. (HBP) is a manufacturing facility producing finished pharmaceuticals for Helsinn's partners and managing the outsourcing of specialist dosage forms for existing and new products.

The second Helsinn facility, Helsinn Chemicals Ireland Ltd. (HCI), is located at an adjacent site and involved in the production of Active Pharmaceutical ingredients. This plant, operating since 1993, complements and extends

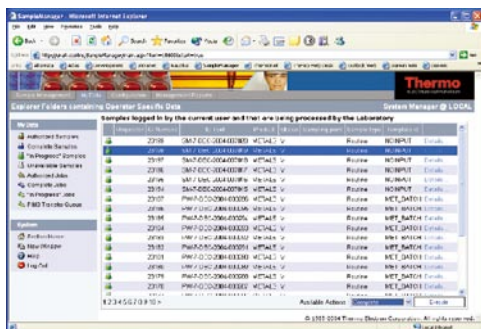
the production capacity of the Group's chemical operations in relation to the development and manufacturing of Advanced Intermediates and Active Pharmaceutical Ingredients (API) in the European Union.

An additional facility is located in Biasca, Southern Switzerland. Helsinn Chemicals SA (HCB), an API manufacturer, has over 20 years of experience in custom synthesis dedicated exclusively to the life science industry.

Requirements

In 2001 the Helsinn Group elected to implement a Laboratory Information Management System (LIMS) in the QC laboratories of its three manufacturing facilities.

At that time the system at Helsinn was a manual process utilizing paper systems, Word, Excel spreadsheets and an Access database. The company recognised a need to utilise the latest technology to improve the



manner by which laboratory data was being managed and controlled within these facilities.

The initial objectives for the proposed LIMS included the complete automation of existing laboratory reporting functions and the enhancement of planning, flexibility and efficiency within the laboratory. The implementation of a LIMS was seen as an opportunity to assess the laboratory practices in place at that time. It was also a key requirement that any system development should be delivered within budget and adhere to recognised quality development procedures including GAMP4, cGMP, Annex 11, 21 CFR Part 11 and Helsinn's own in-house standards.

Following an intensive, year long tender process Orbis Information Systems – a Strategic Implementation Partner of Thermo Electron - were the vendors selected by Helsinn to implement and validate Thermo Electron's SampleManager LIMS. Local training, implementation and technical translation services required by the Swiss facility in Biasca were provided by LabSystems Italia. In their evaluation Helsinn placed much emphasis on Orbis' track record of delivery of a reputable LIMS to the pharmaceutical industry and their capability of delivering a multi-language solution to meet the needs of both the Swiss and Irish sites. Of equal importance to Helsinn was the long term, local support available from this team of LIMS experts.

Solution

To meet the needs of the three manufacturing facilities, two separate LIMS were installed. A LIMS server in Dublin hosted both the HCP and HCI systems on the same instance, while an independent system was deployed in the HCB facility in Biasca. The overall solution consisted of the core SampleManager product and the fully integrated add-on modules, or EFM's (Extended Functionality Modules), Stability and Statistical Quality Control (SQC). The Stability Module was only required by Helsinn Birex Pharmaceuticals.

This was an eight-month implementation cycle from initiation to completion of the operational qualification for both the pharmaceuticals and chemicals divisions. The rollout to the Biasca facility included Italian localization of the product.

During the initial phase of the project, the core system was designed and built in Dublin encompassing the requirements common to all sites. The principal aim was to ensure that both

systems would share a common design to minimise validation and future administration. To this end workshops were held to give visibility of the proposed solution to end-users and to provide a means whereby a common approach between sites could be agreed. Any site differences were managed through the use of configuration settings. The Dublin system was subjected to a full OQ incorporating both standard and configured functionality. The Biasca system leveraged the OQ from Dublin and was thus able to restrict its OQ to site-specific configurations.

Business Benefits

After a thorough PQ the SampleManager LIMS went live in Dublin in September 2003, followed by a rollout to Biasca in early 2004. The initial development of the core LIMS in Dublin resulted in significant cost savings for Helsinn in the validation phase of the project and longer-term savings in the administration of the system.

At a functional level, in addition to providing sample management (login, receipt, test assignment, worksheets and reports) the system has been configured to perform scheduled login for environmental samples, record reagents and instruments used in testing and to track the generation of worksheets and Certificates of Analysis (CoA). There is extensive CoA functionality to support the significant range of product that is manufactured on license. Benefits have also occurred in the following areas:

- Enhanced data processing
- Reduction of paper in a 21 CFR Part 11 compliant LIMS
- Automation of the laboratory reporting functions and
- Improved product release in an expanding production environment.

Helsinn is satisfied that its original objectives for the project have been met by the implementation of SampleManager LIMS. Its three manufacturing facilities in Ireland and Switzerland are now using a common LIMS, which was implemented and validated in adherence to the requisite quality standards.

Future Plans

Looking to the future, Helsinn and Orbis are committed to an ongoing annual review of the system in place. The continued support offered by Orbis post-implementation facilitates this process. A number of areas for future enhancements have been discussed including extension of the CoA functionality and advanced training in report creation to improve system utilization in the short term and a longer-term plan to integrate the existing HPLCs and Group ERP systems to the SampleManager LIMS.