

Supporting Innovation by Implementing a Lean Paperless Lab

Client: Chiesi Ltd.

Technology: ACQUITY UPLC with NuGenesis Laboratory Management and Empower Chromatography Data Systems

BACKGROUND

Chiesi Farmaceutici is a privately owned international research and strategic innovation-focused company in the Pharmaceutical sector that develops and markets products in the respiratory, cardiovascular, and musculoskeletal therapeutic areas.

Part of corporate R&D, Chiesi Ltd. is a technology research laboratory in Chippenham, UK that became fully functional in 2009. Chiesi Ltd. has initiated cutting-edge research in the field of inhalation delivery, with a special focus on pressurized systems. The aim is to leverage and broaden Chiesi's technology capabilities and to find innovative ways to deliver drugs to the lungs. In order to remain at the forefront of inhalation delivery technology, Chiesi is constantly examining new and existing technologies with a view of enhancing the performance of current and future pipelines.

CHALLENGE

Chiesi's Technology Research laboratory was created de novo with a long-term vision of enabling innovation, while taking full control of all data without the need for role segregation and specialist input. The entire laboratory staff of 12 people possess flexible skill sets that allow them to run all laboratory equipment. Hence, every aspect of the laboratory is designed to support science and innovation and minimize any non-value added activities.

BUSINESS BENEFITS

- Increased efficiency and data integrity.
- Improved data management.
- Increased lab productivity and reduced staff turnover.



The laboratory was designed around the concept of a paperless system for data capture, retrieval, and archive. An electronic solution was sought to provide an alternative to paper-based processes and disparate databases, which many of Chiesi's users had experienced at previous companies. Their aim was to speed up and automate activities, such as processing, transcription and cross-checking of data, in order to provide a more rapid and reliable information system that allowed innovation and interpretation of data to take priority.

Based on user requirements, data retrieval and collaboration were two compulsory key functionalities. Hence, from a technology perspective, they desired a solution that utilized a relational database with a centralized server in order to facilitate easy storage and location of data.

Another aspect was the compatibility of the proposed software with their instrument hardware. The research laboratory simultaneously acquired two ACQUITY™ UPLC™ systems from Waters, and several analytical balances from METTLER TOLEDO, and had recently added Sartorius. As a result, these analytical instruments needed to interface with their new software solution.

THE SOLUTION

Besides fulfilling the technical requirements, Chiesi's purchasing decisions were driven by the capability of the software and instrumentation solutions to streamline and simplify their laboratory-based processes. The demonstration phase of the instrument and software solution confirmed this and built confidence within the team.

In order to achieve a paperless lab and eliminate all non-value added manual and paper based steps in the laboratory, they selected the complete laboratory informatics solution from Waters, that included Empower™ Chromatography Data System (CDS) and NuGenesis™ Laboratory Management System (LMS).

Two ACQUITY UPLC systems with ACQUITY SQD (single quadrupole MS detection) running under Empower were implemented. Each of the systems were equipped with Sample Organizer, Binary Solvent Manager, Sample Manager, Column Manager, PDA Detector, and SQD MS Detector.

On one of the systems, a CoronaUltra RS for charged aerosol detection was utilized, also controlled by Empower. In addition to the comprehensive multi-vendor instrument control, other key functionalities of the networked Empower CDS were custom fields and custom calculations allowing Chiesi Ltd to eliminate isolated spreadsheets for any CDS-related calculations.

For laboratory data management, NuGenesis LMS was interfaced with all instruments in the laboratory. Although Empower is capable of managing chromatography data, it was decided that all laboratory data should reside in a single data repository. Therefore, data and reports from Empower, as well as all results generated by any other instrument, were automatically captured into NuGenesis LMS. Additionally, all scientific documentation created internally or by external collaborators was securely stored. The automatic metadata extraction capability enabled the easy retrieval of any information for collaboration.

The creation of electronic documents plays a major role in the paperless environment. The potentially time-consuming process of searching for data and manually transcribing it has been replaced by automatic import and storage of information into NuGenesis LMS.

Even though the Chippenham Technology Research Centre does not work under GxP regulations, reviews/approvals and double signatures are an integral part of their data system – the ability to verify continuous processes, concept development, and project progression is essential for intellectual property protection. The signature process is fully integrated into the electronic workflow to demonstrate the integrity of the data.

Every staff member was trained by Waters – this was identified as the most efficient method to cross-train the entire team. With everyone equally trained on all equipment and software, workflow bottlenecks were eliminated. Shortly following training, the staff confidently designed custom fields in Empower CDS and templates for documentation in NuGenesis LMS. As a result, the team was able to utilize the solutions within a short timescale.

BUSINESS BENEFITS

The main goal of implementing a paperless lab by utilizing Waters solutions was to prioritize innovation activities at Chiesi Ltd. Key benefits include:

- With UPLC and Empower, an example run time was reduced from ten minutes to one minute, while solvent consumption was reduced approximately twenty-fold.
- By using UPLC, the lab required fewer instruments compared to traditional HPLC – this translated to reductions in individual system suitability checks, maintenance, waste, and occupied lab space.
- Use of Empower CDS not only provided Chiesi Ltd with increased efficiency and data integrity by reducing manual calculations and transcription; but also enabled rapid identification of unexpected results by setting definable thresholds within Empower.
- Creation of documents for experiments had previously been a paper-based and manual process. Entering information electronically into NuGenesis LMS greatly reduced the time spent on this activity.
- Review and signature activities were performed easily and quickly within NuGenesis LMS by research peers. Due to the automatic transfer of data, cross-checking has been reduced to a minimum, freeing up time for scientific tasks rather than non-scientific, time-consuming activities.
- Proof of scientific integrity as well as Intellectual Property protection is possible with NuGenesis LMS.
- Basic method development can now be completed in a few hours, and entire feasibility studies in a markedly shorter length of time.
- Elimination of superfluous documentation tasks has contributed to very positive employee morale, keeping the turnover minimal and allowing the team to remain agile by keeping the staff number low.

Waters

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