

Improving Laboratory Efficiency and Reducing Compliance Efforts with a Networked Chromatography Data System

Client: Erregierre

Technology: Empower Chromatography Data System

BACKGROUND

Erregierre is a leading international manufacturer of active ingredients for the pharmaceutical and generics industries. The company has two cGMP manufacturing sites in Italy and includes a Research and Development organization that enables Erregierre to provide fast-track process development and a high level of service in custom synthesis. The products include cardiovascular, central nervous system disease, antifungal, anti-inflammatory, gastrointestinal, anti-allergic, and expectorant areas. The broad area of products demand about thirty different synthesis reaction categories, which require high flexibility in the production process, as well as in the accompanying quality control testing and review. Erregierre serves international markets requiring compliance with FDA and EMEA regulations; hence, the business and laboratories must strictly adhere to GxP regulations.

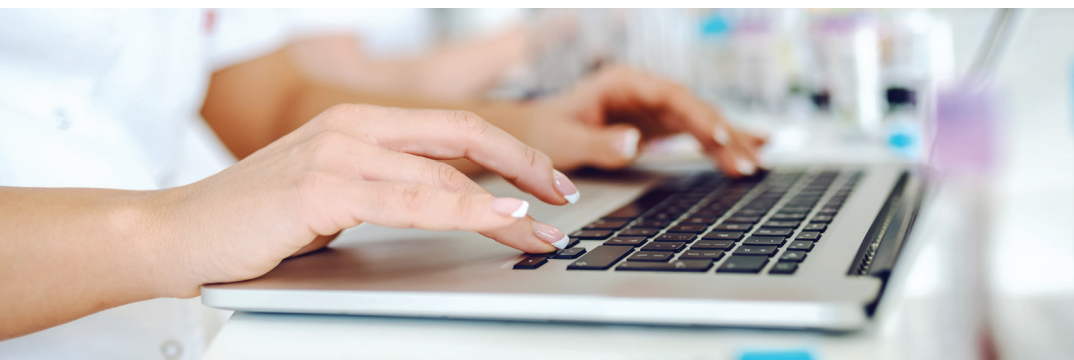
CHALLENGE

The main site in San Paolo d'Argon includes a Quality Control and an Analytical Development laboratory with 20 HPLC and UPLC™ instruments and nine users. The site in Sovere has a Quality Control lab where three people work with five HPLC instruments. All of the liquid chromatographic instruments were manufactured by Waters and controlled by separate Empower™ Chromatography Data System (CDS) personal workstations.

The laboratory challenge centered on supporting quality testing for a large variety of products with differing production timetables. Chromatography testing on different projects often required the development and utilization of different separation methods; however, reliance upon un-networked personal workstation chromatographic systems meant that it was necessary to manually maintain projects and methods for each of the 25 individual instruments. The ideal solution to avoid the redundant manual work was to convert the isolated Empower personal workstations into a single networked CDS so developed methods were available on appropriate HPLC and UPLC instruments.

BUSINESS BENEFITS

- Increased efficiency in method creation and maintenance.
- Cost savings of 50,000 Euros per year.
- Reduced qualification and validation efforts by 20%.
- Increased regulatory compliance adherence.
- Increased data security.



Backing up chromatographic data represented an additional challenge because utilizing isolated personal workstations meant backups had to be done manually by saving data on CDs or the Intranet. This process was tedious and there was no guarantee that all data would be securely stored.

Working as a Contract Manufacturing Organization (CMO) in an international market, Erregierre is subject to audits and inspections by regulatory agencies and customers on a regular basis. Customer audits require the laboratories spend approximately one week per month focused on inspection and related activities, such as preparation. While this is a necessary part of doing business for a CMO, inspection activities are time-consuming and considered non-value added with regards to laboratory productivity.

THE SOLUTION

The decision was made to migrate from Empower CDS personal workstations to an Empower CDS network because the functionalities of the network solution were suitable for Erregierre's chromatographic quality testing application and regulatory compliance requirements. They were also satisfied with the unique range of service offerings, including qualification for HPLC instrumentation.

Tremendous efficiency gains were achieved for chromatographic method development by using Empower as a single CDS network solution. Once a method was created it could be used by all compatible chromatographic systems in service, simplifying their activities and increasing productivity.

Compliance efforts were significantly reduced because only one network CDS solution required validation versus 25 separate personal workstations prior to the migration. An additional observation was made during regulatory audits.

The backup of chromatographic data was now done automatically from the individual client systems to the Empower server. This automation of the process not only saved time but has also increased data security. Erregierre's reduced their qualification and validation efforts by 20%.

After the implementation of the Empower CDS network, Erregierre took an additional step to improve their lab efficiency. Waters Global Services provided maintenance and qualification of their chromatographic system. After deployment of the Empower CDS network, the staff received additional training on performing periodic qualifications themselves by using the Automated Qualification Tool (AQT). AQT is an electronic tool for Empower that fully automates and simplifies the qualification process for Waters chromatography and electronic data management systems. With this training Erregierre became self-sufficient in their CDS qualification activities. They now perform the tests four times a year, whereas previously they had only performed qualification once per year. The time effort remained the same, but now they have the opportunity to update and cover more aspects of the system. By using the self-directed AQT, Erregierre could qualify more systems in a more complete way, leading to time savings and increased confidence at the same time. Additionally, they achieved a cost savings of 50,000 Euros per year.

Waters

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