

Improving Quality Control and Stability Testing Efficiency with Standardized Chromatography Operations

Client: Napp Pharmaceutical Group

Technology: Empower Chromatography Data System

BACKGROUND

UK-based Napp Pharmaceutical Group is part of a worldwide association of independent companies. The company manufactures and markets innovative products in the areas of oncology, respiratory, and pain management – with analgesia being their largest therapeutic area.

One of Napp Pharmaceuticals core values is innovation, which defines behaviors and decisions within the organization and therefore drives strategies in the laboratory and informatics environment.

At the site in Cambridge, the Quality Control (QC) and Stability laboratories perform the required testing of raw materials, intermediates, and final release. A total of 22 people are tasked with release and shelf life stability testing. The two laboratories are equipped with 54 chromatographic instruments from multiple vendors where 34 of the 54 systems consist of dissolution baths. The chromatographic data system (CDS) used in the two labs is considered vital for achieving release of the products to market – and therefore a key element in ensuring success of the entire organization.

BUSINESS BENEFITS

- Easier sharing of data between the labs.
- Improved communication.
- Removal of transcription errors.
- Easier access to information.
- Reduced errors because of a smoother and undisturbed workflow.
- Reduced bottlenecks in the lab workflow.
- Increased sample throughput without compromising on release times.
- Flexibility in staff allocation.
- Reduced training costs.



CHALLENGE

The difficulties in managing and efficiently using different chromatography data systems for chromatography and dissolution represented the largest challenge for the laboratories. Further adding to the complexity of operating separate CDS solutions, the laboratory's on-going data generation started to exceed the limits of the existing file-based system data management process.

In addition to the data management challenges, the use of Microsoft® Excel® for calculations and reporting was an additional source of waste and variability in laboratory workflows. For example, manual steps in documentation workflows provided the opportunity for errors due to incorrect data transcriptions. Furthermore, managers sometimes interrupted analysts during testing to request access to reports.

In recent years, Napp Pharmaceuticals' success in the marketplace has translated into greater product demand, which in turn led to the need for more sample testing and reduced result turnaround times. Any delays in testing translated into delays in product releases, thus directly impacting revenue. Since chromatographic testing was recognized as vital for the product release process, management determined that a single compliance-ready CDS solution was required to improve data management, boost laboratory productivity, and reduce compliance risk.

In order to deliver a single compliance-ready CDS solution for the laboratory operations of Napp Pharmaceuticals, the IT department developed a plan to implement a commercial off-the-shelf software (COTS) package. The ideal solution would standardize chromatography operations on a single comprehensive CDS solution that included integrated data capture, analysis (including automated calculations), and reporting.

For a forward-looking company such as Napp Pharmaceuticals, the new CDS should not only satisfy the needs of today, but also serve as a platform for the needs of future business growth.

THE SOLUTION

A dedicated team of four analysts was assigned to the CDS implementation project. During the six months analysis phase, the team identified data security and integrity as key aspects of the project. Armed with vendor selection criteria, the team chose Waters™ Empower™ Chromatography Data System as their new CDS standard. Empower was identified as a complete solution for data capture, data analysis (with automated calculations), and flexible reporting in one platform. As future workflow needs arise, Empower offers a large variety of add-on options such as Data Guard for database replication and Enterprise Data Manager (EDM) for archiving and restoring Empower projects.

With the comprehensive reporting capabilities of Empower, the team was able to replace other reporting tools, including Excel. Managers now have better access to critical reports by logging onto Empower from their own computers without the need to stop an analyst during a testing procedure. Making use of Waters' "train-the-trainer" concept, the project team has designed custom training for their colleagues to fit the workflows that analysts perform routinely.

An additional advantage of Empower is its advanced technology and the fact that it is based on an Oracle database. It is considered a complete but continuously evolving solution and therefore a sound investment for the future. The selection process was weighted heavily on the capabilities of the product, but the team also valued the culture of innovation prevalent at Waters – one which aligned well with Napp Pharmaceuticals' own culture.

BUSINESS BENEFITS

Standardizing on Empower CDS has enabled Napp Pharmaceuticals QC and Stability laboratories to increase sample throughput for product release. At the same time, it provides a foundation for future chromatographic data handling needs, enabling innovation – one of the core values of this organization.

Benefits include:

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