

## Empower Cloud Allows Analytical Data to Be Accessed Any Place and Any Time

**Client Representative: Analytical Team Leader of a Research Arm of a Government Innovation Company**

### BACKGROUND

As the research arm of a national government innovation company, the organization is a leader in the development and manufacture of active pharmaceutical ingredients (APIs) for pre-clinical and clinical trials, ranging from conventional small molecules to dendrimers and complex oligosaccharides. They also undertake custom, specialty manufacture of commercial ingredients under contract. One of the world's leading experts in both carbohydrate chemistry and Good Manufacturing Practice (GMP), the organization is known for its ability to solve complex problems for clients worldwide.

The analytical department's remit includes analytical development, validation, quality control, and stability testing for products. Their clients range from multinational pharmaceuticals to biomed start-ups coming out of universities – including those involved in Intellectual Property research.

They also work closely with a local research institute of an university on carbohydrate development, supporting its contract research work to bring better drugs, materials, and technology to the world.

The organization has 35 people working in various research and manufacturing teams. This includes eight researchers in the analytical department, six in the manufacturing development team, nine in the chemistry development team, and the rest in the two reactor teams for GMP manufacturing.

### THE RESEARCH LAB CURRENTLY USES TWO PRIMARY WATERS SOLUTIONS

- Waters™ ACQUITY™ UltraPerformance Liquid Chromatography (UPLC™) System (x3)
- Waters Empower™ Chromatography Data System (CDS) Enterprise Network

The whole system is maintained for GMP manufacturing, with the Empower configuration and instrument qualification setup for maximum compliance.



## CHALLENGE

Back in 2006, when the Team Leader first joined the organization, they were using three different chromatography data software solutions in the laboratory, including what was then Waters Empower 2. The solutions were software packages installed on stand-alone PCs. Researchers had to manually input data to get them analyzed – a very tedious process that took as much time as the actual lab work itself.

When the first of these packages reached the end of its lifespan, the team voted on the preferred solution that worked best to meet their needs. All the team members chose Waters Empower CDS and the decision was made to migrate all their systems to Empower Software. Coincidentally, they also decided to upgrade Empower to an enterprise server option, working with workstations and a central server located onsite.


This upgrade to Empower Enterprise brought a whole new set of benefits to the lab. All of the data was centrally located and easy to access, analyze, review, and share. There were fewer paper trails and there was no longer a need to transfer data from one PC to another.

## SAVING TIME

Clients often choose this research arm because of their experience in delivering complex projects. What is also important to customers is the time the organization can save them. As early adopters of Waters equipment, the research lab acquired a Waters ACQUITY UPLC System very early on. They found that the improved Waters solution allowed them to vastly reduce method development time, enabling them to deliver results faster to their clients.

For the research lab, their biggest single investment is the chromatography data system, and they need one system that does it all – a CDS that can minimize both product validation and ongoing operating costs, and provide reliability: *“One of the key things that we have with Empower is the mass spectrometry option. So, having one software package that gives us everything is perfect – the UPLC, the PDA, and High Performance Liquid Chromatography (HPLC) mass spectrometry, and also allows us to do the HPLC CAD, iChromatography, size exclusion, and molecular weight determination.”*

Having everything in one package also allows them to have a platform that can support them in large-scale production: *“Most of the time we are the first people trying to make things on scale, beyond single milligrams sometimes. If someone’s not made it on any kind of scale before, that’s the biggest challenge for our organization – doing something for the first time with the equipment we have at our disposal.”*



*“Clients want things as quickly as possible. If we can double the plate count for separation, that makes method development a lot easier. So, it’s pretty common for the team to start method development with a 15-cm BAH Column with the UPLC. They can then screen through the ultraviolet with a photodiode array and Charged Aerosol Detector all in one go.*

*Its speed to getting to a method. It doesn’t mean that a runtime has to be quick. Some people use UPLCs for the short runtime. In contrast, we often take 30 to 60 minutes for UPLC separations, but if we can separate everything very early on in the project, it speeds up that delivery time.”*

– ANALYTICAL TEAM LEADER

## MIGRATION TO THE CLOUD

In 2018, there was a shift in the organization's IT policy. The IT team told them to investigate the feasibility of the Empower Cloud solution, giving the potential of even more freedom to use any screen to access data, using apps for the processing and user interfaces as well.

Working closely with Waters, the upgrade of the Empower CDS to the cloud was very smooth. Benefits are already being seen, with the cloud allowing staff to be more productive. Previously, with the onsite server, it was difficult to access data outside of the lab, due to the security setup. But with Empower Cloud, the team can access lab data results anywhere in the world and immediately work with a client on a project in real-time.


*"We still use the same interface, but because we are now allowed access anywhere, my team can literally grab their laptops, set the test run going, do some simple system suitability checks, go out, and then finish off the work at home,"* said the Team Leader.

However, it was during the recent COVID-19 pandemic that the solution came into its own. When the team realized they were going into lockdown, they were all issued laptops so that they could work from home and reduce the impact on their clients. With the ACQUITY UPLC running, and the Empower Cloud Amazon Web Services (AWS) workspace solution in operation, they were able to make a seamless transition.

## IMPORTANCE OF LONG-TERM RELATIONSHIPS AND SUPPORT

The Team Leader also expressed thoughts about collaborating with Waters: *"Over the years, support from Waters Australia has been nothing short of excellent – and is crucially one of the reasons why the research arm has kept faith with Waters. It wasn't just the support. It's also the quality of support received for both hardware and software – especially with the big change of moving to a cloud-hosted system."*

The Team Leader related an experience of working with a support engineer: *"A Waters engineer came over from Australia to install our new ACQUITY UPLC. We found out there was a small fault with the PDA. The engineer arranged for a replacement part to be shipped from Singapore. He then changed his flight and stayed on until the weekend, not just to fix the problem, but also to finish the qualification of that instrument. He wouldn't leave until it was working."*



*" It felt exactly like being onsite working with the system. While most parts of the lab were shut down, my team still had access to information remotely. This allowed them to do the processing, all the necessary report write-ups, and answer as many questions as possible from clients while at home."*

– ANALYTICAL TEAM LEADER

## NEXT STEPS

With the migration to a cloud-based system now completed, the research arm is firmly looking forward to benefitting from new versions of Empower Software in the future. The Team Leader said that the company will continue to use Waters because of its strong industry reputation.

*"Familiarity, and trust in the Waters brand across the industry, is of huge benefit to all users. It's been a positive experience, and most helpful in the recent working-from-home situation – we now have access to data, can write peer reviews, and also sign off on reports through digital signatures from home.*

*We also have current clients who use Waters products. This allows for easy and free interchange of data. For example, we can now simply drag and drop chromatography results. It also helps to have an internationally respected and adopted chromatography package for use. We have successfully gone through regulatory audits with the Waters system for many years now and I don't see why we would need to change that."* said the Analytical Team Leader.

# Waters

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