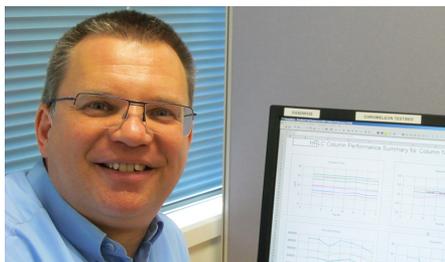


Chromeleon reports provide significant time and cost savings for New Zealand pharmaceuticals manufacturer

Introduction

Douglas Manufacturing was established in 1967 as a spinoff of Douglas Pharmaceuticals. The company operates GMP-compliant, FDA-approved, state-of-the-art manufacturing facilities in New Zealand and Fiji. Both sites produce and package pharmaceuticals, nutraceuticals, dietary supplements, cosmetics and animal health products. In addition to its FDA compliance, Douglas Manufacturing is licensed by the New Zealand Ministry of Health, and by the New Zealand Ministry for Primary Industries. To complement its manufacturing, the company maintains advanced laboratories that conduct analytical testing and engage in new product development.



Douglas Manufacturing conducts stability tests, microbiological assays, and various analyses on raw materials, intermediates, and products. The company follows guidelines from appropriate pharmacopoeias (United States, British, and European) for its monograph testing of excipients and Active Pharmaceutical Ingredients.

For raw materials, the company assays for residual solvents, purity and impurities, moisture, pH, specific optical rotation, density, and other relevant parameters. Analyses of products and intermediates include limit tests, tablet dissolution/disintegration, and numerous methods employing ultra-high performance liquid chromatography, high-performance liquid chromatography, and gas chromatography.

Bernd Boscolo received an Engineering Diploma in chemistry from the University of Applied Sciences, Isny, Germany. He worked for more than three years at privately held pharmaceutical manufacturer Swiss Caps AG, Kirchberg, Switzerland before joining Douglas Manufacturing eight years ago. In his most recent position as QC Improvement Projects Team Leader, Bernd oversees Chromeleon CDS operation in his company's Quality Control and New Product Development laboratories. His duties include the design and validation of Chromeleon Report Templates.

“The Chromeleon Report Designer is a mighty tool to calculate and present data, and to our understanding is far better than any other software package ... With the Chromeleon Reports, we are seeing time and cost savings saving equivalent to four to five full time employees depending on the workload in each month. These savings are higher than anticipated.”

Bernd Boscolo
QC Improvement Projects Team Leader
and CDS Administrator
Douglas Manufacturing Ltd.
Auckland, New Zealand

Improved sample throughput

Douglas Manufacturing uses the Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) software to control more than thirty-five gas and liquid chromatographs, of which nearly two thirds are from Dionex.

Of the 500 to 600 analytical runs Douglas conducts each month, approximately 90% employ Chromeleon Report Templates to calculate results directly within the Chromeleon CDS software. Before it had this capability, the company used validated external spreadsheets to calculate results from some of the tests.

“Historically, we calculated all results by hand and checked them manually. The implementation of validated Calculation Templates for our high-volume products improved the situation significantly. However, Calculation Templates were unavailable for the majority of the tests. Although manual checking of the results was not required when results were calculated using the Calculation Templates, transcription errors were still very common.

We now have two product-specific and three generic Chromeleon Reports for calculating the results of 13 different GC and LC tests. All results are calculated in Chromeleon without the need for third party spreadsheets. These five reports replace more than 30 of our Calculation Templates, so the maintenance effort is much lower. In particular, we are very proud of our report for related substances/known impurity content. This report alone replaces 20 of our product-specific Calculation Templates for our high-volume products and it can also be used for most of the raw material methods where Excel templates were previously unavailable.

The starting points for our reports were the templates in the Chromeleon Extension Pack; these templates were provided with helpful information on how to modify the formulas contained within to our requirements.”

The Chromeleon Extension Pack is a set of templates, provided at no cost, containing sequences, methods, and report templates. It allows users to quickly and easily perform and report common tests that otherwise can take considerable amounts of time to process. The templates will automatically compare the analysis results to specifications and let users know immediately if the tests have passed or failed.

Choosing the right CDS

As many rationales exist for acquiring a CDS as there are companies. Some organizations decide based solely on sample throughput or number of instruments; others on the desire for consistency across methods and instruments.

Without centralized control and data storage, separate stand-alone computers may control anywhere from one to several instruments. Keyboards, monitors, and peripherals multiply with scheduling and logistic issues when, for example, two analysts need to work on different instruments controlled by the same computer. Methods operating across multiple chromatographs must be manually entered or ported and decentralized control means more manual operations that carry a greater risk of human error.

“Before installing the Chromeleon CDS, we stored HPLC data locally on server PCs. The installation of the CDS in a client/server environment provided secure data storage. Our manufacturing plant is GMP compliant and FDA approved, with all our Chromeleon Reports validated according to GAMP5.”

Perhaps the most costly consequence of not having a centralized chromatography data system is the need to train workers on multiple instrument software platforms.

“The learning curves for laboratories that use LCs and GCs from multiple vendors can sometimes overwhelm. Workers who are untrained in a particular instrument model are by definition less productive. With Chromeleon scientists and staff need only learn one platform.”

Douglas Manufacturing became a Chromeleon CDS user through a typical route. At inception, the company purchased both HPLC instrumentation and software from one top-tier vendor.

“Although the hardware as such was robust, we found the software to be rather unintuitive, so we began looking at other control packages. At the time, products from Agilent and Waters were too expensive, whereas Chromeleon CDS offered just the right compromise between price, performance, and user-friendliness.”

Bernd also states, *“Chromeleon CDS offers the best support for third party instruments; competitors’ software provided only limited support for far fewer third party instruments.”*

Realizing immediate benefits

Before installing a networked CDS, Douglas had traditional workstation-based software controlling its analytical instruments. Chromeleon CDS provided modern networking capabilities, which improved the laboratory data flow.

“We now spend less effort on data and system maintenance, and can now process data remotely. Our data-checkers and reviewers no longer need to be in the same room as the instrument, as they all have Chromeleon CDS installed on their personal workstations.”

According to Bernd, setting up analytical sequences and methods is straightforward and amazingly flexible.

“The setup of sequences, processing methods and instrument control programs is easy, and also offers a lot of flexibility during set up. We use our own sequence templates, which work perfectly.”

Chromeleon CDS has also simplified how Douglas Manufacturing performs data searching and trending. The company now relies extensively on the built-in data Queries to prepare monthly reports.

Bernd has also recently designed a report to monitor the performance of his company’s hundreds of HPLC columns.

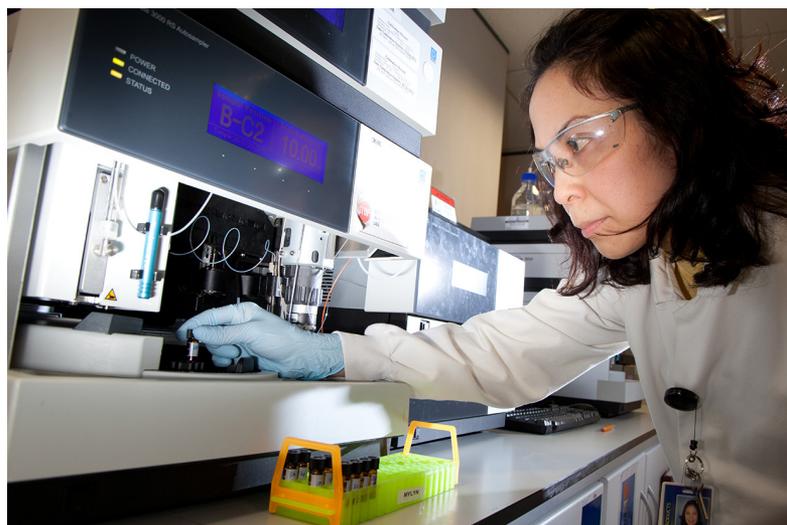
“The old process involved entering results manually into Excel spreadsheets. Each column had its own workbook. Now, straightforward Queries for each HPLC column pull data out from the Chromeleon CDS database, and provide trend charts for pressure, resolution, plate count, asymmetry, and retention time. We also use a utilization report to monitor the workload for each of our instruments.”

Chromeleon CDS provides Douglas Manufacturing with numerous time- and cost-saving benefits, including 21 CFR Part 11 compliance. Bernd’s experience with fully-compliant electronic signatures is typical.

“We immediately recognized the security benefits of e-signatures, which protect the sequence and any calculated data. And of course, we save reams of paper...”

Before the CDS installation, Douglas employees hand-signed critical documents. For some time afterwards, the company transitioned to what Bernd calls a “hybrid system” combining both printed documents and e-signatures.

“The hybrid approach allowed us to examine closely the value of e-signatures, and how best to employ them moving forward. In the near future we will move to using e-signatures exclusively. We immediately recognized the security benefits of e-signatures, which protect the sequence and any calculated data. And of course, we save reams of paper, which reduces costs and helps protect the environment.”



Reducing maintenance and errors

Like many busy pharmaceutical service laboratories, Douglas Manufacturing maintains a very large number of test methods and analytical procedures – approximately five hundred, according to Bernd. Maintaining this number of methods previously required a full-time staff of three, with one worker dedicated to designing and validating their Calculation Templates for methods devoted to high-volume products.

“Now the Chromeleon Reports take care of this. Because we can keep most of the reports generic, there is far less maintenance work and these reports can also be used for low-volume products for which no Calculation Template is available.”

As previously mentioned, at one time workers calculated and checked results manually. Lab workers needed to be next to instruments where test data resided, and had to enter numbers into calculators.

“Before we implemented validated reports, manual calculation was the only way to determine percent differences of peak areas and retention times, duplicate injection times, and percent differences of check and calibration standard peak responses. We had to check critical parameters, which are part of our system suitability requirements, during the run. When data is entered into Excel after the run ends, it is too late to take corrective action. At that point, when a parameter failed, we faced producing a time-consuming laboratory investigation report.”

Today, Chromeleon Report Templates show results immediately, enabling Bernd and his colleagues to react to problems in close to real time. Chromeleon CDS alerts workers to samples requiring re-injection, for example, when peak areas from two injections differ by more than two percent.

“The benefits are sometimes difficult to quantify, but I know that because of Chromeleon, we’ve been able to avoid many laboratory investigation reports.”

Technical support capabilities

Networking multiple instruments through a chromatography data system can be a daunting exercise without a high level of customer support. Douglas Manufacturing, which is halfway around the world from Thermo Fisher Scientific headquarters, experienced the value of support and training first hand.

“Overall we have been well supported throughout, especially during the setup stage when technicians visited us frequently.”

Conclusion

Selecting a chromatography data system involves a thorough assessment of a laboratory’s workflows, throughput, personnel, and existing instrument base. Like Douglas Manufacturing, both large and small laboratories report tangible benefits such as centralizing instrument control, networked accessibility, automated data reporting and storage, lower costs, and greater efficiency.

Using Chromeleon Report Templates, Douglas Manufacturing saves the time and cost equivalent of four to five full-time employees, depending on the month’s workloads.

“The cost and time savings are much higher than we anticipated. Based on our experiences, we would expect to see Chromeleon to become the number-one chromatography data system.”



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