

Regis Technologies Gains Significant Efficiencies in Pharma/Biopharma Manufacturing

Integrates Chromeleon 7.1 CDS Software into Their High-Volume Contract Manufacturing Operation

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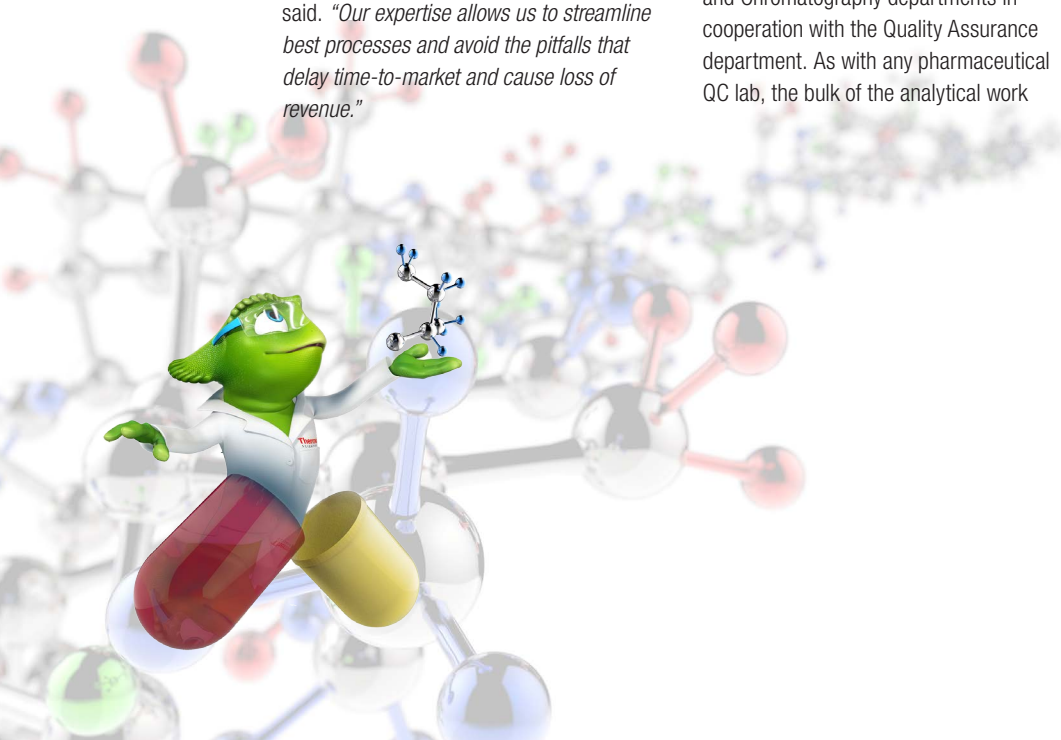
Maurice Andrew (Andy) Hippleheuser,
Director of Quality Control at Regis Technologies, Inc.
Morton Grove, IL, USA

Andy Hippleheuser heads one of several critical roles at the contract management organization (CMO). He's the Director of Quality Control at Regis Technologies, a Chicago-based company that provides synthesis and separations services to pharmaceutical and biotechnology companies throughout the drug's development process. *“We help our customers expedite drugs to market,”* Andy said. *“Our expertise allows us to streamline best processes and avoid the pitfalls that delay time-to-market and cause loss of revenue.”*

The company has developed the expertise needed to excel in scaling up active pharmaceutical ingredients (APIs) as they progress from initial process development, to validation and commercial manufacturing.

Andy provides analytical quality control (QC) support for the Production, Process Research, Supercritical Fluid Chromatography (SFC), Analytical Method Development, Stability, and Chromatography departments in cooperation with the Quality Assurance department. As with any pharmaceutical QC lab, the bulk of the analytical work

is done primarily by high-performance liquid chromatography (HPLC), with gas chromatography (GC) being a close second. Being connected to 14 HPLC and 6 GC systems, the Thermo Scientific™ Dionex™ Chromeleon™ 7.1 Chromatography Data System (CDS) software plays a big part in that mix. Here is a recent interview we had with Andy about why they chose Chromeleon CDS software when it came time to upgrade, how they use it, and what their experience has been.



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Why Regis Technologies Chose Chromeleon CDS Software

Feature 1: Cobra Wizard Integration Tool

Cobra™ is a peak detection algorithm that ensures consistent and reliable peak detection and integration across multiple chromatograms. Integration of chromatographic peaks determines the area under the peak, the height of the peak, and the peak's retention time.

The Cobra Wizard interface guides you through the correct setup of peak detection parameters in three easy steps that: 1) define the integration range, 2) specify the smoothing width, and 3) identify the smallest peak to be integrated. These settings give the Cobra peak detection algorithm all the information needed to accurately and concisely integrate the peaks of each chromatogram within a sequence.

[For more, read "Taking the Pain Out of Chromatographic Peak Integration"](#)

Feature 2: Automated System Suitability Testing

Chromeleon CDS software automatically performs SST calculations. In U.S. FDA, USP, and EP regulated laboratories, SST is required to ensure that a chromatography system (instrument, reagents, columns, and analysts) is suitable for the intended application. The general goal is to monitor chromatographic results to ensure chromatographic suitability (e.g. by testing tailing factor, column efficiency, and resolution of critical peak pairs) and consistent system performance (e.g. by using replicate injections of test standards).

Unregulated laboratories can benefit from automated SST as well. There are hundreds of calculations to choose from. In addition to key values recommended by the FDA, Chromeleon CDS can automatically perform SST on injection repeatability, capacity factor, peak tailing factors, relative retention time, area %, peak width, concentration, and many more criteria. SST can also be performed during sequence acquisition, and the sequence can be automatically aborted if any value fails.

[For more, read Thermo Scientific Technical Note 708: "Chromeleon 7 Chromatography Data System Software"](#)

Interview with Andy Hippleheuser of Regis Technologies

Q: You must have compared other CDS softwares. Why did you consider Chromeleon 7.1 CDS for your situation?

Andy: We did consider several alternatives to our old software system. Our previous system had been around for many years and it began to require large monetary investments just to keep it running. Having had experience with the original PeakNet software provided by Dionex in the early 2000s, I selected the Chromeleon software to be evaluated by the team in the vendor supply process.

After the initial vendor selection, the choice of Chromeleon was based on three specific items: the Cobra Wizard integration tool, the SST piece within the Processing Method, and the real-time MiniPlot thumbnail presentation of the chromatography run.*

Q: What was your experience setting up and learning the software?

Andy: After deciding which CDS to go with, it was now time for me to learn the system. As the head of the project team for the Chromeleon software implementation, I became intimately knowledgeable with the software system. From my previous experience implementing three other software systems at Regis, I knew preparation was the key. I had only three months to learn the system and attend training classes. From that, I was able to prepare all procedural documents and prepare structural organization to be utilized by the QC department after installation.

We divided installation into three phases that took one week for each:

- Phase 1: Half the QC instruments were converted to Chromeleon, while I performed a four-day training session on the specific procedural documents related to Regis' use of the system.
- Phase 2: The other half of the QC instruments were converted to Chromeleon.
- Phase 3: Was devoted to method development and the SFC groups.
- Week 4: We performed validation by quality assurance (QA) to prove 21 CFR compliance of the software for our use.

We were up and running the following week. It took about four weeks for what I would call complete operation of the system by each individual analyst. After that, Regis opted for Thermo Scientific to provide onsite Chromeleon CDS User Level 1 and Level 2 training.

Q: How many methods do you perform?

Andy: Regis has multiple Data Vaults based upon the various laboratory departments. Data Vaults are distinct storage locations for information and processes used by the Chromeleon software. Each Regis Data Vault has distinct privileges provided to the users and has been validated for use in a 21 CFR environment. Regis has about 800 test methods and 300 validated methods in use. We have converted about 30 test methods and 20 validated test methods to Chromeleon 7 CDS. Conversion is an ongoing process and will continue as new methods are needed or created.

Being a CMO, we conduct methods with a lot of variations. Chromeleon lets me create and 'lock' individual templates for each method, process, and report. We can even lock down the view so the same scale is shown every time. There are 15 analysts on the system and 5 QA reviewers. We use all of our 15 licenses.

*See the sidebars article for a description of these features.

Q: Did Chromeleon software change the way you do things in the lab?

Andy: Absolutely! We have now moved to electronic signatures and this allows us to save time and paper. Only the final approved report is printed and goes into the individual batch record. Through the use of templates for methods we have saved time because the analyst does not need to build the methods and this also saves on internal errors.

Even larger is the gain in efficiency from the use of the Report Designer feature for creating reports that can be locked down so that entry of data such as area counts etc. is handled automatically by the system. This has taken what was a 2–3 hour job to <1 hour in most cases. This comes with an upfront cost of allowing the time to build the templates, which the Regis team can use more than once.

The largest savings is in the use of Chromeleon software's SST feature in the processing method. Since Regis runs a two-shift operation, there was always an 8-hour period/day when analyses would run but could not be monitored. This meant running finals at risk since you could not physically view system suitability criteria. Now SST data allows me to build the criteria into the run and the software can decide to continue or abort any run. Now I can make use of a whole extra shift.

Q: What are the drivers, issues, and concerns of your lab?

Andy: As with any lab, it is efficiency followed closely by the audit trail. Even in non-GMP activities you want to be faster and able to track events within the system.

Q: How does Chromeleon software help with compliance?

Andy: It contains the necessary pieces for software compliance: unique login control, individual security privileges and levels, complete audit trail, and server security.

Q: What is the major benefit to your lab? Why is it important to your customers?

Andy: I would say, for customers, the greatest benefit is the report. Regis has 20 to 30 different projects/customers in a year. Each one has their own preference as to what they want in a report. This made working with past systems cumbersome and in many cases, different parts of the report would need to come from a combination of the operating software, Microsoft Word®, and Excel®. Now it all comes from the Report Designer and Electronic Report features in the Chromeleon software. Everything is in one report, which can be converted to several viewing stills with the click of a mouse.

Q: What are your plans for Chromeleon software moving forward?

Andy: Plans for the future are already being worked on. The system is being used to replace tracking and trending for the different labs to provide information on the 'readiness' of the analytical run through the use of limits. Area, retention time, plates, and other parameters are being put into a template so that they can be pulled up for any method where the use of tracking and trending is necessary. Efficiencies will be gained since data from the operating system will no longer be transferred manually to another system.

Additionally, Regis is working directly with the Thermo Scientific team to use Chromeleon to capture electronic data from instruments not controlled by the software, such as FTIR, UV-VIS, NMR, etc. Further investigation is going on to see what data types can even be evaluated within the Report Designer Pro feature. We are currently purchasing a new Thermo Scientific™ TRACE™ 1310 GC system and developing the process for its data capture.

After that, plans are being considered on an annual basis. From the new capabilities of future upgrades annual projects will continue for the next several years.

Why Regis Technologies Chose Chromeleon CDS Software

Feature 3: Ability to Visualize Data Instantly with MiniPlots

The MiniPlot data visualization tool in Chromeleon CDS is one of our customers' favorite features. It presents large amounts of data graphically, simultaneously, and clearly. For example, MiniPlots instantly display detailed miniature thumbnail images of chromatograms corresponding to each injection in a list—you can rapidly scan through dozens of injections and immediately compare and identify gross differences. This new tool is a fast and convenient way to keep up with today's deluge of data that demands faster analysis of larger data sets.

Chromeleon CDS follows these simple principles of Operational Simplicity™:

- Minimize the number of steps needed to perform any task
- Make all the steps easy to understand and use
- Minimize time needed to perform any task

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