



Chromeleon CDS Enterprise

Compliance, connectivity, confidence



A Chromatography Data System (CDS), networked or enterprise, is vital for compliant, efficient and reliable operation of any modern chromatography laboratory – it will manage all the analytical processes from instrument control, to raw data storage and processing, right through to generating the final results.

Delivering these capabilities across a network brings a unique set of challenges. Thermo Scientific™ Chromeleon™ CDS has been designed and optimized to overcome these challenges. The Chromeleon software architecture can connect multiple sites and locations to a central data center with the same performance as a fully local operation. With its forward-looking architecture Chromeleon CDS is cloud-ready today.

Chromeleon software supports your chromatography operation throughout your enterprise – from research to routine quality testing – connecting people, instruments and other laboratory software, while delivering proven productivity gains for faster return on investment (ROI).



Chromeleon CDS brings...

...compliance >>>



- Highest degree of data integrity and traceability with comprehensive security tools
- eReports and eSignatures ensure regulatory compliance
- Automated software and instrument qualification routines and qualification monitoring



“We found the software very easy to learn and to use day-to-day as it is extremely intuitive with a clean, user-friendly interface.”

Tiziana Nardin - Food Technologist, Fondazione Edmund Mach



...connectivity >>>

- Built for scalable network deployment
- Utilize instruments suiting your business's needs
- Easily interface with relevant laboratory software



...confidence >>>

- Unique network failure protection ensures 24/7 laboratory uptime
- Future proof and scalable software solution
- Access to up-to-date laboratory performance information



...productivity >>>

- Increased efficiency via toolset providing 'right first time' analysis
- Reduced data processing time using built-in smart tools

compliance



With the ever-evolving emphasis on data integrity, data security and compliance, it's of vital importance that your CDS provides comprehensive preventative and detection technical controls to enable you to meet modern regulatory requirements.

> **Data Integrity** is becoming one of the top reported global issues that regulated companies face. The increased focus on Data Integrity during regulatory audits has led to serious consequences for several companies.

Chromeleon CDS gives you audit-safety. Its functionality to support GLP, GMP and 21 CFR Part 11 regulations has been further extended to support evolving Data Integrity demands. External network and connection problems that can affect the operation of the Chromeleon software are now logged in Chromeleon Audit Trails in the Chromeleon Data Vault and can be searched and filtered for specific high-risk events.

Chromeleon CDS provides:

>>> Traceability

Track and record activities

- Automatically-created comprehensive set of secure, computer-generated, time-stamped audit trails track and record all changes for:
 - Instruments
 - Users and user databases
 - Data objects
 - Administrative tasks
 - Results
- A relational database records all versions of data objects and provides sequence-centric storing of audit trails, facilitating audit trail review and retrieval.
- In addition, a simple version comparison tool provides easy side-by-side comparison, and even restoration of previous versions of data objects.

>>> Security

Control access

- The advanced security system, capable of linking to LDAP, ties into the operating system security so that users require only one login, while benefitting from all security levels. With over 160 different privileges that can be allocated to any number of user roles it is designed to fit any chromatography workflow.
- Privileged Actions provide confirmation of user identity and capture comments for user activities, maintaining compliance.
- Organizational Units and Access Groups control devolution of administrative tasks and user access to instruments or data objects, ensuring control of the system.

“Chromeleon CDS allows us to audit trail everything that we need to, making it easier when we are audited. The user management system and centralized resourcing means that data access and backup is easily managed, ensuring data integrity.”

Adam Neaves - Quality and Compliance Specialist at Broughton Laboratories



Chromeleon XTR: More than a Chromatography Data System

Thermo Scientific™ Chromeleon™ XTR Laboratory Management System adds key features to expand Chromeleon software capabilities beyond a traditional CDS. It manages the entire laboratory, ensuring adherence to processes, maintaining data integrity and facilitating complete regulatory compliance. All data, all users and all instruments in one compliant system.



>>> Record management

Manage data security

- Beyond the protections afforded by the Operating System, data security is assured through centralized relational databases, either Microsoft SQL Server or Oracle Database Server.
- A comprehensive, chromatography-oriented security system controls access to data and records which can also be electronically signed with two levels of protection:
 - Electronic Reports – providing a controlled pre-submission preview of final results for structured review
 - Electronic Signatures – the Electronic Report and entire sequence are locked and protected from further changes

>>> Validation

Verify correct performance

- Validation of chromatography systems usually includes installation, operational and on-going performance qualifications (IQ, OQ, PQ respectively) of both instruments and software.
- Chromeleon software has built-in automated IQ and OQ routines for both itself and LC instruments. These procedures can be executed any time, reducing costs and eliminating user errors.

connectivity



It is a huge challenge to find software that can efficiently and effectively handle all the chromatographic laboratory data, controls all your instruments, is easy to administer, connects to other laboratory software and will expand with the laboratory while having a low cost of operation.

Chromeleon CDS is designed to address these challenges and provides an easily deployable single software platform controlling all chromatography instruments in the enterprise, drastically reducing training and maintenance effort. It scales from a single workstation up to global multi-site deployment connecting different laboratories to one central data center, seamlessly growing with the laboratory, while maintaining an identical user experience.

...to your network

Chromeleon CDS offers compatibility with most network infrastructures, including Microsoft™ Terminal Server and Citrix™ Virtual Application Platforms. It also provides built-in functionality for load balancing, failover, and hierarchical user management. This ensures highest data security and allows distribution of resources between laboratories while retaining central control, making administration easy and economical.

Cloud-ready

With deployment of key Chromeleon software elements in the cloud, a wealth of advantages opens up. Cloud deployment provides a reliable, scalable and flexible solution with a lower cost of deployment, ownership and operation with the capabilities to access your data anywhere and easily share it.

Simplified Deployment

The Discovery Service ensures all computers in the network are automatically connected to and configured for the Chromeleon Domain with just a few clicks, simplifying and accelerating deployment.



From workstation to global deployment

Chromeleon CDS scales seamlessly to any business, from a single workstation to a global multi-site enterprise, while maintaining an identical user experience. It delivers a unique architecture which grows with your business and maintains a uniform, easy deployment experience in any cloud or network environment.

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0	0	1	0	1	0
1	0	0	1	0	1
0	0	1	1	0	0
1	0	1	0	0	1

...to your laboratory software

It is almost a requirement that your CDS can connect to other laboratory and business software platforms. Chromeleon CDS is designed to be flexible and open, simplifying connection to any third-party software application.

An out of the box application provides connection to the Thermo Fisher™ SampleManager LIMS™ suite while alternative tools enable connection to any LIMS.

A Chromeleon Software Developers Kit is available for programming of custom interfaces or applications for connection to any business or laboratory critical software.

...to your instruments

Chromeleon software is the only CDS providing full control of chromatography instrumentation from Thermo Fisher Scientific and many other vendors, including support for quantitative mass spectrometry workflows for all separation techniques and Thermo Scientific™ MS variants, all using the same intuitive user interface. This gives the flexibility to use the instruments of choice, best suiting the laboratory's needs, using a single CDS software solution.

Comprehensive Instrument Control

Reliable control for over 450 different instrument modules, including over 300 chromatography instruments from other LC and GC vendors.



confidence



In daily laboratory operations, confidence in your CDS is of utmost importance. Instruments must keep running, people must be able to keep working, data and results must be complete, consistent and accurate, and the CDS must be advanced and adaptable. Only Chromeleon CDS provides the necessary tools to deliver this confidence.

24/7 laboratory uptime

You need to ensure highest instrument uptime and keep the laboratory fully up and running even during a network outage, planned or not.

Intelligent Network Failure Protection (NFP) allows fully compliant operation independent of the network. When the network is down, the unique XVault technology keeps instruments running, data accessible for processing, and even allows creation and running of new sequences – ensuring 24/7 laboratory uptime.

Future proof and scalable

Leverage the adaptability and scalability of Chromeleon CDS architecture to seamlessly support your growth. Expand without changing the software from a single workstation, through a standard network connecting one or multiple laboratories at one site, right up to a global multi-site deployment connecting different regions to one or more data centers.

Using the latest development and secure communication standards and the built-in technical functionality of Chromeleon CDS, the Thermo Fisher product team is dedicated to keeping you one step ahead of the next regulatory or market change.



“We have used the system now for five months and it works very well. In total, we have analyzed over 9,000 samples so far and in 90% of cases where the target mass was in the reaction, we have found it automatically.”

Rene Spang - Head of Laboratory Mass Spectrometry Service, Bayer Pharma AG



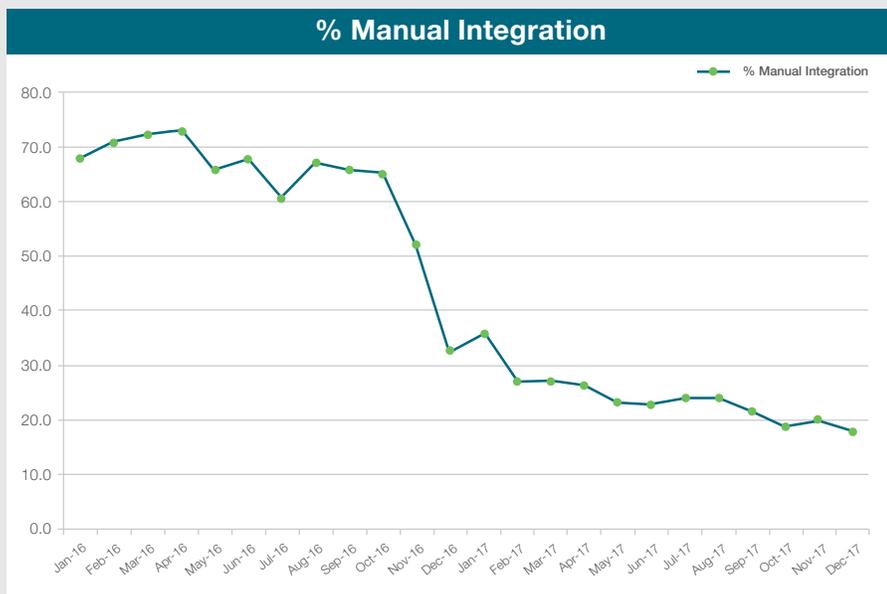
Industry leading support

As your CDS is a critical component of your laboratory and your organization, it is important to have confidence that your software is up-to-date, properly supported and running at optimum efficiency.

Your support and maintenance agreement maximizes and future-proofs your investment with an uninterrupted, cost-effective protection plan, providing regular product updates, dedicated expert support, direct access to relevant information and membership of our customer partnership development process.

Laboratory monitoring

Having up-to-date information about laboratory performance allows for informed decision making. Chromeleon CDS can evaluate all data from all instruments and easily visualize this information, for example, to show column performance, instrument utilization, incidents of testing into compliance or laboratory performance statistics.



Sterling Pharma Solutions Ltd use the Chromeleon Query and Report to monitor and control manual integration levels.

“Monitoring the percentage of manual integrations is used to drive improvement. Before we were probably a little ‘heavy’ on manual integration. Chromeleon CDS and the Cobra Wizard have readdressed this balance with manual integration becoming the exception and not the norm.”

Brian Alliston - Data Integrity Expert and CDS Specialist at Sterling Pharma Solutions Ltd.



productivity



Boost laboratory efficiency with one CDS

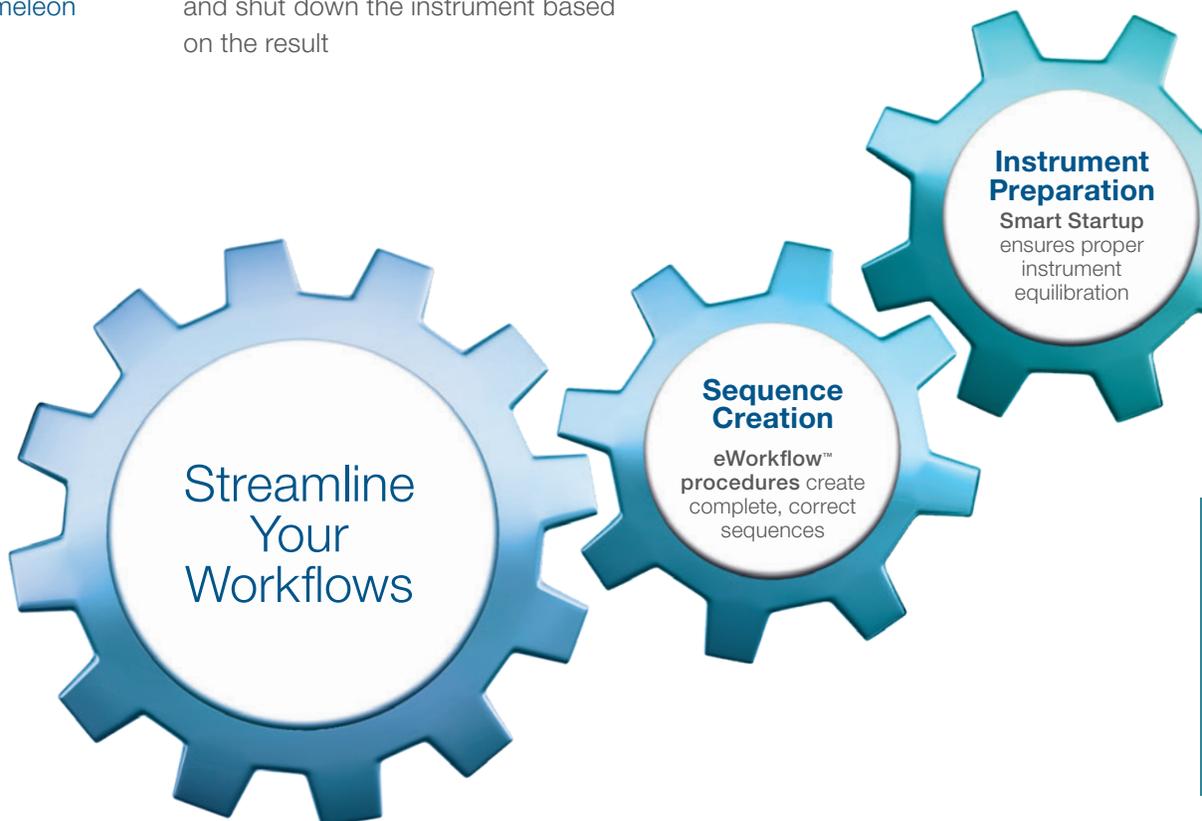
Streamlining the laboratory using one centrally implemented CDS for both chromatography and quantitative MS workflows results in considerable efficiency gains; reduced training effort for your lab staff, reduced time for implementation, validation and maintenance, and access to all resources, data and results from any location.

As Chromeleon CDS was designed with scientists and technicians in mind, the productivity increases exponentially. It simplifies repetitive tasks, reduces errors and helps you to achieve more 'right first time' analyses. These smart tools make your work faster and easier while ensuring reproducible, quality results:

- **eWorkflow™ procedures** – error-free execution of each analysis to meet SOP requirements. Create complete, correct sequences with all required elements (methods, reports, structure and other files such as the SOP)
- **Smart Startup and Sequence Ready Check** – worry-free analytical runs by ensuring everything is equilibrated and ready to run
- **Report Designer** – powerful, spreadsheet-based templates simplify report creation and meet all reporting and charting requirements
- **System Suitability Tests (SST) with Intelligent Run Control (IRC)** – automated checks for in-run pass/fail limits that can be configured to reinject samples or even abort the run and shut down the instrument based on the result

AppsLab Library: Quickly Implement New Methods

Search and find applications and download ready-to-use eWorkflow™ procedures from Thermo Scientific™ AppsLab Library of Analytical Applications right into Chromeleon where they can be directly executed.



Chromeleon XPS: Walk Up and Run

Thermo Scientific™ Chromeleon™ XPS is the open access solution for Chromeleon CDS. A simplified front-end lets any user run samples on their own with just a few clicks.



Data Processing
Dynamic Data Processing, SmartPeaks and Cobra Wizard for fast data processing

Data Reviewing
SmartLink for easy data evaluation and Electronic Reports for controlled result sharing

Data Reporting
Fully traceable Report Designer with built-in Report Check

Increased Productivity

Faster data processing

Batch review and reprocessing of data can be very time consuming, subjective and error-prone. The Chromeleon CDS smart tools increase laboratory productivity by simplifying and controlling this process, reducing errors and time spent processing, checking and reporting results.

- **MiniPlot™ Graphs and Result Columns** – immediate, in-sequence overview of data and results
- **Dynamic Data Processing** – all selections and changes are instantly reflected in the data and results, for all injections in the sequence, saving time
- **SmartLink** – visualize all the information needed for fast, easy data evaluation
- **Cobra Wizard and SmartPeaks Integration Assistant** – quickly set optimal detection settings and consistently integrate peaks for each analysis with just a few clicks

“Setting up sequences on the LC-MS is really simple and guided through the use of eWorkflows; analysts can come in and select the relevant workflow which contains all the relevant methods which are locked down and validated, only needing to add the samples to the LC as the system automatically brackets samples.”

Kerry Malone - Team Leader at Broughton Laboratories





Join the Chromeleon CDS community to future proof your investment:

thermofisher.com/chromeleonsupport

Like Charlie Chromeleon on Facebook to follow his travels and get important updates on chromatography software!

facebook.com/CharlieLovesChromatography

Visit AppsLab Library for online access to applications for GC, IC, LC, MS and more. **thermofisher.com/AppsLab**

Learn more about the Chromeleon XTR Laboratory Management System:

thermofisher.com/ChromeleonXTR

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