Thermo Scientific Enterprise Software Solutions for Compliance and Data Integrity

Compliance, Connectivity, Confidence
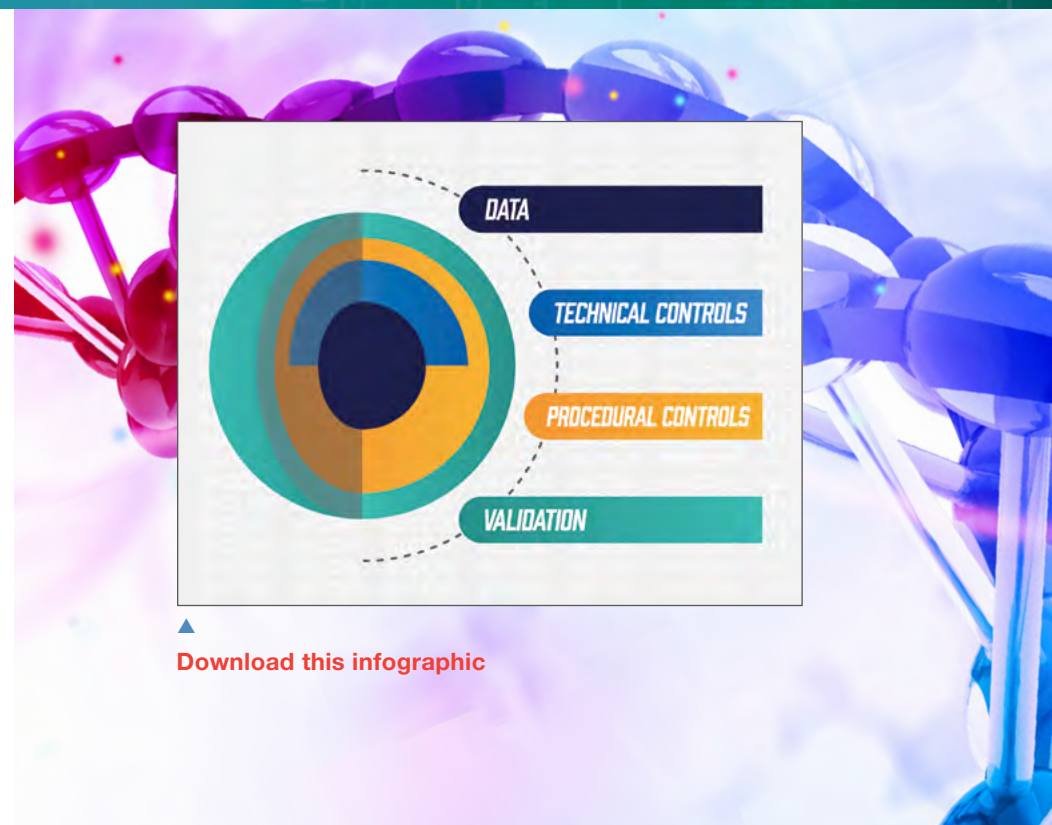
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Introduction

Compliance and, specifically, adherence to Data Integrity guidelines, is a critical focus for any business that follows regulatory guidelines. It requires that both procedural and technical controls are in place to ensure data validity is not compromised, while system validation provides the confidence in laboratory workflows that utilizes these controls.

The key elements of compliance are access control, traceability, data security and data retention. In turn these elements merge together to ensure that products are safe for release, giving confidence to the consumer. A chromatography data system (CDS) is a critical partner in delivering technical controls that encompass the areas of compliance. These will inevitably sit alongside both procedural and administrative controls such as Standard Operating Procedures (SOP's), user manuals, training and administration that must be put in place by the user.

With this is mind a CDS product alone, without a robust quality system, cannot meet every regulatory requirement, but having the right CDS can certainly minimize vulnerabilities and simplify the whole process. The following pages highlight how Enterprise software solutions from Thermo Fisher Scientific™ can help drive innovation, productivity and help you keep one step ahead of the next regulatory or market change.

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Comply with **21 CFR Part 11** using one CDS package

Implement a chromatography data system (CDS) and ensure your electronic records and electronic signatures are trustworthy, reliable and equivalent substitutes for paper records and traditional handwritten signatures.

21 CFR Part 11 requires Food and Drug Administration (FDA)-regulated industries, including medical device manufacturers, drug makers, biotech companies and biologics developers to implement controls around electronic systems the same as they would for paper-based systems. The regulation details the requirements that the agency considers in determining when electronic records are equivalent to paper records. There are 19 requirements in 21 CFR Part 11, with many of them having a direct connection to a CDS, such as electronic signatures, user access and audit trails.

The ability of a CDS (or any laboratory software system) to address these requirements is essential in a regulated environment because all electronic data generated is considered official. Chromeleon CDS provides all of the necessary functionality built into one package and can significantly reduce the effort required to achieve compliance with 21 CFR Part 11.

▲ Download the white paper

In this white paper we discuss:

- What procedural and administrative controls are needed for compliance to 21 CFR Part 11

- Which requirements apply to software and systems involved in processing electronic data to demonstrate compliance with FDA predicate rules

- How Chromeleon CDS facilitates compliance to 21 CFR Part 11 by evaluating each of the 19 requirements

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Achieve compliance and
ensure data integrity

An increased focus on data integrity by international regulatory agencies has resulted in it becoming one of the top-reported global issues that regulated companies face. Regulators, globally, are increasingly approaching audits with the assumption that there are data integrity issues in the lab, and putting the responsibility on you to prove your data can be trusted.

An ideal CDS has features available that, when configured properly, will prevent data integrity issues from occurring. An example of this would be disabling the ability of an analyst to delete sample injections. Not all data integrity issues can be prevented by software, though. In these cases, it is vital that the CDS has the ability to detect when events have occurred. Audit trails can be a good example, as they should capture who, what, when and why a change to an object occurred. Having this information readily accessible, and being able to clearly present it during an audit, will go a long way in building trust with the regulatory agency.

A chromatography data system implemented appropriately, and managed correctly, can simplify system administration, and ensure regulatory compliance (including 21 CFR Part 11) and adherence to data integrity guidelines. Chromeleon CDS has all of the necessary preventative and detection technical controls built into one package that is easy to use and demonstrate a level of trust.

Download the white paper

In this white paper we discuss:

- Impact of the latest data integrity compliance guidelines

- Key aspects of the guidelines applicable to CDS systems

- Controls Chromeleon CDS apply to these guidelines

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Data Integrity: focus on audit trails

Audit Trails are an important regulatory requirement and are a proven effective means of detecting data integrity issues. It is mandatory for regulated companies to evaluate the audit trail controls and establish a documented process for review of audit trails.

The degree of effort required to configure, access and interpret electronic audit trails can vary, dependent upon the system. Electronic audit trail solutions also differ in the functionality that they provide such as searching, sorting, filtering and reporting.

How can the CDS help?

• Provide a solution that's easy to setup and configure

• Be comprehensive to ensure full traceability (who, what, why and when)

• Enable historical data to be reconstructed on request

• Simplfy the process of reviewing data

• Ensure that audit trails are accessible and preserved for the entirety of the data life cycle

▲
Find out how Chromeleon CDS can help make life easier by providing audit trails that are comprehensive yet simple to review in the this white paper

Improved **performance and cost savings** by using "the cloud"
The sky is the limit!

With the rapid global adoption of cloud computing, many laboratories are now looking to leverage the benefits of the cloud for their enterprise laboratory solutions. The proven cost, performance, and stability advantages of cloud computing significantly outweigh the concerns for most people, placing it firmly on the migration path of many private and public laboratories.

As the world continues to become smaller due to the advances in technology, it is becoming increasingly common for the need to share data outside the laboratory. Putting data in the cloud allows for quickly sharing information with multiple locations, either down the street or around the globe, with just a few mouse clicks. Data integrity in the cloud still needs to be a high priority, as the security needs to be maintained with the increased access. This will require the lab to be heavily involved in the decision-making processes. When discussing a possible cloud integration it is important to understand exactly what the cloud is, how it is implemented and the technologies available, so the needs of the lab can be fully considered in the IT solution.

This White Paper will discuss the options available today for laboratory software systems moving from a traditional, on-premise setup, to a cloud-based deployment and the associated benefits and challenges, including:

- What is the cloud and why are so many businesses looking at it?

- Options available for laboratory software systems moving from traditional on-premise setup to cloud-based deployment

- The potential benefits and challenges associated with cloud-based deployment

- The three primary service models for cloud computing

Download the white paper

Enterprise CDS saves UK organization time and money

"Chromeleon CDS is an excellent CDS which has saved our organization both time and money."

Sterling Pharma Solutions, a Contract Development and Manufacturing service, provides innovative process development and optimization, small-scale manufacturing for clinical trial supplies and full-scale commercial production of advanced intermediates and Active Pharmaceutical Ingredients (APIs).

The UK site carries out analysis of raw materials, intermediate process checks, final product APIs, stability testing and clean-out samples as well as method development, transfer, and validation activities. With such a high throughput of samples ranging from simple area % purity measurements to complex assay and impurities measurements, Sterling Pharma Solutions decided to deploy Chromeleon 7 CDS software as a multi-laboratory solution, supporting a total of 58 instruments across two laboratories.

▲
Download the case study

"We chose Chromeleon CDS for several reasons, the main one being the centralized data storage. Also, the fact that both separate parts of the site could operate the same system, the high level of cGMP compliance and data integrity, the ability to create bespoke product specific report templates and the fact we could continue to use our existing instruments."

By implementing Chromeleon CDS, Sterling Pharma now feels confident that the laboratories are well positioned to meet the goals set out at the start of projects as well as ensure compliance with the latest regulatory requirements.

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A networked solution with a **centralized data storage** system designed for the user

"After a brief familiarization it felt like you could just walk up to the system and accomplish what needed be done without jumping through an excessive number of hoops. You can tell that the software was built for the user's ease."

Millipore Sigma is one of Sigma-Aldrich's many contract manufacturing organizations (CMOs) facilities catering to pharmaceutical and biopharmaceutical organizations in need of development and scale-up manufacturing of an active pharmaceutical ingredient (API). The analytical lab performs method transfer, development, and qualification of assays designed to measure the purity of final product and intermediates, mostly by liquid chromatography (LC) and gas chromatography (GC). The lab is charged with performing an analysis at various stages of synthesis and also with the scrutiny of each analysis technique.

◀ **Download the case study**

Before installing Chromeleon CDS, every two instruments from a variety of manufacturers had a separate computer and software. The fact that their systems were not networked created several problems and significant losses in efficiency including:

- A lack of sufficient flexibility for multiple analyses, and controlling two instruments with one computer
- Gathering and entering data manually for reports
- Time lost training users on various operating systems

Millipore Sigma selected Chromeleon CDS because it was very intuitive and had an easy-to-use interface. The Chromeleon CDS software networking capability solved many of their analytical challenges by controlling the different types of chromatography systems (e.g., LC, GC, IC) from multiple manufacturers. From any location, employees with appropriate predefined access privileges could control instruments, review data, generate reports, and move information from one instrument to the next and from one lab to another.

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Resource center

Product spotlights

Ensure compliance
With Chromeleon CDS you can satisfy regulatory requirements without sacrificing efficiency using the integrated security system, audit trails and version management tools.

Intelligent LC: Advanced control
Chromeleon 7 CDS software is recommended for control of Thermo Scientific LC instruments as it offers unique, smart features, such as, the ability to monitor the qualification status and performance of specific LC modules. We call this Intelligent LC.

Deliver Results
Chromeleon 7 CDS provides the reporting options necessary to meet the requirements of your organization. The powerful Report Designer makes creating reports easy due to the familiar spreadsheet format, yet secure due to the built-in security tools and audit trails.

Streamline your workflow
The Chromeleon CDS makes following your SOPs easy. Use eWorkflows to ensure the correct instrument, processing and reporting methods are always used, then create the correct sample sequence with just a few mouse clicks.

More 'right first-time' analyses
As a standard requiring no extra licenses, the Intelligent Run Control (IRC) feature in Chromeleon 7 CDS gives you complete control over your running sequence, giving you more "right the first-time" analyses.

More product spotlights featured resources ▶

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Articles

Ensuring data integrity

This article explains the importance of integrating LIMS into the pharmaceutical data chain.

Ensuring data integrity is not a simple task. With such a complex chain of events and multiple groups working together to achieve an end goal, preserving data integrity across an entire process is an enormous challenge. Consider the need to track every lab employee's activity, every instrument calibration, use and reading, every compound analysis step and every quality control point. The data collection alone can quickly become a significant undertaking.

The pharmaceutical industry generates a massive amount of information through the research, discovery, and development of drug products, and Regulatory agencies, including the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) recommend five key data principles to assist labs in good industry practices. In addition to these principles, labs must routinely audit their processes and systems to ensure they are being followed. To successfully demonstrate that a lab complies, evidence of a monitored production chain across the complex phases of drug development must be readily available. Successful LIMS implementation will put all of this information at the fingertips of lab management, allowing them to quickly, and thoroughly, demonstrate compliance.

▶ **Read how a good data collection and management systems is central to any lab's priorities.**

Utmost Integrity

In this article, learn why data integrity is so important to the biopharmaceutical industry.

The biopharmaceutical market continues to grow every year. There are over 7,000 drugs in development, with 70% of them potentially being first-in-class therapies. The impact to patients, world-wide, from these drugs will be enormous, so getting them through development and into commercialization is vital. The technology required to test these products continues to improve every day, so the amount of data generated in support of them will continue to increase. The importance of data integrity is nothing new: the accuracy, consistency, and completeness of biopharma data have long been of interest to regulatory bodies. However, as international outsourcing becomes increasingly commonplace and supply chains grow in complexity, regulatory authorities are raising their expectations when it comes to the integrity of this data.

▶ **Read about why a number of high-profile cases and practices that might once have passed are now inadequate from a regulatory standpoint.**
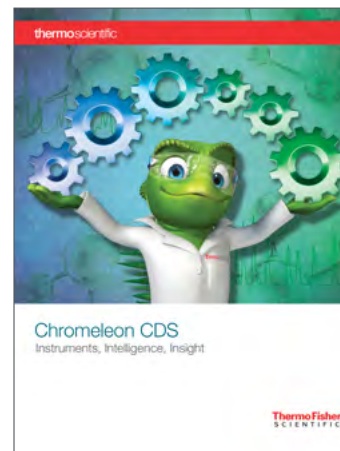
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Brochures

Chromeleon XTR software brochure

Chromeleon CDS Enterprise brochure

Chromeleon CDS workstation brochure

Case studies

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

Chromeleon CDS Software integrates high-volume contract manufacturing operation at Regis technologies for significant efficiencies in pharma/biopharma manufacturing

Single-vendor LC-MS and CDS Delivers Benefits to Fondazione Edmund Mach Chemistry Lab

Delivering client success through unique and pre-emptive service – A global analytical GMP business perspective

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Videos

The Age of Informatics In and Out of the Lab

David Leitham, VP/GM Informatics & Chromatography Software, highlights the need for robust software and LIMS solutions to harness the power of data in and out of the lab and how Thermo Fisher Scientific can be a partner to customers. Learn about our leading LIMS and other software solutions, including Chromeleon CDS, and unleash the power of your data across your enterprise.

Leading LIMS Solution Bridges the Lab and Enterprise

Katie Evans, Sr. Product Manager, talks about Thermo Fisher™ SampleManager LIMS™, the leading LIMS solution, and how Thermo Scientific software solutions bridge data gaps in the lab and across the enterprise with leading laboratory management technologies.

Chromeleon XTR Laboratory Management System – More than a Chromatography Data System

Hear from Darren Barrington-Light on the latest Chromeleon XTR software features that are for laboratories focused on data integrity and compliance of all their instruments in the laboratory, within one system.

Chromeleon Enabling Seamless Data Flow from Lab to Enterprise

Darren Barrington-Light talks about Chromeleon CDS and the latest release of the leading chromatography software from Thermo Fisher Scientific. Learn how our CDS solutions link into Laboratory Information Management to unleash the power of data in your enterprise and across your research.

Introducing AppsLab — Your Online Access to Thousands of Apps & Experts

Whether you need to find a solution to a new separation challenge or just want to optimize your chromatography – the AppsLab Library gives you access to Thermo Scientific application notes and methods online. It already holds more than 1,900 applications for GC, HPLC, IC, GC-MS, IC-MS, and LC-MS, and continues to grow. Search, filter, and download complete applications and one-click workflows for immediate execution.

Chromeleon CDS combines LC, GC, MS Instrument Control as well as Method and Data Management

Unifying workflows for these analytical instruments means that different sources and types of data can be overlaid, compared, backed up, and processed in one application. Chromeleon CDS combines method creation and quantitation, and performs library-based compound identification. Streamlining data collection and experimental management liberates time for scientists so they can focus on science instead of logistics. This increase in efficiency is invaluable in an enterprise or other high-throughput environment.
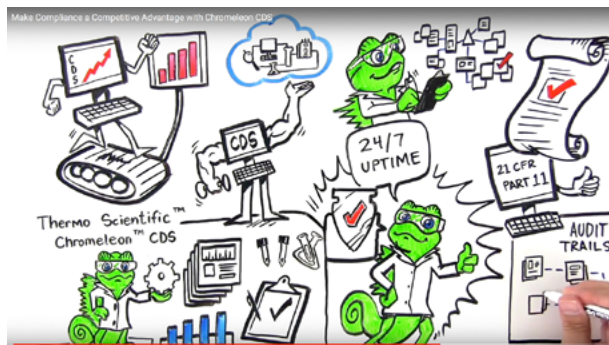
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Videos

Chromeleon XTR Laboratory Management System Software
Andreas Brunner, Senior Manage of Product Management highlights Chromeleon XTR software for managing the data management system for the entire lab and ensures only trained personnel can run analysis on calibrated instruments to ensure compliance and a more efficient worklfow, ideal for regulated industries.
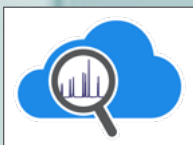
Make Compliance a Competitive Advantage
Simplify meeting the latest demanding regulations. With audit trails tracking all actions, you can defend your data with utmost confidence.

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Web links

◀ **Thermo Scientific AppsLab Library of Analytical Applications – Methods, eWorkflows and more**

◀ **Chromeleon Chromatography Data System**

◀ **Enterprise Software Solutions Resource Center**

◀ **Chromeleon CDS Resource Center**

◀ **Charlie's Facebook Page**

◀ **Blogs on Analyte Guru**

An increased focus on compliance and data integrity by international regulatory agencies has led to serious consequences for several companies. Having an integrated enterprise software solution provides the functionality to achieve compliance, a vital partner in data integrity.

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OnDemand webinars

Achieving and Demonstrating Compliance and Data Integrity with Your CDS

Data integrity continues to be a hot topic and is becoming one of the top reported global issues that regulated companies face. Join our two-part webinar series to discuss these issues and learn how to address the challenge of ensuring data compliance.

Part 1: Sterling Pharma Solutions Ltd
It was important to have one system for the entire company spanning both laboratories that could work with the existing instrumentation.

Previously, there were two separate CDS, one for each laboratory, each with their own shortcomings on compliance and efficiency, each with their own specialist users and setup, leading to a lack of cohesion between the laboratories. The new CDS would have to be able to unite the laboratories and provide improved compliance, data integrity and efficiency to the whole business.

▶ **Register now**

Part 2: Broughton Laboratories
Commercial laboratories operating in regulated industries continually face the challenge of maintaining efficiency and compliance. With goals of reducing errors, encouraging 'right first time', and preserving data integrity, it is important to source the right systems that facilitate these practices. This webinar will demonstrate how Broughton Laboratories has used Chromeleon CDS to maintain efficient and compliant processes that support their delivery of unrivalled customer service.

▶ **Register now**

Ensuring Data Integrity Using Enterprise Software

This webinar series will discuss how having an integrated informatics solution providing the functionality to achieve compliance is a vital partner in data integrity. Discover the key features of a combined CDS, LIMS and SDMS that help you ensure data integrity and compliance for your laboratory.

Part 1: In Part 1 of the series, Katie Evans, Senior Product Manager – Informatics and Chromatography Software at Thermo Fisher Scientific, discusses what data integrity means and the associated regulatory expectations and hearing examples of how integrated informatics helps to ensure data integrity in your laboratory.

▶ **Register now**

Part 2: In the second part of the series, learn from Shaun Quinn, Marketing Manager – Compliance, informatics and Chroamtography Software at Thermo Fisher Scientific on how SampleManager LIMS and Chromeleon CDS enable data integrity in the laboratory.

▶ **Register now**

DATA INTEGRITY COMPLIANCE

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Data integrity is a fundamental element of ensuring compliance in a regulated laboratory and is not a new concept – it dates back decades. However, with computerized laboratory systems now taking the place of paper systems, your compliance strategy must adapt, or you risk difficult regulatory inspections. Ensure you are delivering assurance and credibility by using a modern software system to ensure compliance – such as Chromeleon CDS.

thermofisher.com/chromeleon

The need for awareness has never been greater. Companies face the challenge of ensuring that technical and procedural controls are in place to minimize vulnerabilities to their system while providing evidence that their analytical results are not fraudulent.
Visit us today at thermofisher.com/OneCDS