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Are you audit ready?

Ensuring trustworthy data

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Are you audit ready?
Ensuring trustworthy data

The landscape for regulatory requirements is constantly evolving, and inspectors are asking more and more questions about data. To successfully meet modern regulatory expectations, companies need a deeper understanding of their own data, which requires having the right compliance tools to investigate and truly trust it

In fact, integrity is all about being able to trust the data, and it's vital for ensuring that products are of the required quality, and that the data has been thoroughly verified as accurate and consistent over its entire life cycle. Without data integrity, there's a risk of sub-standard products and medicines, which ultimately impacts patient safety and can lead to potential punishment for those who ignore, falsify or hide inappropriate activities.

Achieving and demonstrating compliance is made easier with the right chromatography data system (CDS). Thermo Scientific™ Chromeleon™ Chromatography Data System is built for compliance, providing reassurance and creating greater confidence for users and administrators in both IT and the laboratory. Enhancements to the software aim to make inspections for customers in regulated industries as stress-free as possible. It can also help customers succeed at the next level of regulatory requirements which look to improve product quality as a means to ensure sufficient product availability.

This ebook will highlight resources that explain and illustrate the comprehensive compliance features in Chromeleon CDS and how those features align with current and potential future requirements for audit review.

Contents

Data integrity: audit trails with ease of review

Shaun Quinn, Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

Audit trails are an important data integrity control required by all international regulations and guidance encompassing GMP, GLP, and GCP; they help distinguish altered or invalid electronic records. Recent regulation makes it clear that audit trails, along with the electronic data they support, must be reviewed as part of the data verification process. Modern compliance with such regulation is increasingly driven by instrument software systems where the controls to configure, enable/disable, and view audit trails are greatly varied including capabilities such as searching, sorting, filtering and reporting.

Chromeleon CDS provides easy to configure, extensive audit trails with context that makes setup, interpretation, and review simpler. In response to the latest regulatory expansions, the software's audit trails also capture information that was previously only recorded in non-permanent log files. This white paper describes audit trail controls in Chromeleon software, including the information provided by the controls along with references to the regulations that require it.

Key points

- Audit trails are required by most international regulatory bodies, and the requirements for what they must encompass have recently been expanded to ensure data integrity
- Instrument control software, such as Chromeleon CDS, are increasingly responsible for the technical controls to achieve and maintain compliance with modern audit trail requirements
- Chromeleon software provides easy-to-configure audit trails with extensive context, and its capabilities have expanded to meet increased regulatory requirements

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Using Chromeleon 7 Chromatography Data System to Comply with 21 CFR Part 11

Shaun Quinn, Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

The Electronic Records and Signatures regulation from the US FDA, known as 21 CFR Part 11, defines requirements for the use of electronic documents in lieu of paper records. It has a total of 19 requirements. Compliance with 21 CFR Part 11 requires both procedural controls, such as Standard Operating Procedures (SOPs), and technical controls that a software system can provide. Instrument software with integrated functions that support 21 CFR Part 11 requirements can significantly ease the task of achieving and maintaining full compliance with the directive.

This white paper lists all 19 requirements of 21 CFR Part 11 and focuses on the required technical controls. These sections that can be easily managed with Chromeleon CDS, and this document provides detail on how the software facilitates compliance.

Key points

- The 21 CFR Part 11 regulation lists 19 requirements – both procedural and technical – for using electronic documents in place of paper records
- Chromeleon CDS facilitates compliance with the technical controls required by 21 CFR Part 11, relieving the burden for companies that must comply with the regulation

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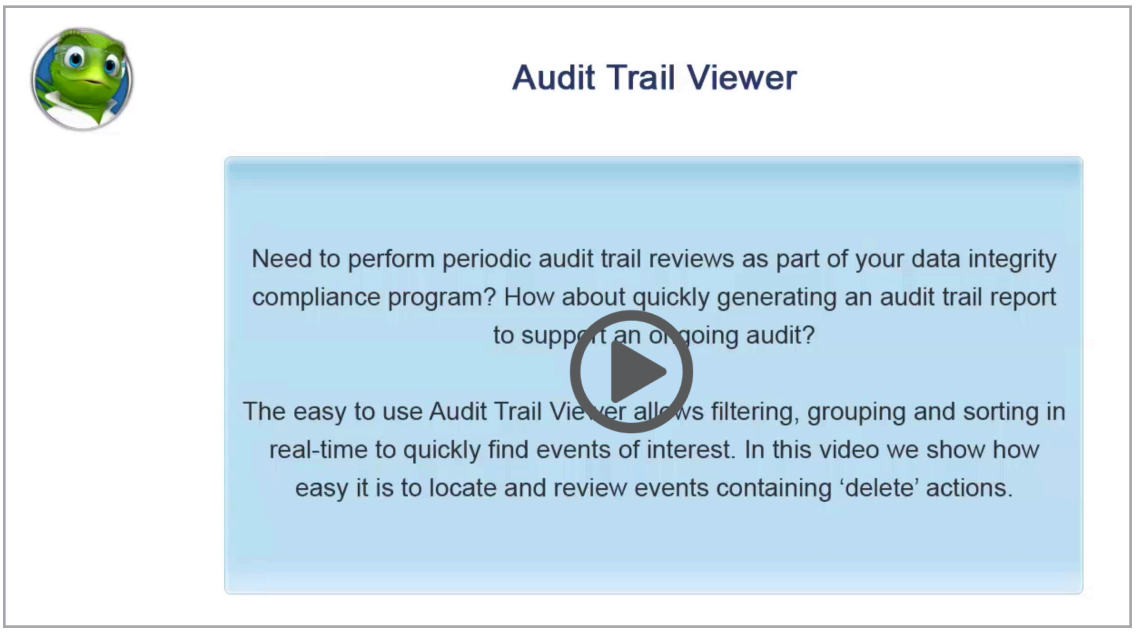

Audit Trail Viewer

Patrick Kenny, Product Marketing Specialist, Validation and Compliance, Chromatography Software, Thermo Fisher Scientific

Overview

Data audit trails are a vital component of any chromatography data system, and their review is often a time-consuming and complex process. However, careful periodic reviews must be in place to ensure data integrity and verify the accuracy of the data.

The Audit Trail Viewer is a feature available in Chromeleon CDS that's designed to make the review process easier and faster, saving time and resource so users can focus on other important activities. This video demonstrates how to quickly find events of interest, such as deletions or modifications, using simple search functions with the ability to produce reports that can be used in an audit situation.

Key points

- Audit trails reports are often required to support ongoing audits and regulatory inspections
- The Audit Trail Viewer feature in Chromeleon CDS allows users to easily find and identify changes made to the data
- Audit trail review helps users verify data accuracy and completeness
- Generate easy-to-read audit trail reports that can be printed or saved in digital formats

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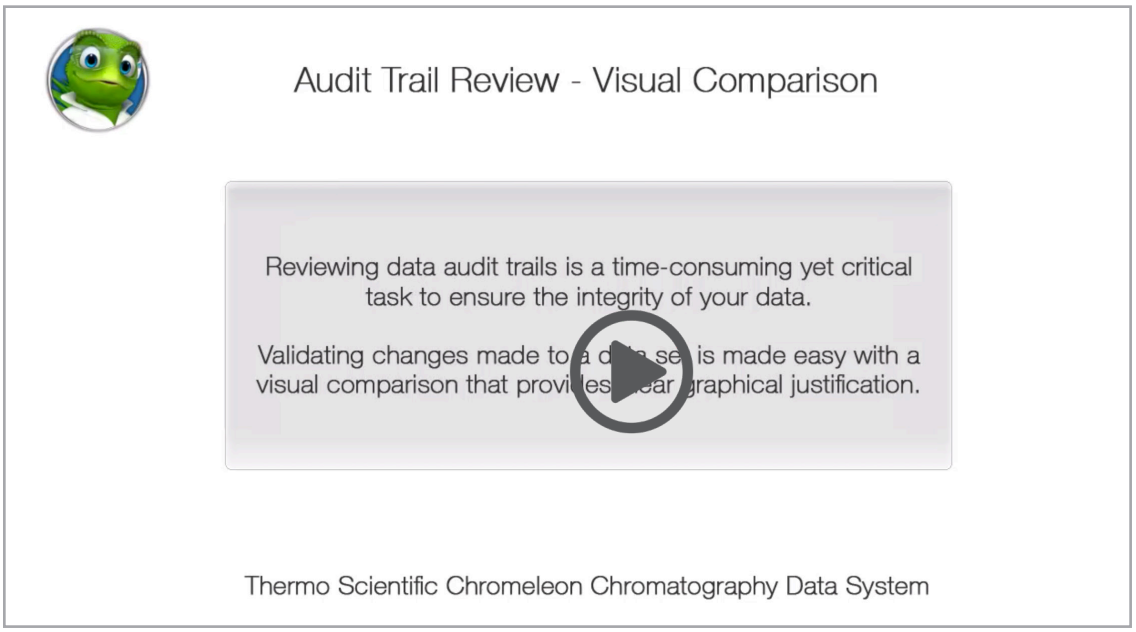

Audit Trail Review – Visual Comparison

Peter Zipfell, Product Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

Audit trail entries are often complex in nature and the process of justifying changes involves multiple chromatogram versions and associated files. To build a complete picture, users might need to reproduce changes or re-trace their steps.

This video illustrates how to visualize these changes in Chromeleon CDS, with the simple click of a button that opens an additional read-only Chromeleon Studio. This enables a side-by-side comparison that can be used to verify the changes and confirm that they were necessary.

Key points

- Data integrity requires time-consuming reviews of audit trails
- The Audit Trail Review function in Chromeleon CDS provides a visual comparison for quick, easy review
- The visual comparison in audit trail review helps verify changes and maintain consistency
- Read-only versions from the Chromeleon Studio create a secure working environment

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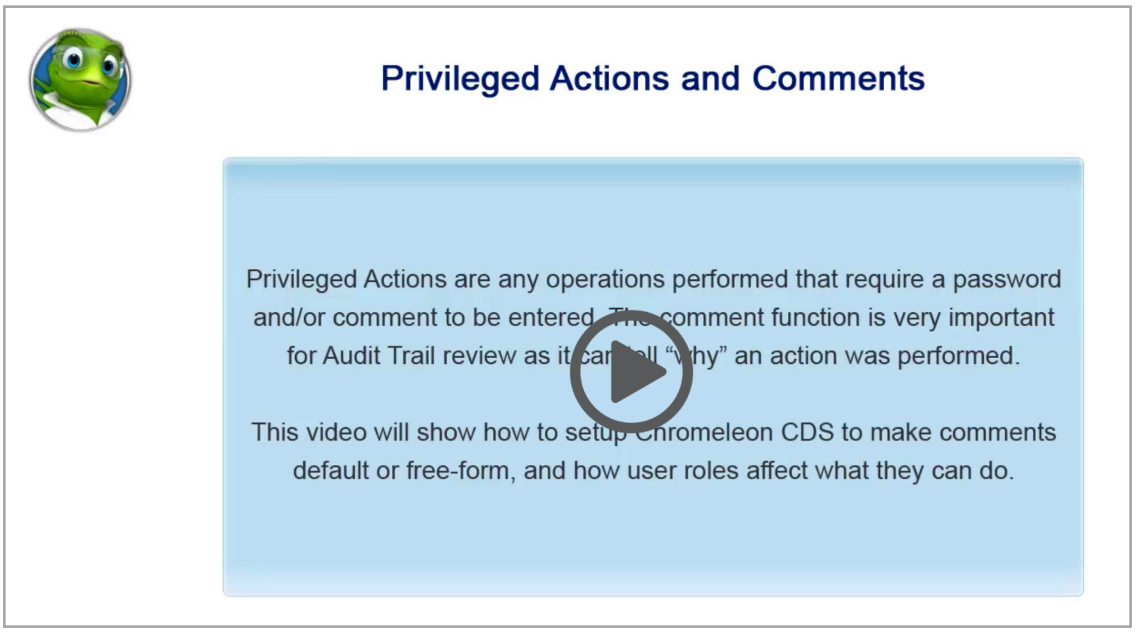

Privileged Actions and Comments

Patrick Kenny, Product Marketing Specialist, Validation and Compliance, Chromatography Software, Thermo Fisher Scientific

Overview

Audit trails are designed to automatically capture who does what with the data, and when they do it. But sometimes it's important to know why data was changed to ensure integrity. That's where privileged actions and comments can make a huge difference during a review. Privileged actions are data operations that require a password or a comment when made. They save time and create greater consistency among different users. These actions can be set to require default or free form comments, and role permission manages who can overwrite those comments providing a more complete picture of why data was changed.

This video demonstrates how the privileged action feature with associated comments in Chromeleon CDS provides greater control of the information captured, and helps to ensure the system is in line with standard operating procedures (SOPs).

Key points

- Understanding why data was changed can help ensure its integrity
- Privileged actions, which require a password or a comment to perform a data operation, and default or free-form comments can help explain why data was changed
- Chromeleon CDS provides users with a better understanding and enhanced trust in their own data through privileged action and comment features

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Data integrity: Technical controls that demonstrate trust

Shaun Quinn, Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

Data integrity is becoming one of the top global issues faced by regulated companies. Inspectors have learned to better recognize data integrity issues and several regulators have responded with additional requirements for evidence that analytical results are not fraudulent. Providing evidence is made easier by electronic data which is often deemed more secure and free of manual error. Yet some analytical activities aren't entirely managed by system software: using someone else's logon, analyzing flawed samples, and instrument configurations are just a few examples. However, software systems can still implement controls aimed at preventing or detecting any compromise in data integrity even in such outside procedures.

This whitepaper covers how Chromeleon CDS achieves compliance with some of the latest data integrity guidance and provides preventative and detection controls to extend coverage electronically to procedural areas.

Key points

- Regulatory agencies are requiring evidence of data integrity in procedural activities as well as in the electronic data captured by instrument software such as a CDS
- Evidence to ensure data integrity for electronic data can be easily achieved via a software system with adequate compliance controls that's been properly set up
- Ensuring data integrity for procedural activities can be partially covered by preventative and detection controls on manual procedures if such controls are incorporated in the software

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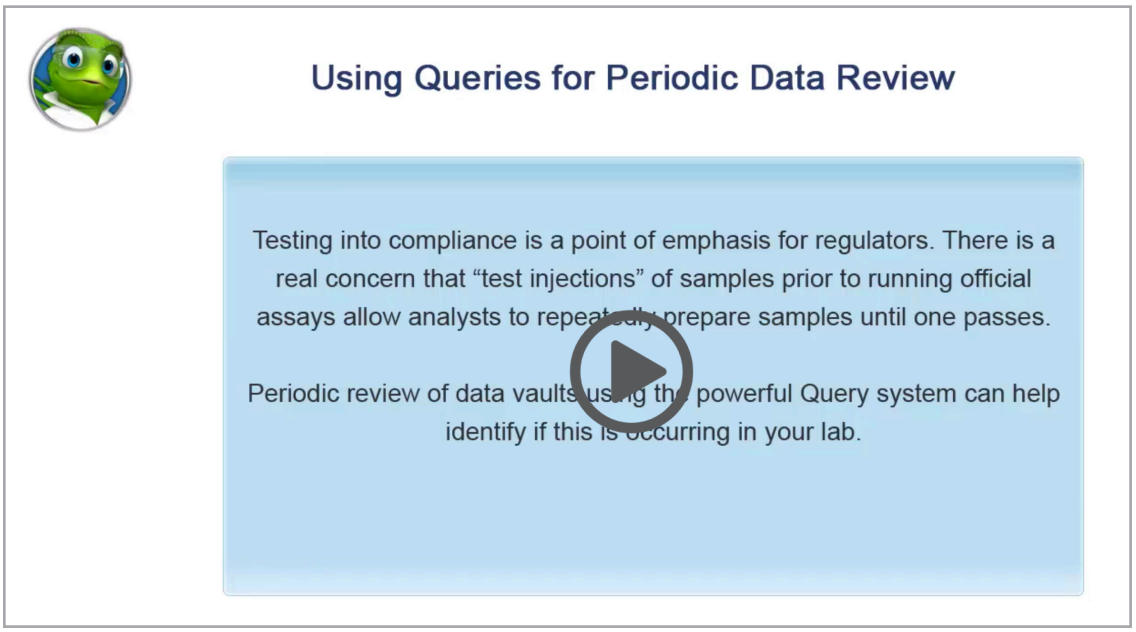

Using Queries for Periodic Data Review

Patrick Kenny, Product Marketing Specialist, Validation and Compliance, Chromatography Software, Thermo Fisher Scientific

Overview

The practice of testing into compliance happens whenever data is created that leads to a decision, but that data isn’t documented in a procedure or included in an official record which is subject to review. A common example is disregarding results that fall out of specification (OOS) or running “test injections” until a reportable value that meets requirements is obtained. Regulators are on the lookout for evidence of testing into compliance so businesses need to be able to investigate and remedy the practice before it leads to fraudulent or illegal actions.

This video shows how the powerful Injection Query function in Chromeleon CDS provides important tools to monitor for indications of testing into compliance. Periodic review of Data Vaults can help identify signs test injections such as sequences where sample injections have been interrupted or with low numbers of injections. All Queries can be saved or edited to facilitate additional investigation.

Key points

- Testing into compliance is an objectionable practice that frequently involves repeated sample testing until one passes, and only recording the passing one for compliance purposes.
- In worst case scenarios, testing into compliance can lead to fraudulent, illegal and inaccurate results
- The powerful Query function in Chromeleon CDS can help spot activity related to testing into compliance so it can be corrected

Product Solution

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From data integrity regulations to Pharma 4.0

A vendor's perspective on recent trends in regulations and the potential future direction for the industry

Christoph Nickel[1], Shaun Quinn[2], Patrick Kenny[3]; [1]Thermo Fisher Scientific, Germering, Germany, [2]Thermo Fisher Scientific, Altrincham, UK, [3]Thermo Fisher Scientific, Waltham, MA, USA

Overview

Regulatory agencies set data integrity guidelines for greater transparency and traceability throughout the drug production lifecycle. Yet data integrity and enforcing compliance haven't necessarily achieved improvements in product quality. The FDA traced a significant number of drug shortages in the US back to product quality issues. Pharma 4.0 refers to a new approach where the pharmaceutical industry moves beyond its focus on achieving compliance to concentrate on improving product quality. That shift would require new practices and technologies in drug development and production.

This white paper covers current compliance guidelines and the gap between compliance and the desired outcome for both industry and regulatory agencies. To enable Pharma 4.0, instrumentation suppliers can deliver more qualitative analysis techniques, such as moving MS/MS down the development chain and enabling MS/MS High Resolution Accurate Mass (HRAM) for deeper insight into processes.

Key points

- Regulatory agencies have worked to set standards and ensure compliance, but that hasn't improved drug quality issues enough to address drug shortages
- Regulators and industry are interested in shifting focus from achieving compliance to significant quality improvement. This transition is often called Pharma 4.0.
- Instrumentation suppliers can help industry achieve Pharma 4.0 by delivering more qualitative analysis techniques

Product Solution

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Thermo Scientific™ Q Exactive™ Plus Hybrid Quadrupole-Orbitrap™ mass spectrometer
Thermo Scientific™ Vanquish™ Horizon UHPLC

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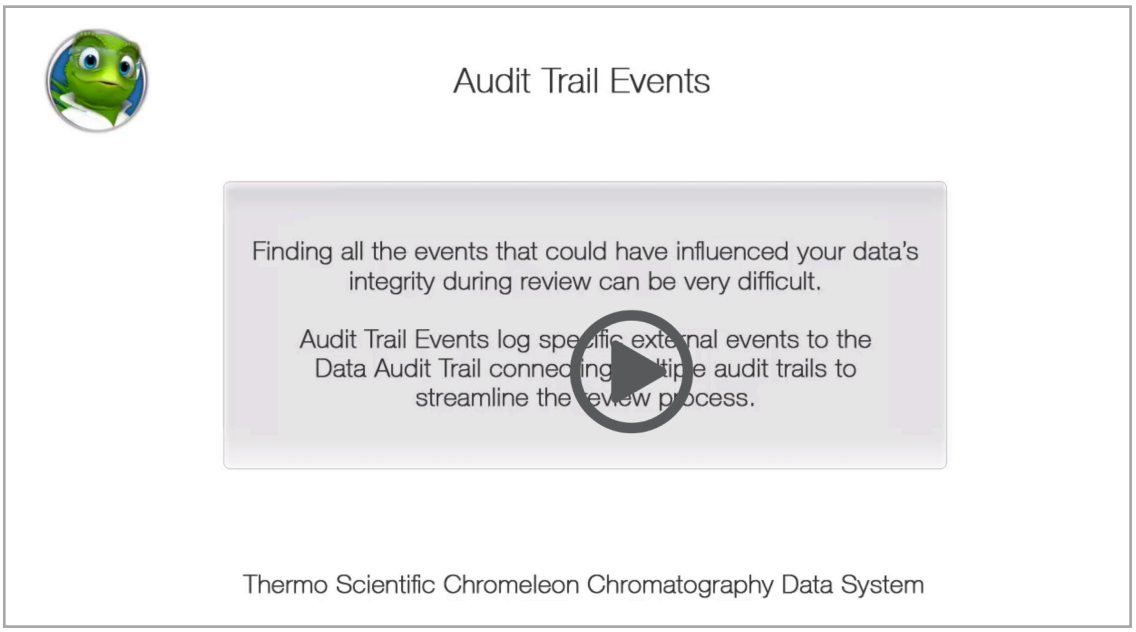

Audit Trail Events

Peter Zipfell, Product Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

It can be difficult and time-consuming during reviews to identify all the events that may have influenced data integrity. Audit trail events (ATE) are any occurrence in the system with the potential to impact the integrity of data. It's important to know about ATE and determine their impact on the reliability of the information involved. Software programs can be instrumental in saving time and helping businesses to effectively investigate significant events in their data.

This video shows how Chromeleon CDS enhances the audit trail review process using its ATE functionality. The software helps users easily connect multiple audit trails and review common events to help streamline the review process.

Key points

- Finding all events that influenced data integrity during a review can be difficult and time-consuming
- Logging specific external events to the data audit trail can speed the review process because it links multiple audit trails together
- Chromeleon CDS helps users connect multiple audit trails and review common events to simplify reviews using ATE

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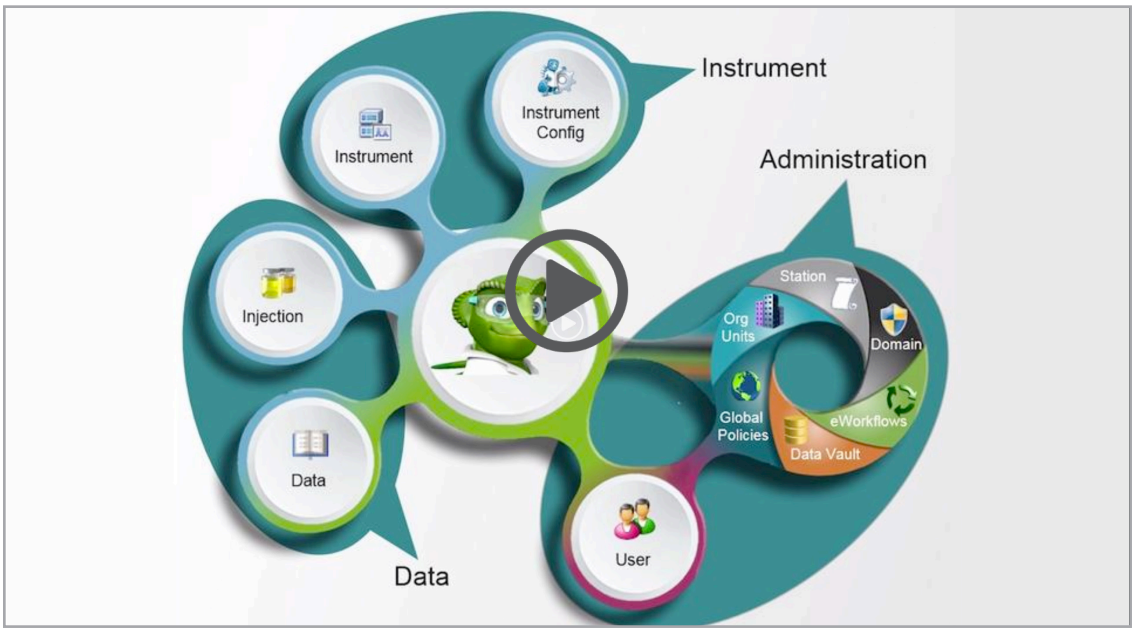

Does your CDS provide a framework for audit trail review?

Peter Zipfell, Product Marketing Manager, eCDS, Shaun Quinn, Marketing Manager, eCDS Validation and Compliance, Thermo Fisher Scientific

Overview

Data integrity and audit trails have been around for quite some time, but simply having them in place isn't always enough. Recent regulatory guidance has made it clear that audit trails and the electronic data they support need to be reviewed as part of the data verification process. Tracking audit trail events can simplify focused reviews and increase confidence in the data.

This video describes the data integrity review framework established for Chromeleon CDS to meet expectations set by the latest regulatory guidance. The framework specifically focuses on how to overcome the challenges of audit trail review.

Key points

- Recent regulations expand data verification processes to cover audit trail reviews and the data they support
- The data integrity review framework for Chromeleon CDS was developed to help simplify the expanded reviews and increase confidence in the data
- Get more information from your data audit trials with Chromeleon CDS
- Audit Trail Events provide real time tracking of audit review scenario's

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Building in the tools

Built for Compliance

Peter Zipfell, Product Marketing Manager, eCDS; Darren Barrington-Light, Sr Manager Product Marketing, eCDS, Christoph Nickel, Sr Director Software Marketing, eCDS; Thermo Fisher Scientific

Overview

Chromeleon CDS presents an extensive and future-proofed solution that provides users with the tools that can help them achieve, demonstrate and monitor compliance. However we also need to maintain data integrity and be able to defend data in an audit situation.

This short video highlights some the key features available in the software that form the framework for a solid platform that underpins the commitment to make compliance easier.

Key points

- Chromeleon CDS has extensive features to help users ensure data integrity and compliance
- Help users to achieve, maintain, monitor and demonstrate compliance with a proven CDS
- Audit trail review is under constant focus, but a CDS can evolve with a framework for investigation

Product Solution

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Audits, Brian and Chromeleon CDS – as easy as ABC!

Brian Alliston, Data Integrity Expert and CDS Specialist, Sterling Pharma Solutions Ltd., England

Overview

Sterling Pharma selected and installed Chromeleon CDS in 2011 after a rigorous assessment, and Brian Alliston was part of the team tasked with making the most efficient and compliant use possible of the CDS.

This blog post is first in a series by Brian (today he is Sterling's Data Integrity and Chromeleon software specialist) where he shares ongoing experiences with Chromeleon CDS as a user. It offers a timeline of key developments with the CDS in Sterling's past, current, and future plans.

Key points

- Sterling Pharma selected Chromeleon CDS in 2011, and Brian Alliston provides data integrity and CDS knowledge at the company
- Key CDS developments are listed for the company's past, current and future CDS plans
- This blog post is the first in a series about Chromeleon CDS at Sterling Pharma, written by Brian

Product Solution

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Read the article

Who did what, when and why?

Brian Alliston, Data Integrity Expert and CDS Specialist, Sterling Pharma Solutions Ltd., England

Overview

A frequent topic arises during Sterling Pharma's customer and regulatory audits: Chromeleon CDS audit trails and their routine review. Yes, the audit trails in the CDS software are turned on, and yes, they are regularly reviewed. Essentially regulation requires that the CDS must have audit trails, they must be on, and companies must know how to use and interpret them.

This blog post presents a quick 5 step guide to understanding the who, what, why and when of regulated data. The steps include turning the audit trail function on and leaving it on, password protecting individual user accounts, securing date and time settings, explaining the importance of sensible comments, and reviewing audit trails.

In addition, privileged actions are recommended as a way to simplify comments and to authenticate users who perform specific actions.

Key points

- In regulated environments, CDS audit trails will come under scrutiny
- Turn the audit trails on
- Train everyone who generates or reviews CDS data
- Encourage users to make clear and useful audit trail comments
- Use Privileged Actions to authenticate who performs key actions

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Are You in Control of Your Chromatography Data System?

Tegan Rawlinson, Chromeleon and Data Compliance Administrator, Sterling Pharma Solutions Ltd., England

Overview

Developing procedures to maintain and demonstrate control of a chromatography data system is not a simple process, but being able to monitor key aspects and present the data to an auditor is a situation that's all too familiar to Sterling Pharma. They make sure that new starters are given clear guidance that will help them get to grips with the software quickly and to ensure it's used correctly.

This blog post explains how the necessary processes and checks have been built around Chromeleon CDS and how its features have been used to monitor electronic signatures and peak integration. With such implementation they have seen a reduction in admin requirements and repeat audit findings.

Key points

- Control is important to adhere to regulatory guidelines and recommendations
- A solid understanding of the system implemented is vital
- Having the right checks in place can make audit review easier
- Monitoring processes can help reduce repeat audit findings
- Setting the right standards can influence how people use a CDS

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Validation for compliance & data integrity. Why do you need it & how do you do it?

Darren Barrington-Light, Sr Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

System validation ensures a process will produce consistent results that are within expected specifications. However when it comes to a chromatography data system there are many processes to take into account, from pre-installation to post installation and all of them must be documented.

This presentation highlights the key considerations and explains how Thermo Fisher Scientific can assist the end-user with guidance and services that provide validation support for Chromeleon CDS.

Key points

- Regulated agencies expect to see a fully documented software system
- All changes must also be documented
- Validation includes qualification
- Vendor assistance can reduce user administration efforts
- The 247 Instrument Controller can deliver significant validation benefits compared to a standard PC

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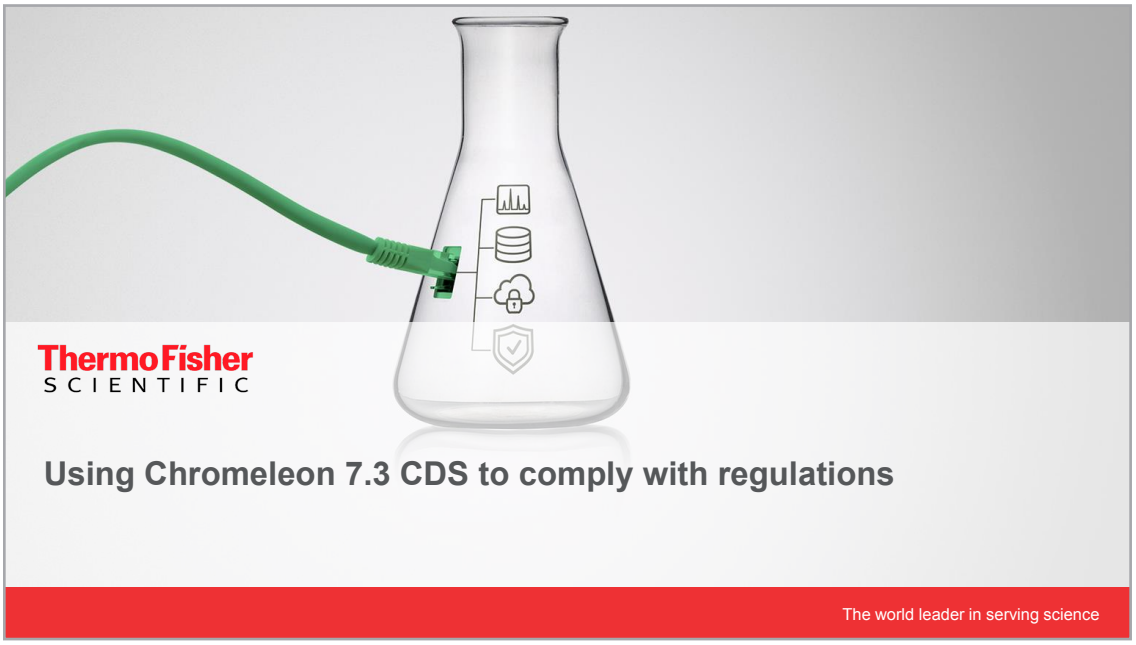

Using Chromeleon 7.3 CDS to comply with regulations

Darren Barrington-Light, Sr Marketing Manager, Chromatography Software, Thermo Fisher Scientific

Overview

Chromeleon CDS was built for compliance and its extensive feature set continues to be developed in order to meet the expectations of regulatory agencies. The launch of Chromeleon 7.3 CDS introduced a new framework for data integrity and by listening to customer requirements it will continue to evolve alongside the existing foundation that delivers a solid and robust solution for compliance and data integrity.

The presentation outlines the approach and methodologies that have been implemented, including both the core features and those that are newly released in the current software version.

Key points

- Chromeleon CDS has the core features for Compliance that provides assurance for the end-user
- Having the features to make audit trail review easier is coming under more scrutiny than ever
- Easy administration, monitoring and demonstration of compliance is fundamental for CDS
- Understanding data is a crucial aspect for data integrity
- Having the right tools and using them correctly is a focus for Chromeleon CDS

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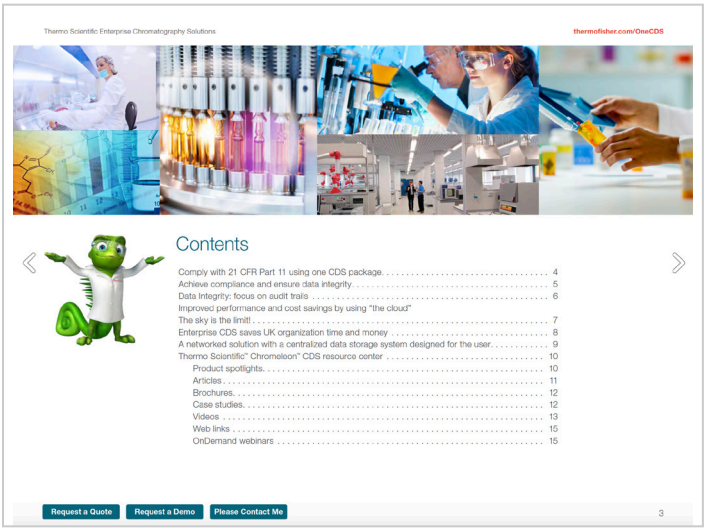
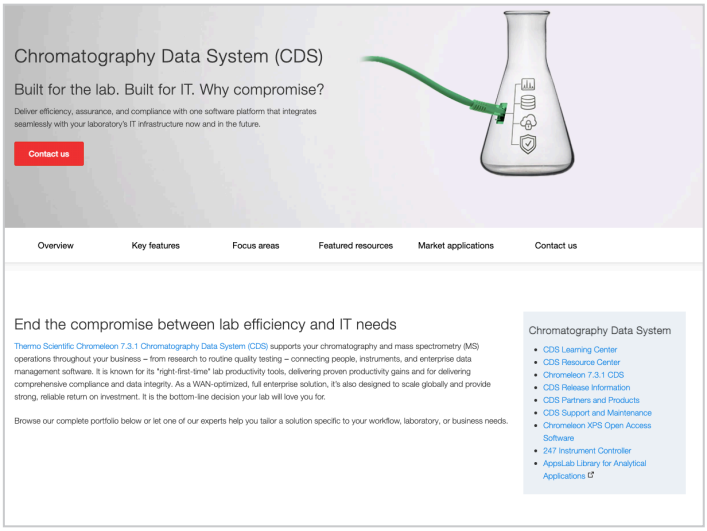
Key resources

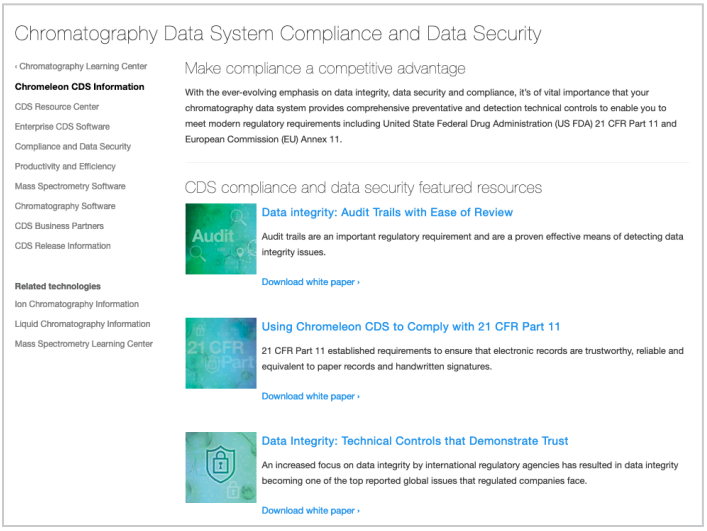
Compliance ebook: Thermo Scientific enterprise software solutions for compliance and data integrity



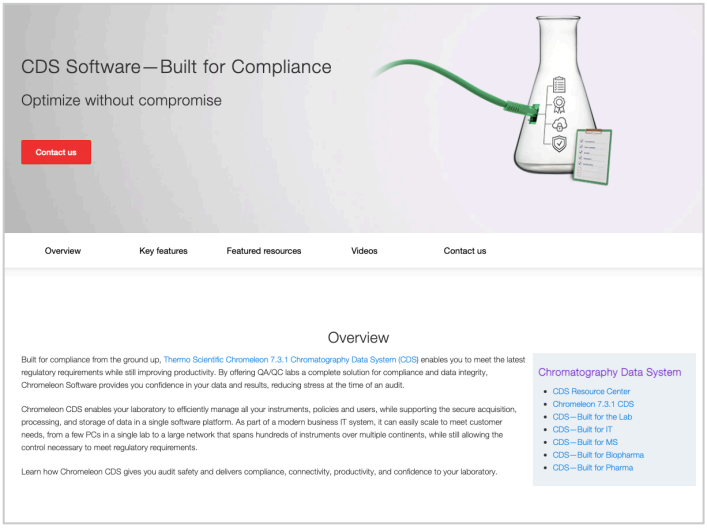
Web page: Chromatography data systems overview



Web page: Chromatography data system compliance and data security resource center

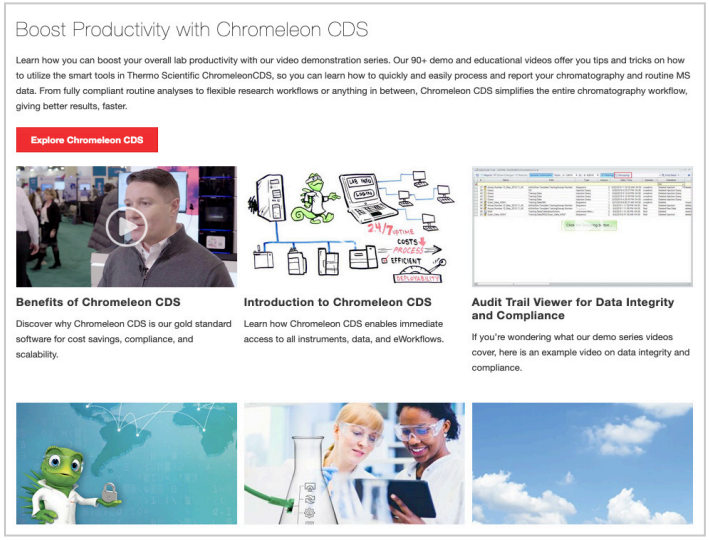


Web page: CDS software – Built for compliance

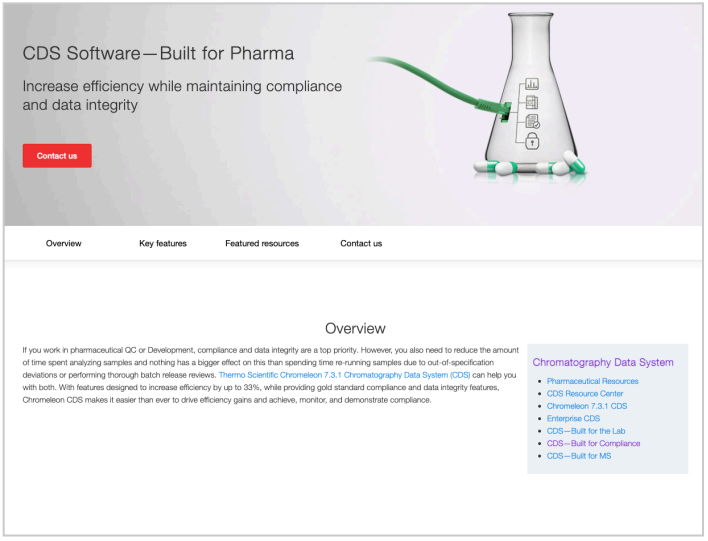


Key resources

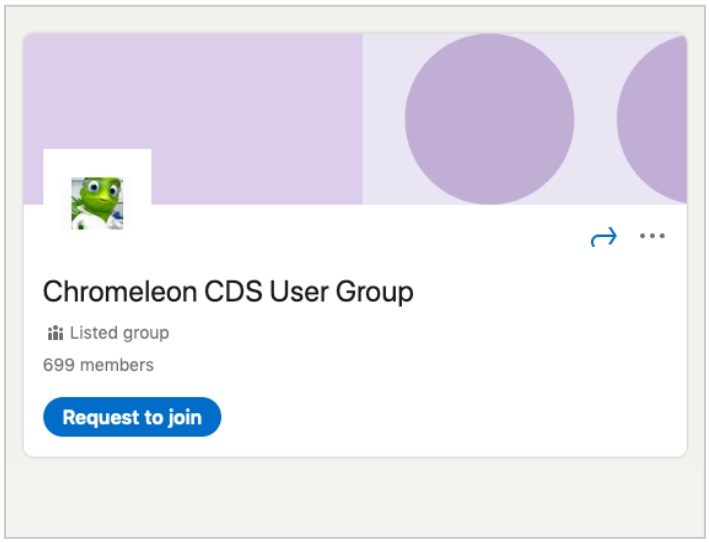
Web page: Boost productivity with Chromeleon CDS – demonstration videos



Web page: CDS software – Built for pharma



LinkedIn page: Charlie Chromeleon



Facebook page: Charlie Chromeleon

Find out more at **thermofisher.com/chromeleon**

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