

Product Guide



Built for IT—why choose Chromeleon CDS

Introduction

During the selection process of a Chromatography Data System (CDS), the role of the IT department should not be underestimated. While the input from end user and lab manager are vital to ensure the CDS will fully meet the needs of the laboratory, the IT team must ensure the CDS fits the company's IT infrastructure and the needs of the business. During the selection process there are four key requirements to consider:

1. Initial cost of implementation
2. Total cost of ownership
3. Adaptability to meet business needs
4. Security, data integrity and compliance

Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) software is built with both the laboratory and IT (Figure 1) in mind. Chromeleon CDS is a fully scalable software solution that grows with your organization and adapts to every infrastructure, such as on-premise, virtual, or cloud installations and provides full compliance for each. Its unique and resilient architecture provides 24/7/365 uptime and optimum protection against malware attacks and allows for operation in the cloud, reducing operating costs. Centralized but devolved administration tools reduce time spent on system administration. This document will discuss how Chromeleon software benefits the IT department in each of the four key areas above.



Figure 1. Key benefits for the lab and IT.

* Compared to version 7.2

** Compared to competitor CDS systems

Initial cost of implementation

When considering the financial impact of implementing a new software platform, the initial license cost is the first thing that comes to mind. However, there are other important factors influencing this; how many software solutions are selected, what changes are required to the existing infrastructure and how much time will be spent on installation, configuration, validation and training.

Using a single CDS solution to control all chromatography instruments and Thermo Scientific™ mass spectrometers reduces implementation, maintenance and training cost, but Chromeleon CDS delivers more.

License only one software

Licensing only one software is the most cost-effective solution, especially when user licenses are distributed on a concurrent basis, like with Chromeleon CDS. The initial investment in client licenses is only required to cover the number of users operating the system at any one time. Also, a key-based licensing system provides independence from the infrastructure (virtual, cloud, physical) and reduces management effort as there is no physical dongle, so no

device and/or software needed to host this dongle. An additional advantage is the reduction in infrastructure, installation, validation and maintenance that comes from only having a single software platform.

Investment in infrastructure

Chromeleon CDS is built on modern technology and with a modular approach. This allows installation in any existing infrastructure, without making radical changes, thereby reducing investment in new hardware. In addition, existing databases, like Oracle® Database and Microsoft® SQL Server®, can be deployed in physical, virtual or cloud environments.

Within a cloud infrastructure, servers, clients and central data storage are hosted with an external cloud service provider (Figure 2) and hardware resources, like processing capacity, random-access memory (RAM) and disk space are not fixed. As these services are only paid when used and can be adjusted according to your business' needs using the elasticity of cloud resources, implementation can be cost-effective and operation costs substantially lowered.

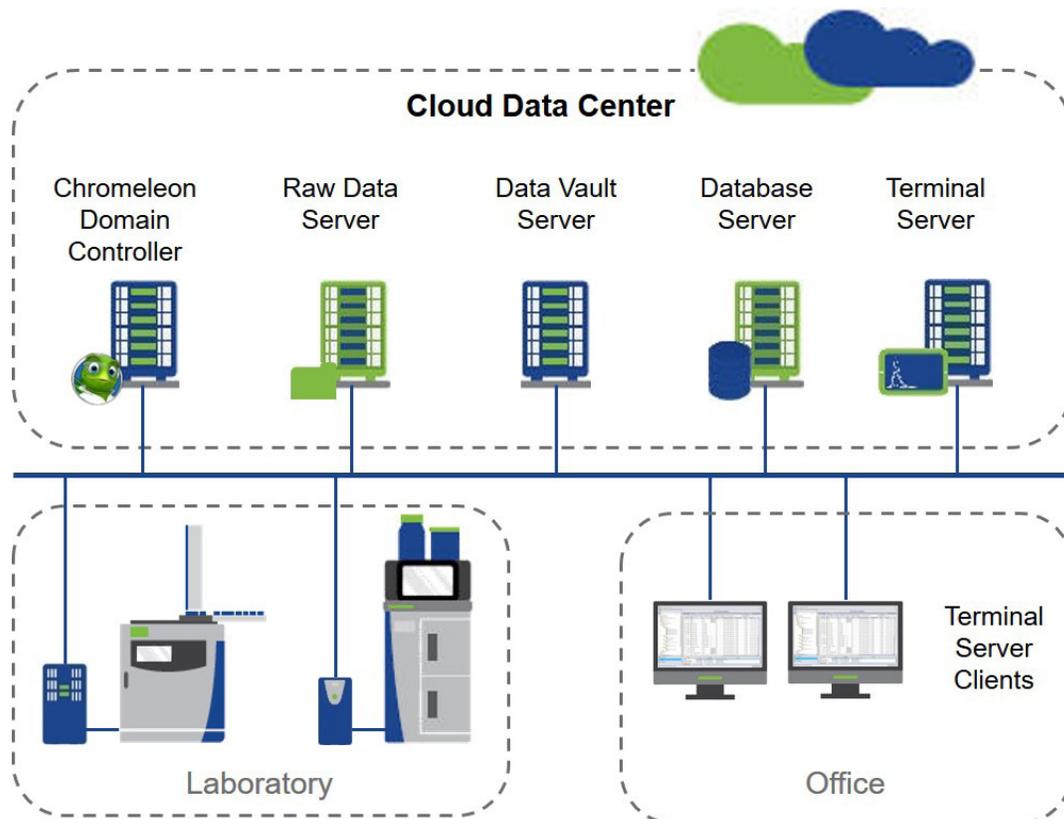


Figure 2. Example of cloud-based Chromeleon CDS infrastructure.

Automated installation and configuration

Once the Chromeleon CDS backbone (Chromeleon Domain Controller, database, file storage, Data Vaults, etcetera) is in place, installation and configuration of the Chromeleon Clients and Instrument Controllers is straightforward. The software can be rolled out using installer packages, including configuration of the Discovery Service (Figure 3). This service connects with the Chromeleon Domain Controller and automatically connects to all resources:

- Instrument Controllers including the instruments
- Distribution of licenses and user management settings
- Connection of system printers.

Adding new computers to the Chromeleon Domain only takes a few clicks, saving tremendous amount of time to deploy the system throughout the organization.

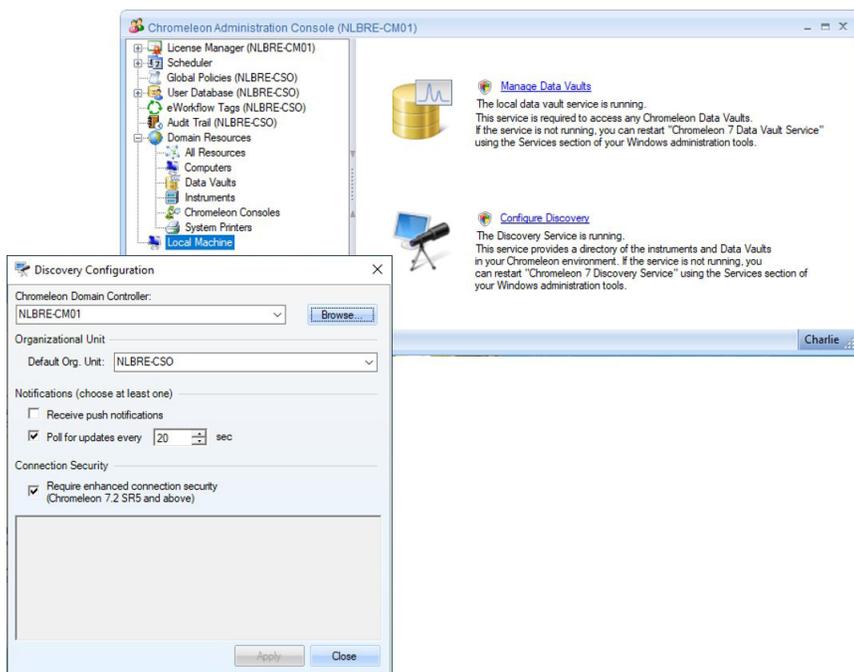


Figure 3. Configuring Discovery Service.

Software qualification

Software qualification is an important part of computerized system validation (CSV) and can be a labor intensive and time-consuming process. However, with Chromeleon CDS most parts are executed automatically and in a minimum amount of time (Figure 4). The software Installation Qualification (IQ) and Operational Qualification (OQ) procedures are fully automated and only take a few minutes to complete. In addition, the automated communication function test of the instrument IQ is supported for all controlled instruments with instrument OQ available for Thermo Scientific instruments.

Enterprise deployment documentation

The Chromeleon Enterprise Documentation is a complete set of documents serving as a guidance for the planning, configuration and installation of enterprise Chromeleon CDS. The document set consists of general documents containing background information, documents specific for the project, database server configuration guides, Chromeleon software installation and configuration guides and installation checklists. These documents reduce the effort of collating all this information and can be used as part of the validation process.



Figure 4. Qualification Tools and Documents.

Total cost of ownership

The cost of ownership consists of the direct and indirect costs of the software during its lifecycle, which includes the aforementioned cost of implementation. In addition, the cost for daily administration, regular maintenance, technical support, hardware replacement and keeping the software up to date should be considered.

Low maintenance instrument controller

The Thermo Scientific™ 247 Instrument Controller (247 IC) provides secure, reliable instrument connectivity (Figure 5) to the Chromeleon Domain with a typical lifetime of ten years. The 247 IC is a small footprint, ultra-low maintenance device designed specifically for enterprise Chromeleon CDS systems. It can reduce maintenance costs by 90% compared to standard instrument PCs and free up valuable bench space in the lab.

The completely locked down, ultra-secure operating system ensures the highest protection against security breaches and minimizes IT maintenance, as it does not require virus protection or security upgrades to the operating system beyond those in the Thermo Fisher image updates. No interactive login is required to perform administrator operations, ensuring tasks on the 247 IC can be performed remotely, all controlled and tracked through the CDS software.



Figure 5. 247 Instrument Controller.

Centralized administration

Within enterprise Chromeleon software, administration can be done from one, local or remote, location – the Chromeleon Administration Console (Figure 6). This includes license, user and resource management, scheduling tasks, for example for archival, and configuration of the Discovery Service.

The Administration Console provides the ability to schedule system maintenance and automatically schedule and roll-out software updates, as well as installation qualifications (Figure 7). This reduces time spent on performing these tasks and minimizes downtime in the laboratory, lowering the administration cost.

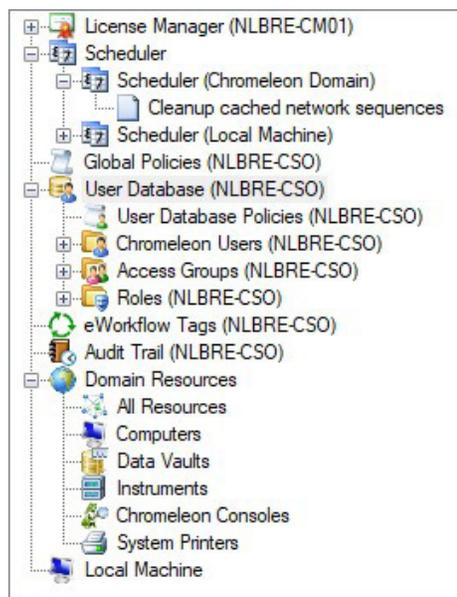


Figure 6. Administration Console.

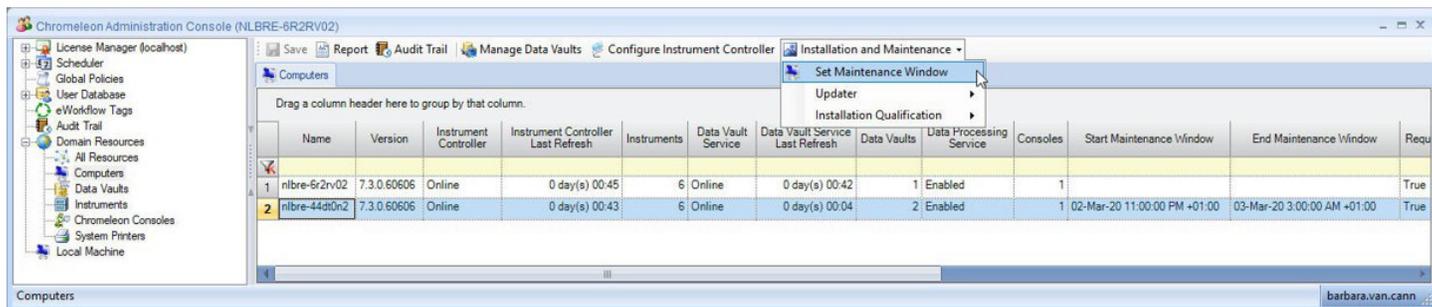


Figure 7. Remote installation and maintenance settings.

Ensuring CDS uptime

The chromatography data system is business-critical software for the laboratory and therefore for the enterprise, and interruptions can have a major cost impact. Protecting your Chromeleon CDS installation with a Support Plan both secures and future-proofs your investment with an uninterrupted, cost-effective protection plan. This provides regular product updates for fast issue resolution and upgrades to access the latest features, dedicated expert support to resolve business-critical issues and exclusive 24/7 access to techniques, tips, troubleshooting and documentation for timely resolution of routine issues. A support agreement is an important part of any business continuity plan, ensuring data security and uptime of the business-critical CDS.

Adaptability to meet business needs

As your business never is static, the CDS should be able to change accordingly. This not only means being able to grow and manage increased demand, but also being able to adapt to the changing requirements of the business and users.

Modular software architecture

The modular architecture of Chromeleon CDS logically separates administration tasks from file storage, allowing IT to seamlessly add capacity where needed. This makes the CDS scalable from workstation to a few instruments to a global, multi-site WAN deployment (Figure 8), without the need to change the software or licenses.

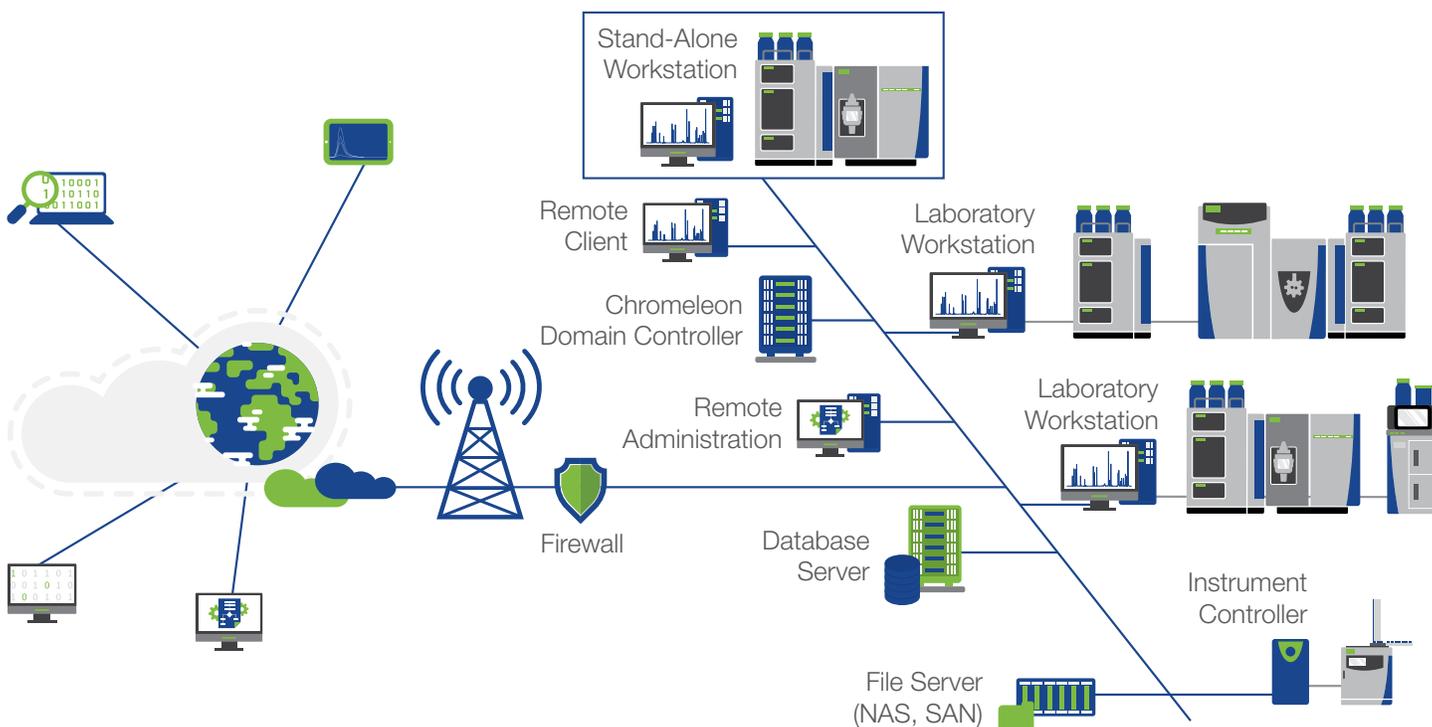


Figure 8. Scalable software architecture.

This architecture also allows solutions tailored to business and infrastructure, like virtualization or the shift of central resources and Chromeleon Clients to the cloud. Figure 9 shows possible enterprise configurations; (A) is a centralized configuration, with one centralized data repository which is accessible from all locations, a potential solution for businesses running on one site, or a couple of locations with good connectivity. Administration is straightforward, with only one set of resources, capacity can easily be added. (B) is a regionalized configuration, with locally deployed Data Vaults for quick access at each location and failover security, a potential solution for global corporations with sites across all geographies. Core administrative tasks, such as user management, license distribution, and system maintenance are still centralized, but data centers with Data Vaults and terminal server capabilities are distributed across the regions, optimizing data access performance at each location when accessing data and adding failover capabilities.

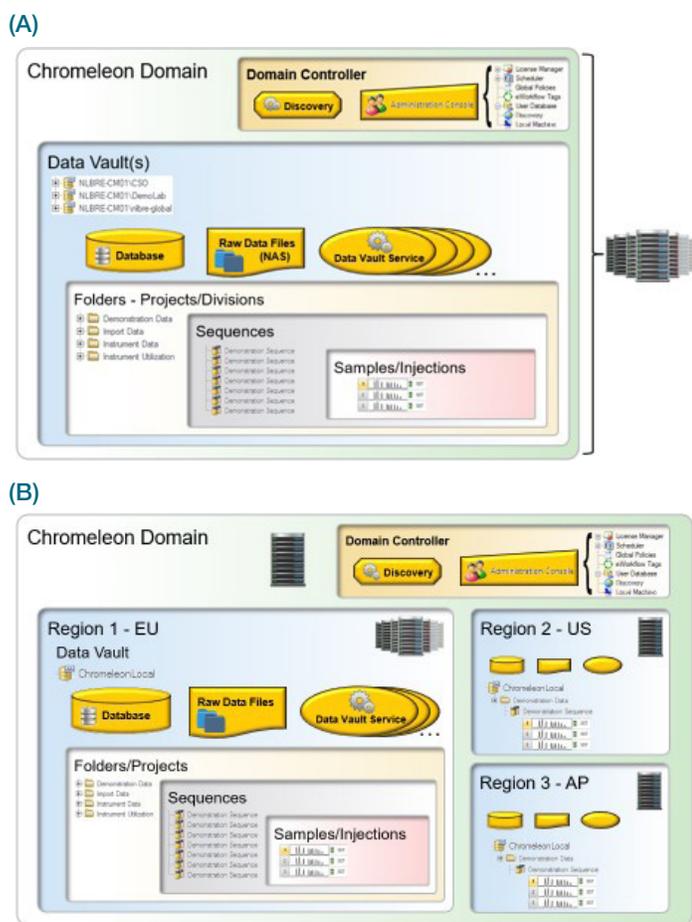


Figure 9. Examples of enterprise configurations.

Chromeleon software's architecture adapts to any business and infrastructure, always with centralized but devolved administration capabilities and the possibility to switch when required and expand where needed.

Connectivity

Scalability can also involve the connectivity to other business critical software and/or hardware, like Laboratory Information Management Systems (LIMS) or Electronic Laboratory Notebooks (ELN). There are several solutions to this.

Chromeleon CDS has an out of the box, seamless link with Thermo Scientific™ SampleManager™ LIMS and Thermo Scientific™ Watson™ LIMS, providing many advantages; Direct overview of real time instrument information in the LIMS, selecting samples in the LIMS to use eWorkflow™ procedures to create sequences, or pulling LIMS samples into existing sequences. It is also possible to show Chromeleon CDS results directly in the LIMS.

Thermo Scientific™ Integration Manager is middleware that provides a bi-directional interface with any existing business software or hardware. In addition, tailor-made solutions can be developed with the software development kit (SDK), an Application Programming Interface (API) to provide connectivity to any LIMS or any other business critical software platform.

Security, data integrity and compliance

The consideration of data security, data integrity and compliance is very important for the entire organization, and not unique to the (bio)pharmaceutical industry (Figure 10).



Figure 10. Security—Integrity—Compliance.

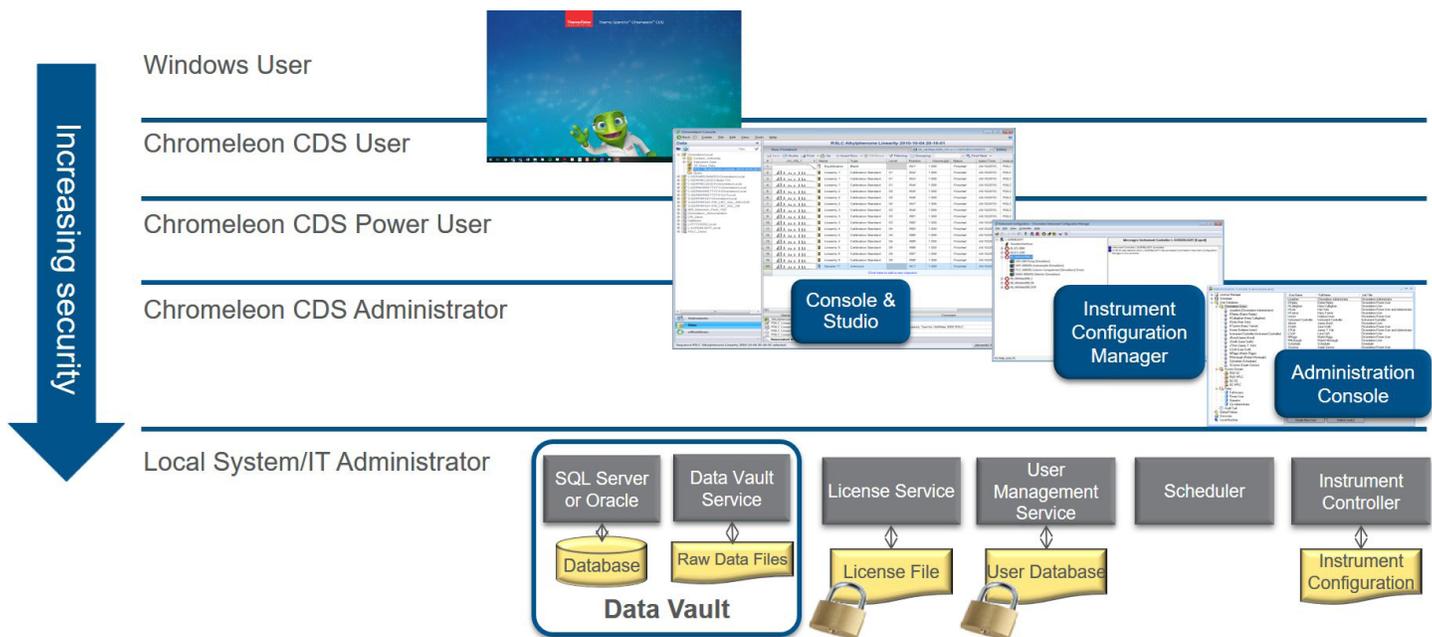


Figure 11. Chromeleon CDS security layers.

Software security

With increased automation of businesses, growing connectivity to the Internet, and remote working, the number of cyber-attacks can increment quickly. Data security breaches increase vulnerability to these attacks and financial impact can be significant. Therefore, software security is of utmost importance.

The security of the CDS is configured on various levels (Figure 11), starting with the Operating System; user access can be limited to just running the application with no abilities to modify the Operating System or computer where the CDS is installed. This is combined with the user management system in the Chromeleon software that allows granular control over user access and privileges within the software.

Finally, with Chromeleon software's modular architecture, all communication and processes of Chromeleon CDS are handled through Microsoft® Windows® services, which are only accessible to IT administrators and use the local Windows account. This eliminates the need for administrator-level 'service accounts', drastically reducing security risks due to malware attacks.

User management tools

The Administration Console provides comprehensive user management tools for the creation of unlimited users, roles and access groups. This allows a granular refinement of what users can and cannot do and access.

Network failure protection

Another key part of data security, especially in a network environment, is ensuring continuity and preventing data loss or corruption during a network or central resource outage. Chromeleon CDS offers a unique Network Failure Protection (NFP) solution. All information required to properly operate the system, like licenses and user data, is securely cached on local instrument controllers and clients and in case of network outage, laboratory operation can continue uninterrupted for up to 7 days.

In addition, Chromeleon software's unique XVault™ technology ensures continuous operation of the lab. Sequences are always run on the XVault, which is present on the local instrument controller, and the data synchronized centrally. Should the network go down, NFP mode is immediately enabled and data acquisition simply continues, with the data stored on the local computer. This data can be easily accessed for processing and reporting and further sequences can be started if required. After network recovery, the data is automatically uploaded and synchronized to the central server ensuring data security, data integrity and compliance.



Figure 12. Chromeleon Audit Trails.

Ensuring data integrity and compliance

Chromeleon CDS has several different audit trailed areas, grouped in three main audit trails; Instruments, data and system administration (Figure 12). These cover everything from instruments, instrument configuration, to all items related to the data, but also system administration and events. For example, the Domain Resources Audit Trail logs manual changes to the domain resources and the Station Audit Trail logs system events, like failure and outages of central resources such as the Chromeleon Domain Controller.

Conclusion

Chromeleon CDS delivers a robust and reliable solution that ensures continuity for the both IT and the laboratory. Covering key areas, such as cost of ownership, including cost of implementation, scalability and security, it provides assurance and confidence where it's needed most.

Chromeleon CDS is built for IT.



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