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# Ensure compliance

## Thermo Scientific Chromeleon 7.2 Chromatography Data System

**With the Thermo Scientific™ Chromeleon™ 7 Chromatography Data System (CDS) software you can satisfy regulatory requirements without sacrificing efficiency using the integrated security system, audit trails, and version management tools. Chromeleon CDS gets you from samples to results quickly and easily, with the security and confidence to back it up.**

### Control and manage your laboratory operations

Today's labs must comply with internal procedures and external regulations to ensure data integrity. Compliance requirements typically involve four areas: security, validation, audit trails, and electronic signatures. Chromeleon CDS provides all the tools you need to ensure compliance, while achieving higher productivity.

### Security

A secure CDS requires two key elements: reliability and access control. Chromeleon CDS is a robust system that provides an outstanding set of access control features.

#### Reliability

Chromeleon CDS is based on modern Microsoft® Windows® technologies that provide optimum reliability, performance, and forward-compatibility. All data are stored in Data Vaults, which are secure storage containers based on a database (e.g., SQL Server Express, SQL Server, or Oracle) in conjunction with a secured file storage system. Objects in the file system can only be accessed through the Data Vault Service, which controls transactions and ensures that only authorized personnel can access the objects. Chromeleon software provides extensive management of concurrent transactions, ensuring that data integrity is never compromised when multiple users access the same object at the same time.

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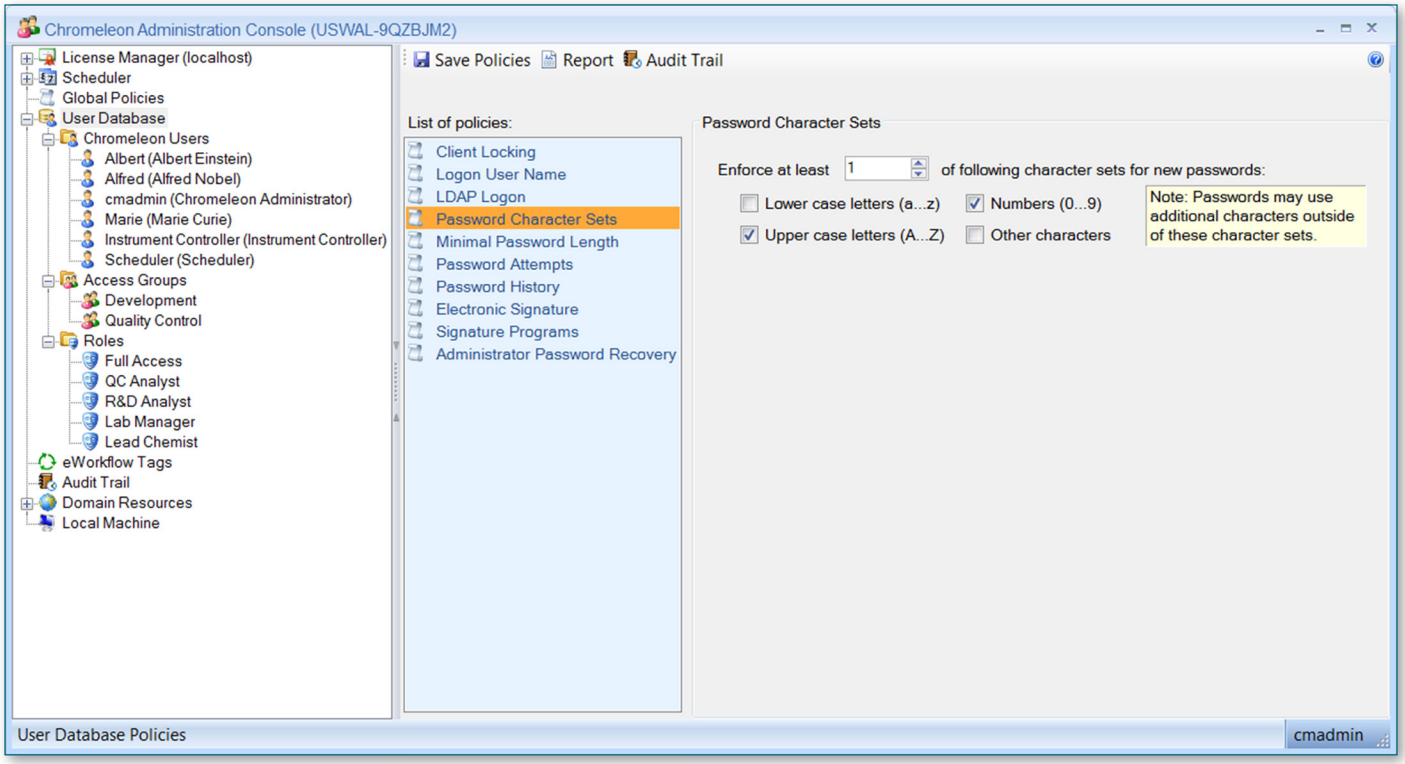
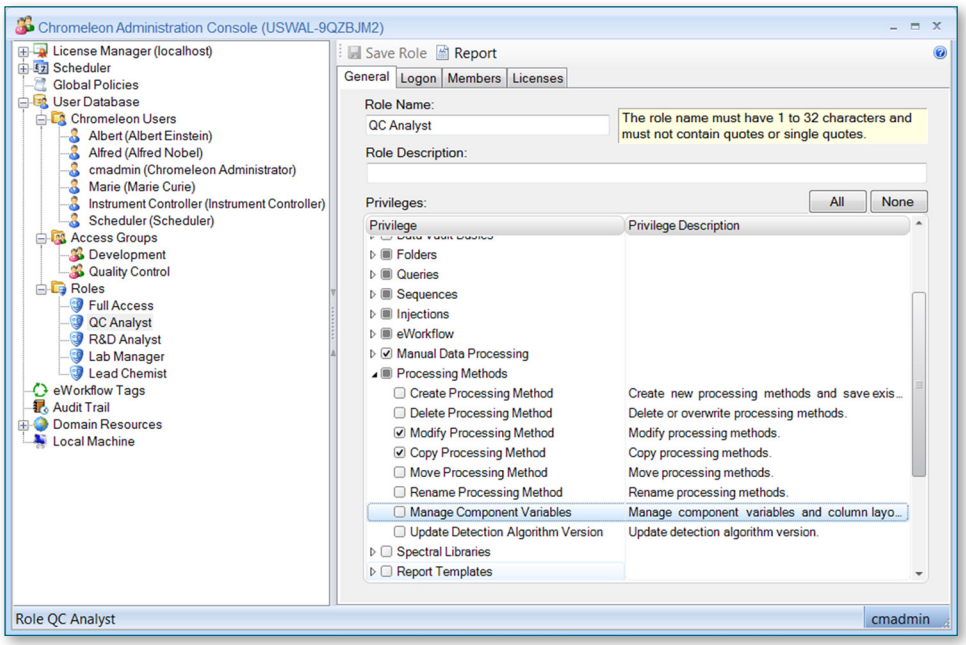
## Access control

Access control is provided by a User Management system that is flexible, secure and customizable. Users are defined with privileges, roles, and access groups. Privileges determine what a user can do. Roles are sets of privileges that can be assigned to a user. Access groups control where a user can exercise privileges acquired through roles.

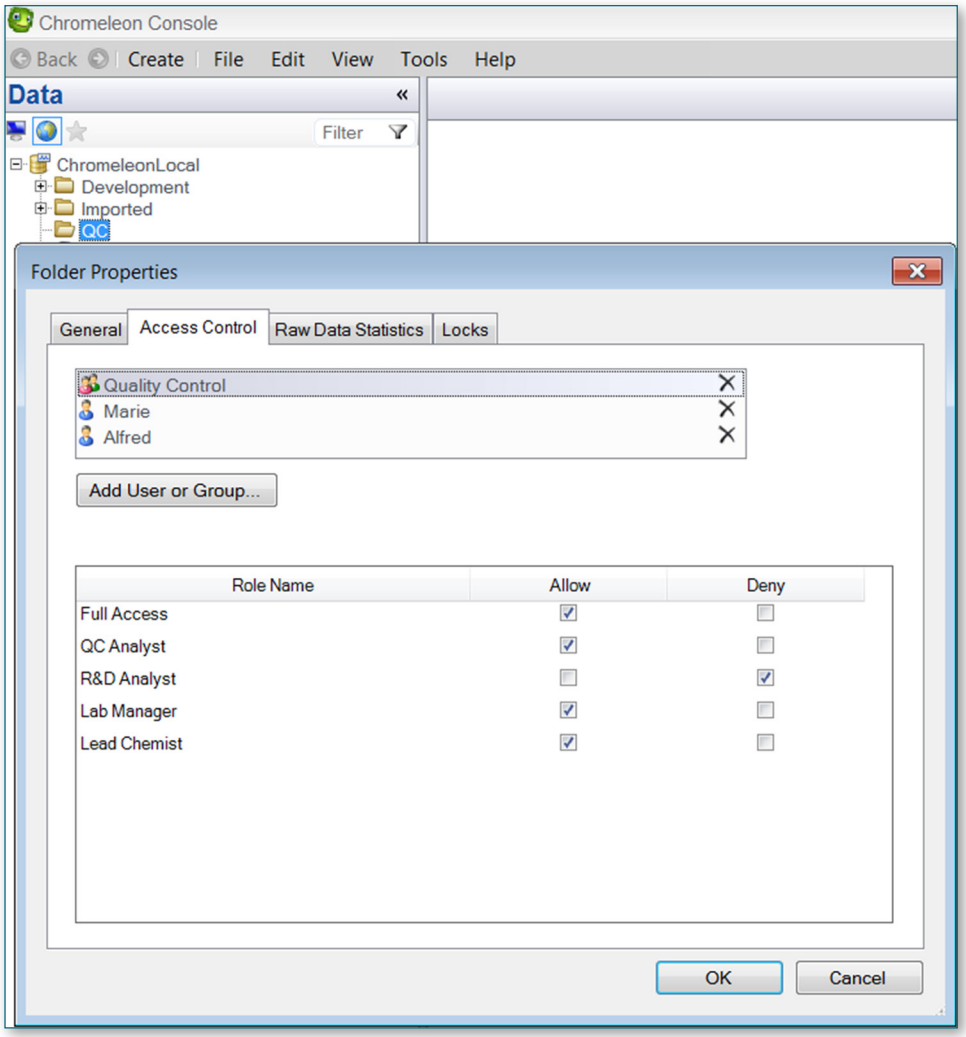



**A variety of different password rules can be implemented based on organizational requirements. These include password length, timed forced password change, lock out after a specified number of unsuccessful login attempts, and LDAP support for organizations that want passwords managed only at the operating system level.**




Over one hundred individual privileges can be assigned, so administrators have control over what users can do. These privileges range from simple Create/Modify/Move/Delete operations to more position-dependent activities such as archiving and administration.

Roles provide administrators with a straightforward method for managing user privileges. Administrators can define roles based on job requirements. Users are provided with a selection of roles available to them during login. Once a role choice is made, the user's activities are governed by the role for that session. This feature allows a manager, who may have report modification privileges in a supervisory role, to login with a standard operator role to run a regulated method without fear of accidentally modifying an approved report.




**Access Groups can be used to control access to specific Data Vaults, folders within Data Vaults, and instruments. Furthermore, for each of these objects the rights of different roles can also be defined. This allows administrators the flexibility to quickly grant expanded privileges to a development area while limiting privileges in other Data Vaults or folders, such as QC.**

## Validation

Chromeleon CDS comes with a complete set of automated tools that greatly accelerate the process of achieving a validated installation of your software and instruments.

### Certificates

Certificates of software validation and of U.S. FDA 21 CFR Part 11 readiness are provided on the installation media.

### Installation qualification

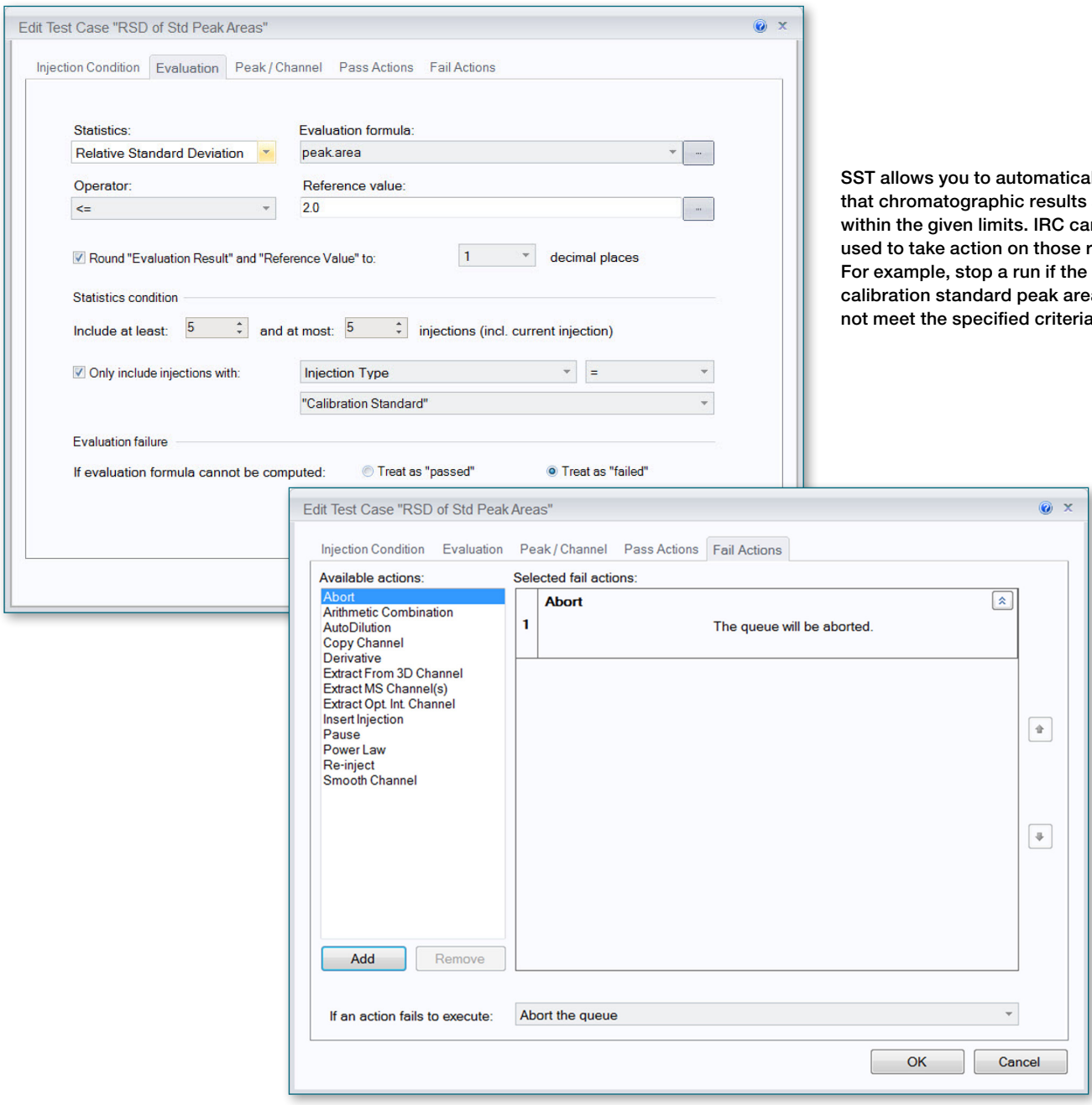
As part of the software setup, Chromeleon CDS automatically performs an installation qualification and produces a detailed report showing all installed files and services, and whether any were not as expected.

## Operational qualification and performance qualification

Automated tools make it easy for you to setup and run sequences that test the performance of all components of your chromatography system. The tools automatically generate detailed reports showing actual performance and comparison against acceptability limits.

## System Suitability Testing (SST) and Intelligent Run Control (IRC)

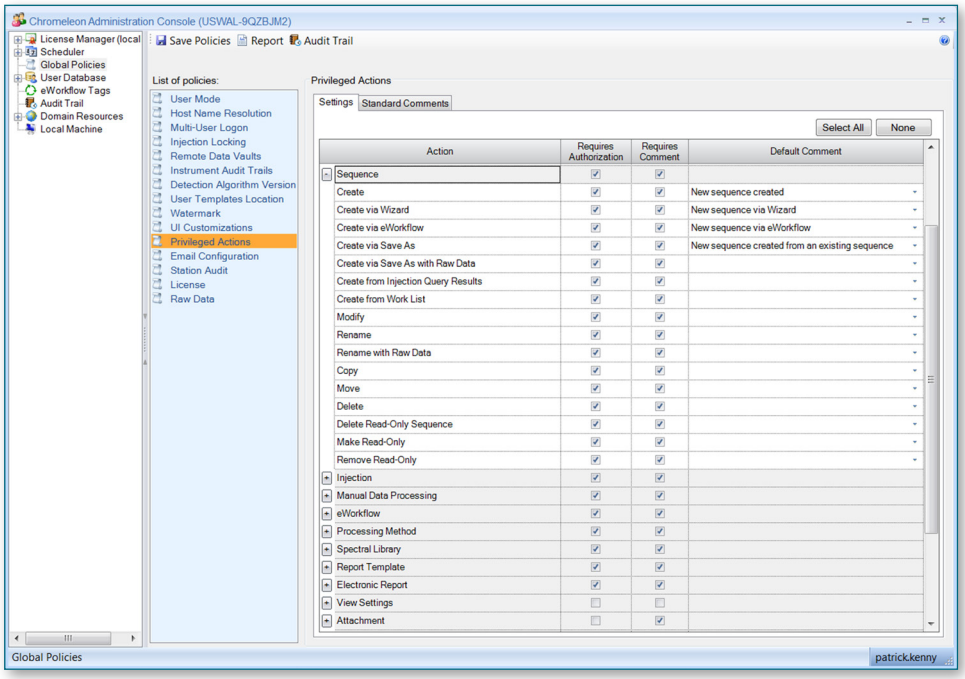
Chromeleon CDS provides complete, flexible SST, so you can easily incorporate performance checks in the daily sequences you use to analyze samples. In addition to common tests like those for peak shape and reproducibility, you can include any number of customized tests based on any of Chromeleon software's extensive set of result variables. With IRC, the results of the SST can be used to make automated, real-time, pass/fail decisions based on actual chromatographic results.




**SST allows you to automatically verify that chromatographic results are within the given limits. IRC can then be used to take action on those results. For example, stop a run if the %RSD of calibration standard peak areas does not meet the specified criteria.**

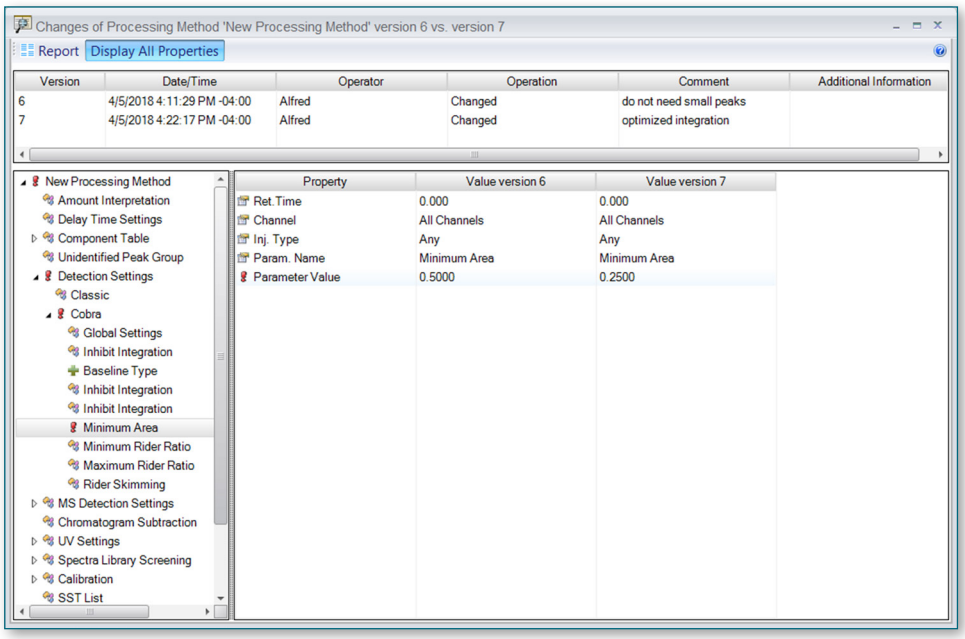
## Audit trails and versioning

Chromeleon CDS provides comprehensive and detailed audit trails for all data objects and instruments. A daily instrument controller log shows all activities related to instruments. The audit trails can be sorted, grouped, and/or filtered to allow for a quick review of relevant information. Administrators can mandate that users must provide a password and/or comment as they commit any changes. Using Privileged Actions, the activities that require these inputs can be fine-tuned to specific operations. The comments required can be pre-configured standard responses, or open, allowing the user to enter a more-detailed response. This further enhances the value of the audit trails by augmenting the what, when, and who, with the why.




**Privileged Actions allows the quality unit to decide when, and how, passwords and comments must be applied when making changes.**

In addition, each Data Vault provides an option to maintain all versions of all objects in it. With versioning enabled, you can quickly and easily compare versions of an object in a simple side-by-side display featuring icons that clearly flag insertions, deletions, and changes. Authorized users can roll back an object to any previous version, if appropriate.



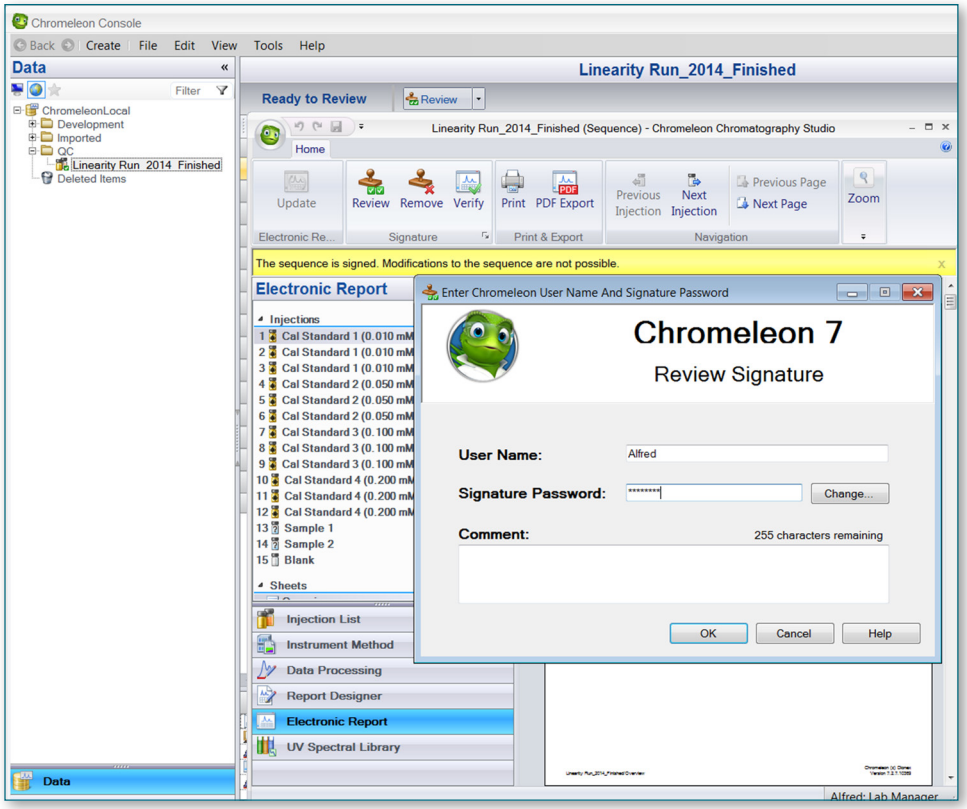

**Comparison of object versions clearly shows what changes were made by flagging them with specific icons.**

## Electronic signatures

Everything you need to implement paperless record keeping in compliance with 21 CFR Part 11 is seamlessly integrated into Chromeleon CDS. You can setup signature privileges and passwords in the User Management system. Define up to three levels of signature (Submit, Review, and/or Approve) per sequence. You can define signature requirements separately for individual sequences, or pre-define the requirements by incorporating them into eWorkflows™.

To electronically sign a sequence, an operator simply clicks Submit, and generates an electronic report that becomes part of the sequence. After reviewing the report to verify that everything is in order, the operator just signs as Submitter by entering his or her own signature password. Once a signature has been applied, all parts of the sequence are locked against modification and an encrypted signature is applied to the sequence.

Signature status of sequences can be easily checked, and queries can be used to locate sequences that are awaiting review or approval. The authenticity of the signatures on any sequence can be easily verified through a simple command.




**If the signature requirements include Review or Approve steps, the next person in the chain of custody can apply a signature to the electronic report in the same manner.**

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



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