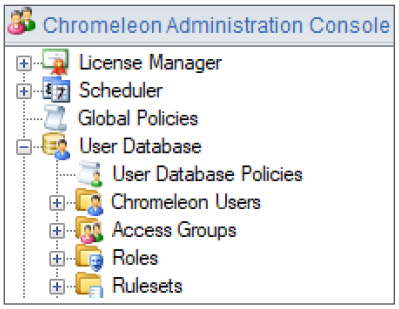
Configuring for compliance

Considerations when selecting a Chromatography Data System (CDS) for compliant operation require that it satisfy ALCOA+ standards for data traceability and possess appropriate tools to implement use under selected regulatory guidelines.

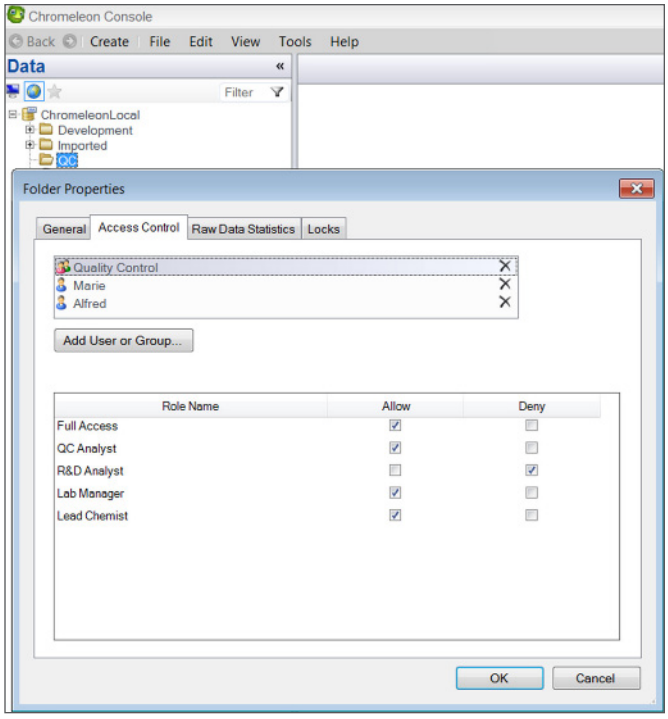
Delivering tools for access control, electronic review, audit trails, and qualification all while providing ease-of-use can present several challenges. Thermo Scientific™ Chromeleon™ CDS has been designed and optimized to overcome them.

Access control

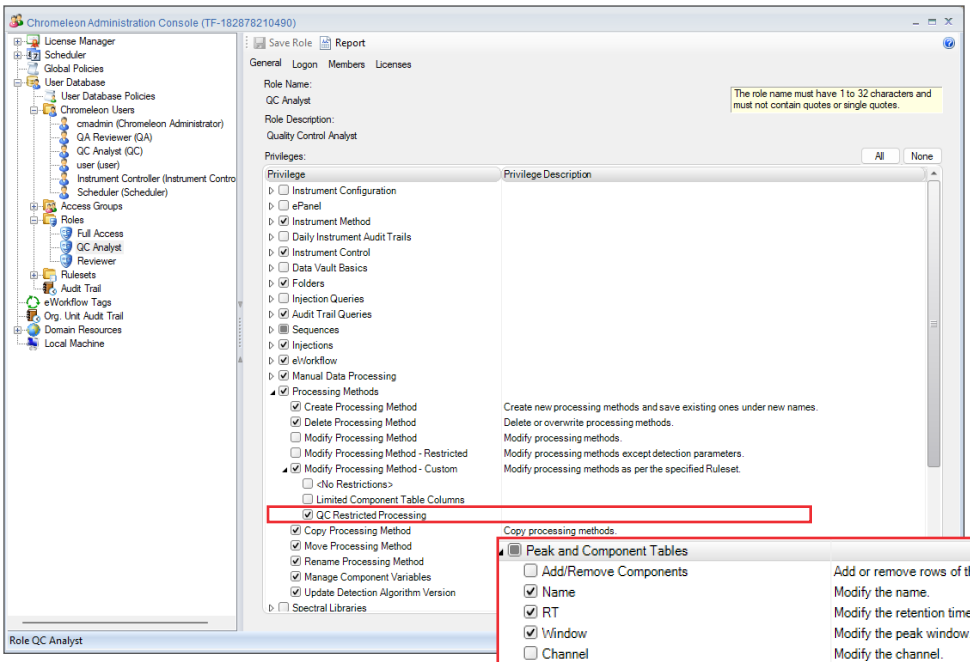
More than just limiting the access to the system itself or use of certain instruments and data folders, Chromeleon also has the ability to configure customized, granular-privelege, rulesets out of more than 180 choices to better define what users can manipulate.



Assign users one or more roles which are comprised of a group of privileges

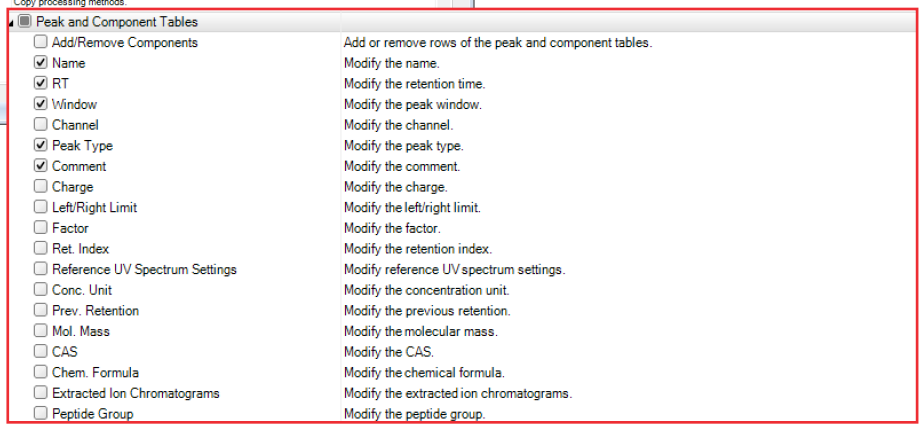


Restrict access to data vaults, folders within data vaults, and instruments by adding users or groups to access control



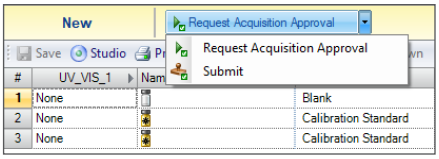
Define roles from intuitive privilege selections for typical operations such as create, delete, or modify, or go deeper with more detailed custom privileges.

Create custom groups, called rulesets, with even more granular selections for privileges

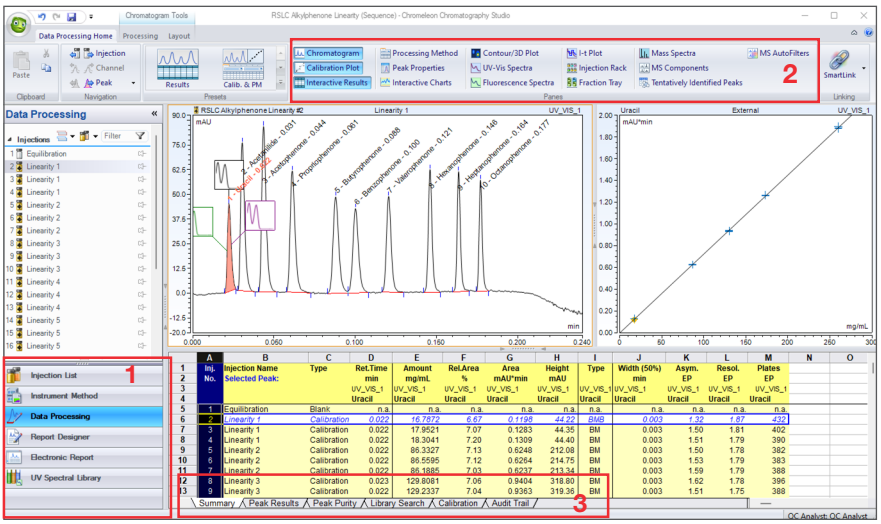


Electronic review

With the ability to add a review step prior to acquisition, centralized data collection with all the associated data organized per sequence, comprehensive tools to monitor changes in methods and chromatograms, and a three-level electronic signature process, it's easier than ever to transition away from paper.

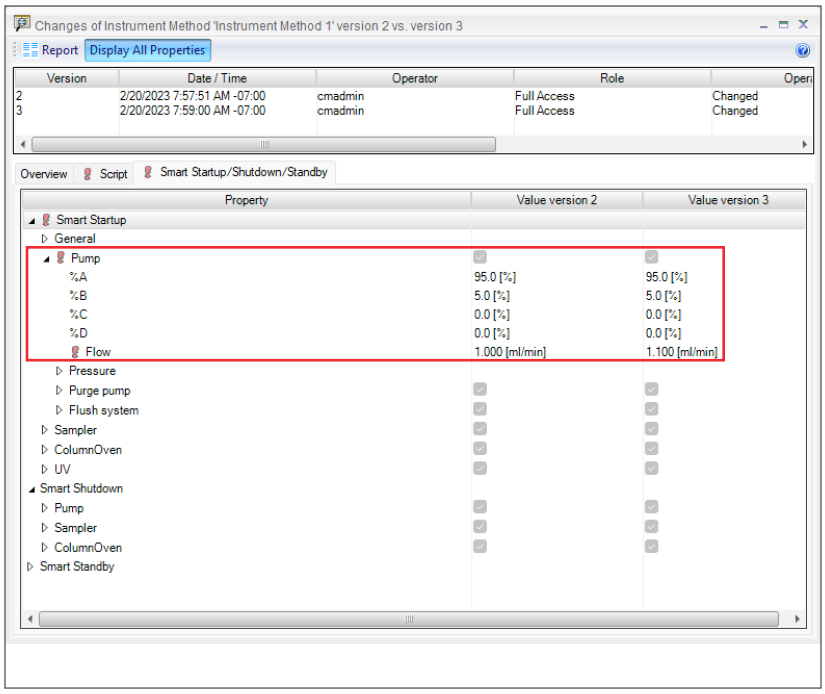


Set up acquisition privileges in administration to require users to request approval prior to starting a sequence.

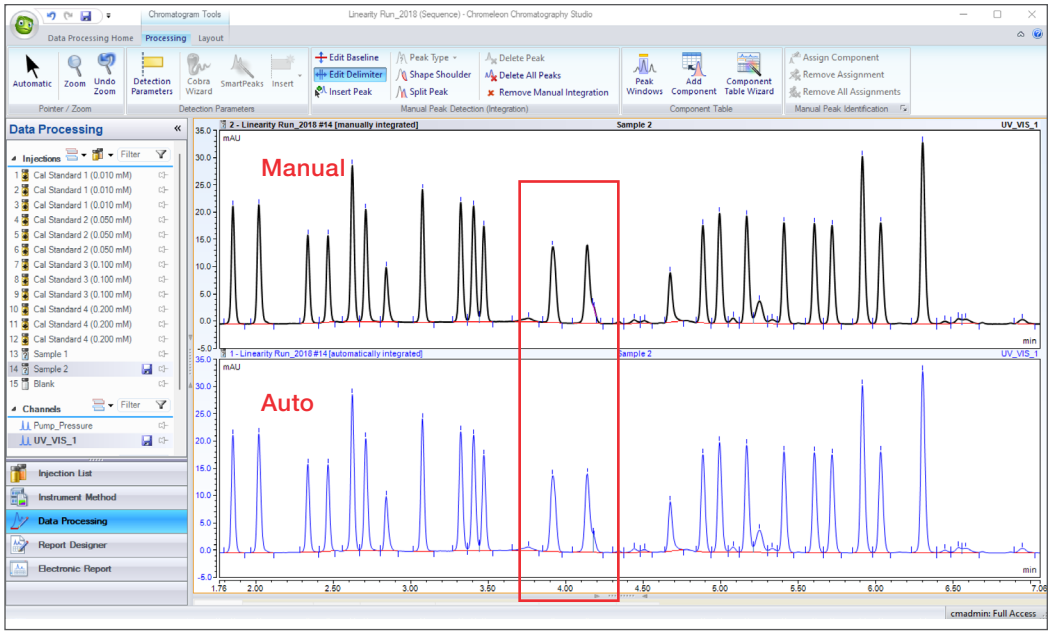


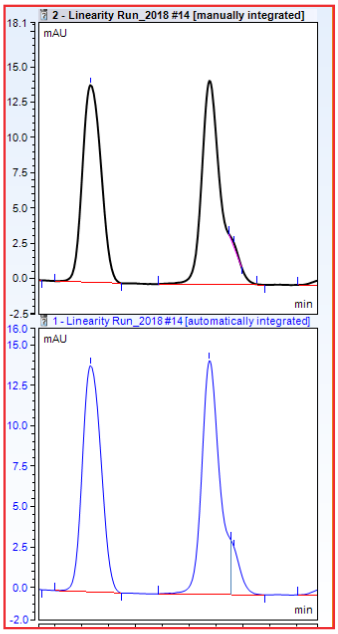
Review all electronic data associated items in a customizable window without navigating elsewhere.

1. Navigate through injection list, instrument method information and more with easy left-panel control.
2. Add and subtract panes for review or customize the pane options altogether with editable ribbons to focus review on what is relevant.
3. Explore each pane deeper with the associated tabs of information

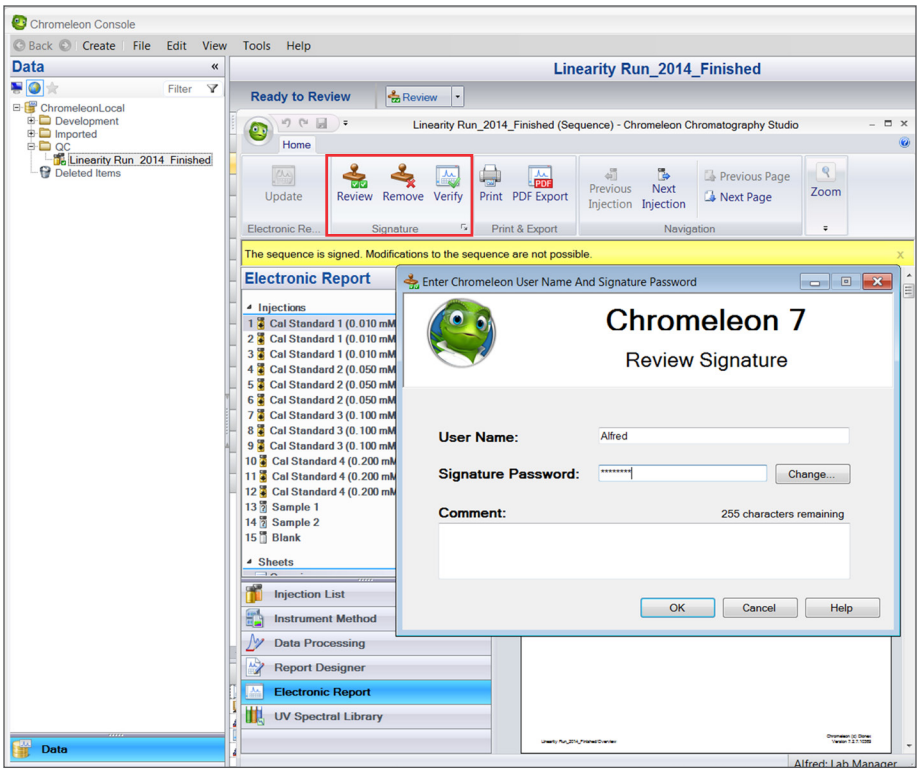


Compare method versions with icon highlighted menus that expand to allow reviewers to view differences side-by-side.





Select the display option to stack auto generated integration with manually integrated versions to visualize and simplify the review of user-made changes.



Define electronic signatures for up to three levels (submit, review and/or approval) for individual sequences or incorporate into eWorkflows.

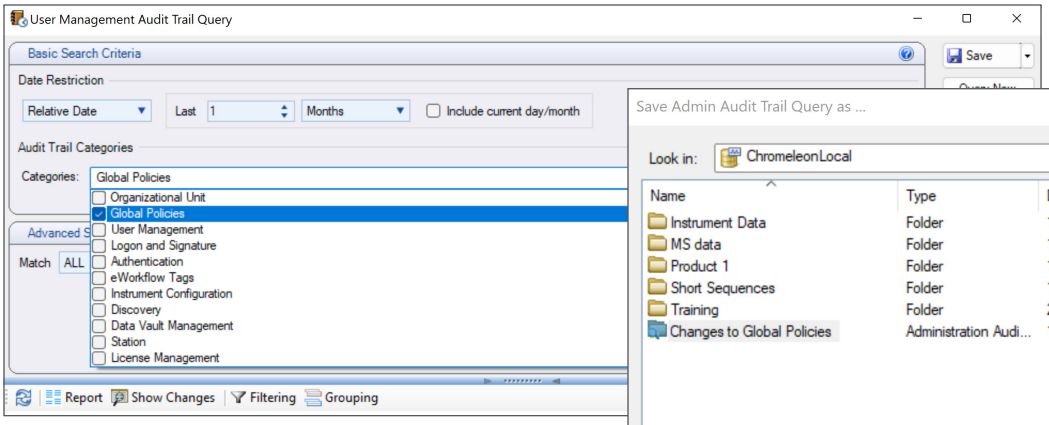
Click submit to electronically sign a sequence and generate a sequence-attached report.

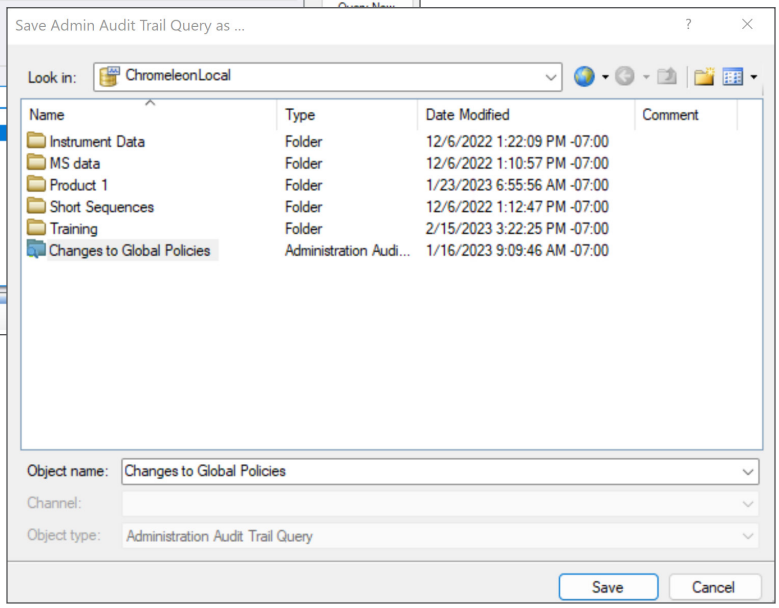
Click review to sign for reviewing and lock the sequence against edits.

Click approve to sign for the final step in the review process.

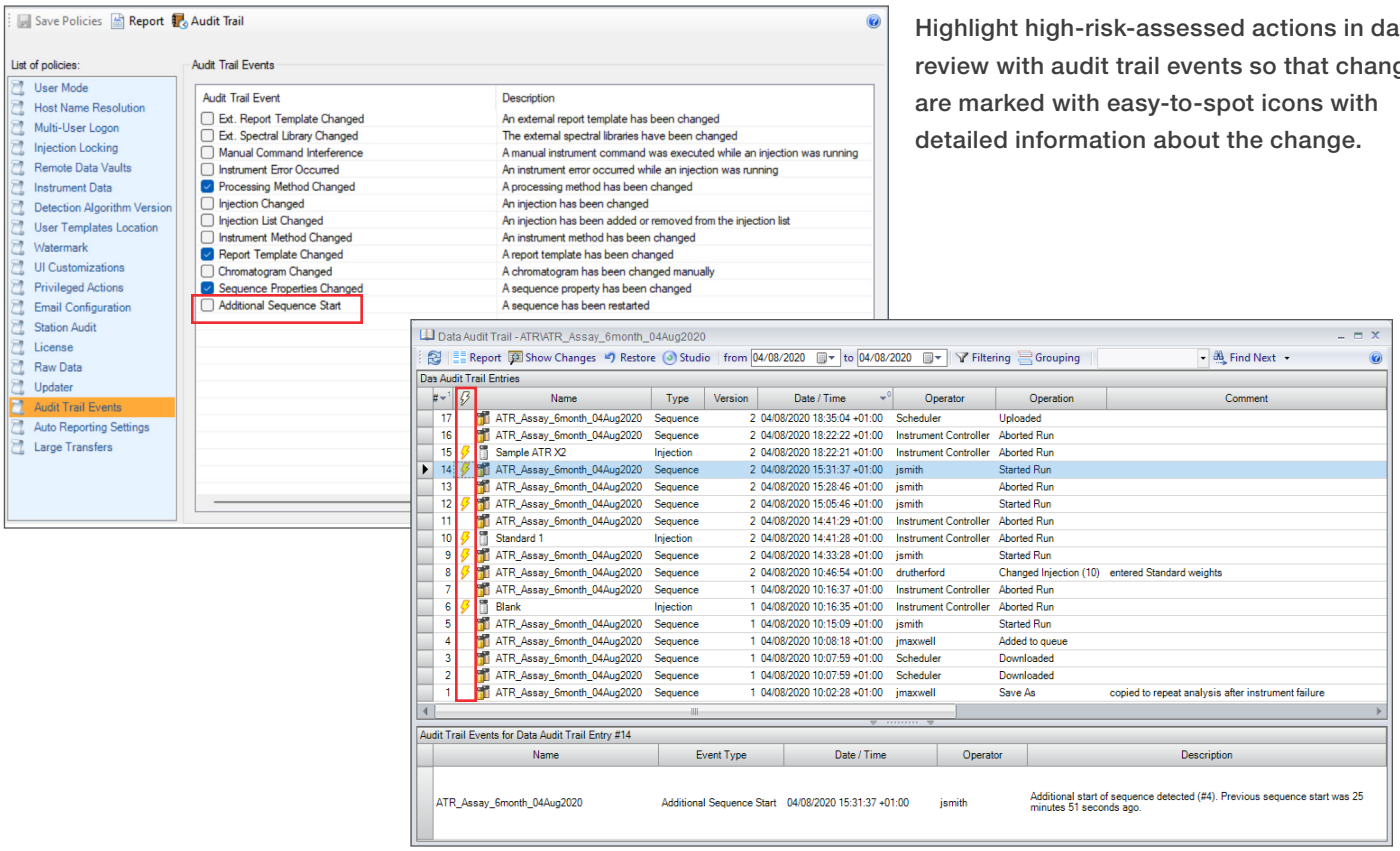
Audit trails

Reviewing audit trails with queries at the administration and instrument level along with adding audit trail events to highlight actions in data review will decrease the effort for this overwhelming activity.





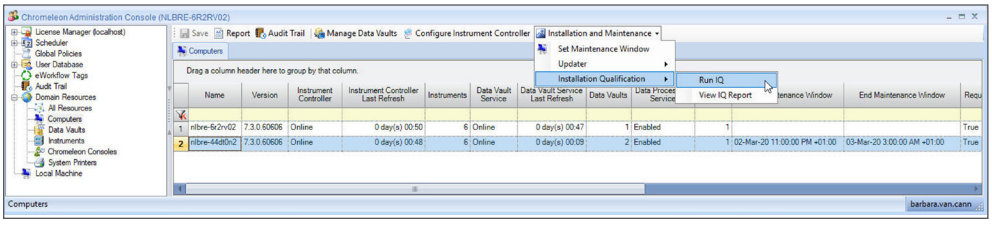
Save common queries to perform at appropriate risk-assessed intervals, such as querying for new instrument configurations in the past month. Once queried, the results can be utilized to generate a report.



Highlight high-risk-assessed actions in data review with audit trail events so that changes are marked with easy-to-spot icons with detailed information about the change.

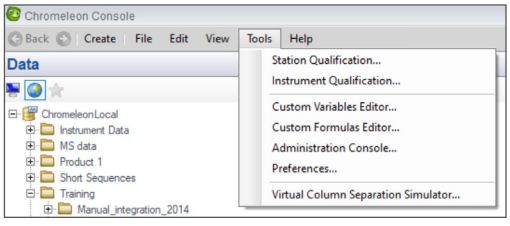
Qualification

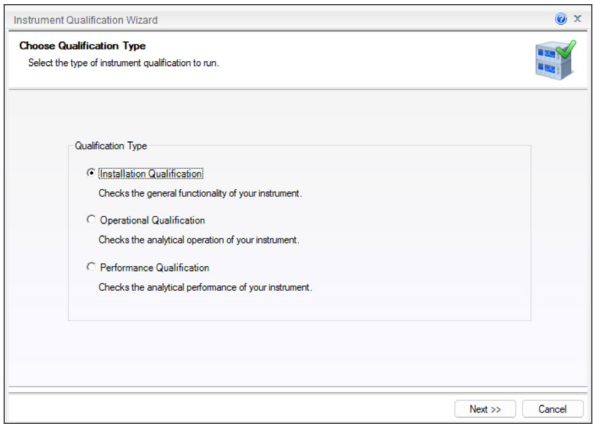
With tools to run qualifications across a larger enterprise installation from the menu in the administration console, or from the menu in each individual stand-alone station, maintaining qualification status is less complex than ever.



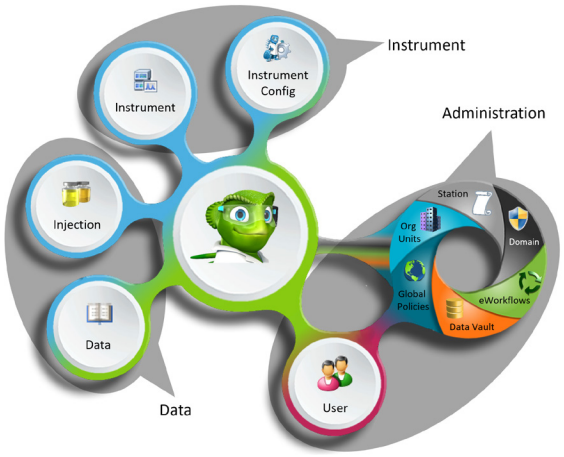
Select the menu option from the console in order to start the Qualification process.

Choose the qualification checks for the system to run.





Generate and retain the resulting report once the process completes.



Conclusion

Chromeleon CDS delivers an easy-to-adopt, easy-to-evolve, and easy-to-deploy software that can support the bedrock of a compliant system.

Meet the challenges of access control, electronic data review, audit review, and qualification with Chromeleon CDS

Built for Stability. Built for Performance.
With no compromise.

Learn more at **thermofisher.com/chromeleon**