



**ThermoFisher**  
SCIENTIFIC

## Using Chromeleon 7.3 CDS to comply with regulations



Built for **Compliance**

Built for **Data Integrity**

Without compromise

Thermo Scientific™ Chromeleon™ 7.3  
Chromatography Data System (CDS)



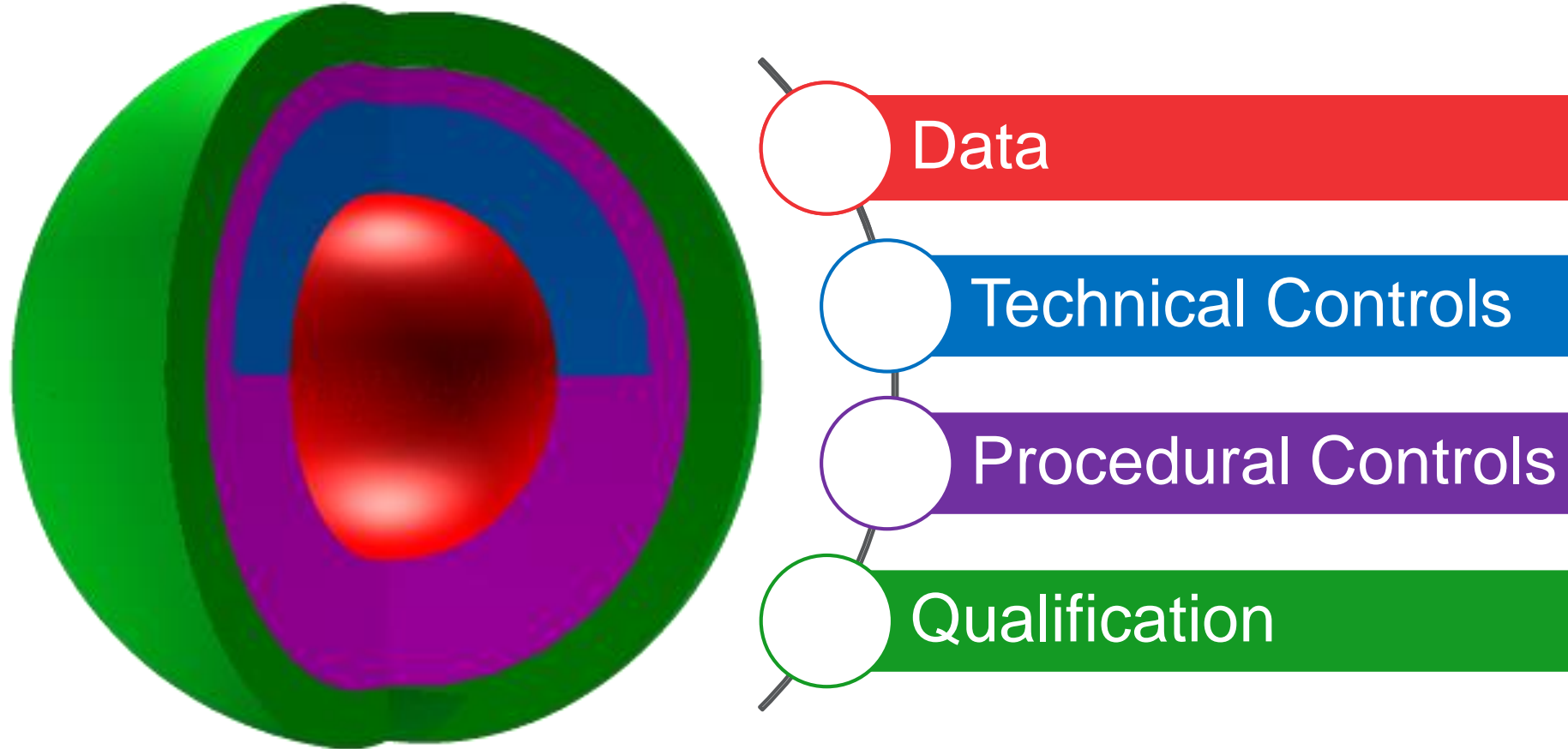
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# Built for Compliance

- Compliance layers
  - Compliance must be combination of technical and procedural controls



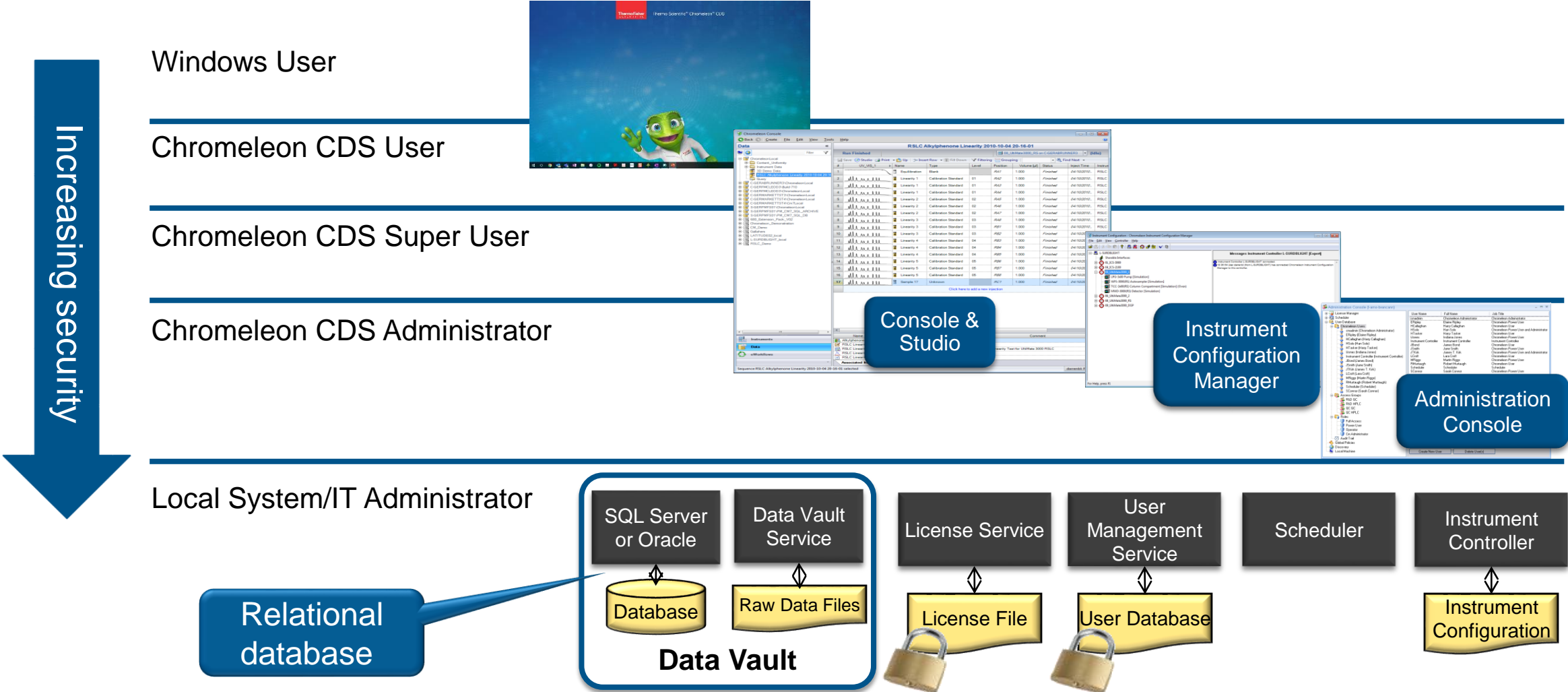
# Built for Compliance

- Software must be capable of 21 CFR Part 11 compliance
- Compliance can be considered in four categories:
  - **Security**
    - Access control and data security
  - **Record Management**
    - All data stored, controlled and archived
  - **Audit Trails**
    - Traceability of all actions in CDS
    - No loss of productivity
  - **Qualification**
    - Verify correct performance
    - Time/costs must be minimized

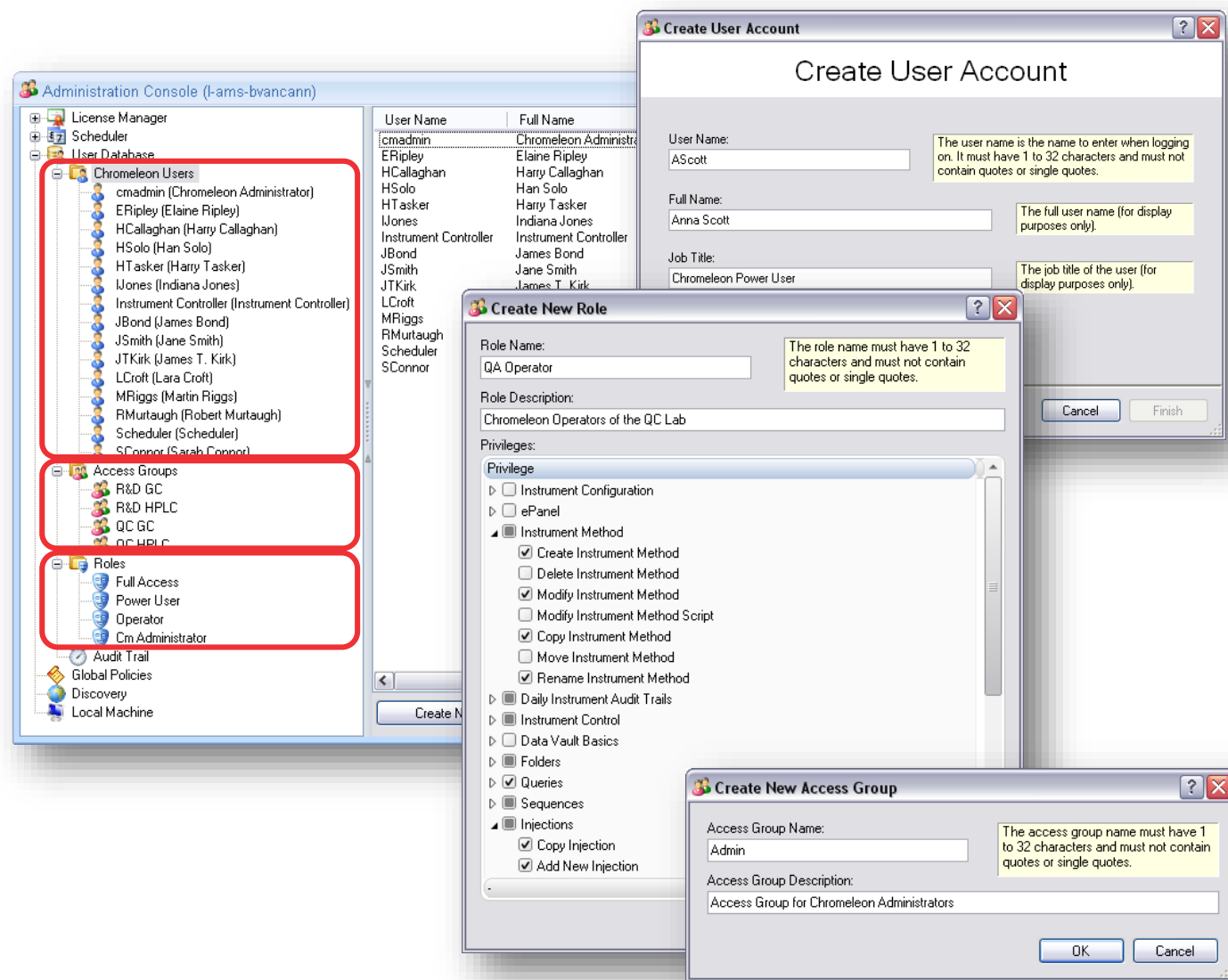




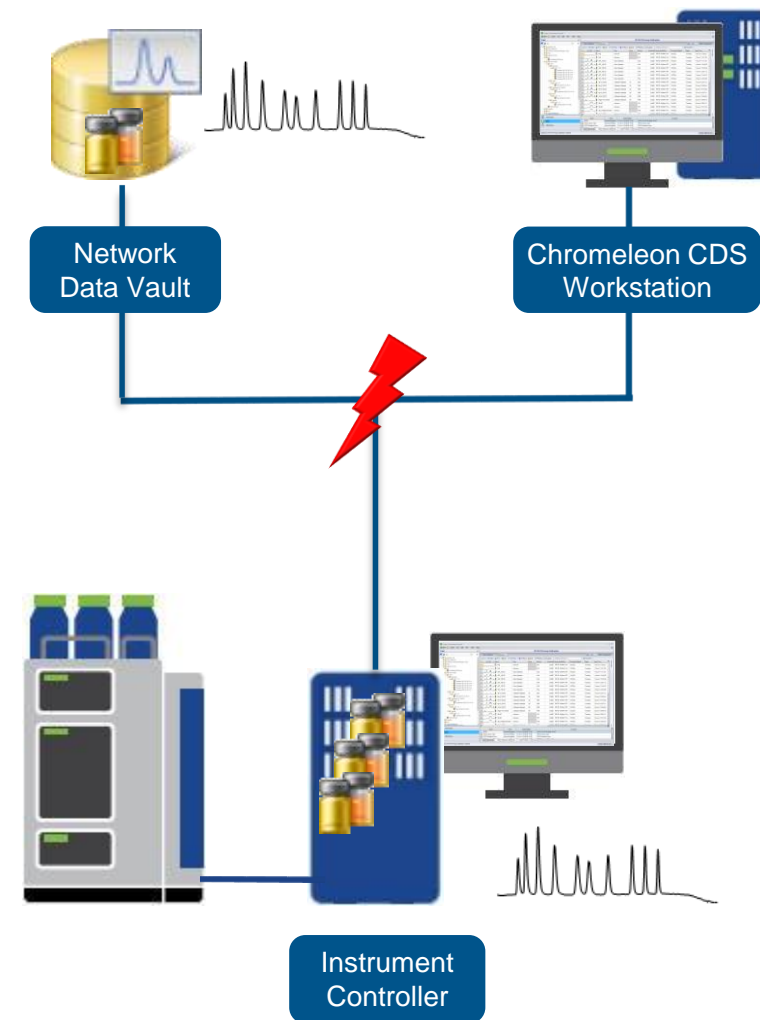
- Multiple levels of access security



- Comprehensive user management
  - Create unlimited users, roles and access groups
  - Role is collection of privileges
    - Defines what user can and cannot do
  - User can be assigned different roles
    - At login can choose an assigned role
- Access and roles can be controlled at every level
  - Data Vault, Folder, Instrument



- Data security
  - No loss of data and 24/7 lab uptime with Network Failure Protection (NFP)
  - License and User Management information cached locally
    - Instrument and user licenses always available
    - Users can always logon and continue to work
  - XVault technology ensures continuous operation
    - NFP mode automatically enabled at network failure
    - Uninterrupted data acquisition
    - After network recovery, data automatically uploaded to central server
    - User can log on to instrument controller to view and edit running queue, submit new analyses, process and report data
    - User management active to ensure data security
    - All information and actions are audited and traceable to protect data integrity





# Built for Compliance – Record Management

- Flexible data organization options
- Integrated electronic signature functions
- Automatic scheduler tool for archiving
- Exporting in FDA-approved formats



## Flexible Data Organization

- Data Vault concept
  - Mount multiple Data Vaults
  - Local, regional and/or global
  - Mount Chromeleon 6 CDS Datasources
  - Controlled access
- Flexible folder structure
  - Can organize by anything, e.g. project, location, date, user, instrument, etc.
  - Controlled access

The screenshot displays the CmServiceAMS - Chromeleon Console interface. On the left, a 'Data' pane shows a hierarchical folder structure under 'ChromeleonData'. The structure includes 'Location 1' (with sub-folders 'Lab B1 R143 - QC' and 'Lab B1 R056 - R&D'), 'Data' (with sub-folders 'Additives', 'Amino\_Acids', 'Aspirin', 'Calibration', 'GC', 'PAH', 'Spectra Sequences', 'System Tests', 'Water', 'Anions', and 'Cations'), 'Template Files', 'Location 2', 'Location 3', 'Deleted Items', 'ChromeleonLocal', and 'CM\_BVC\_local'. A specific folder '20130311 Water Analysis' is highlighted under 'Anions'. On the right, a table titled '20130311 Water Analysis' shows data for various samples. A blue callout box with the text 'Flexible folder structure' points to the folder structure on the left.

#	ECD_1	Name	Type	Level	Position	Volume [µl]	#Amount [mg/L] Chloride [ECD_1]	#Chloride Amount Test [ECD_1]	Processing Me
1									
2									
3									
4		Seven Anion Standard II - 4	Calibration Standard	04	RA4	25.0	19.639	Not Executed	AS12A Anions
5		Seven Anion Standard II - 5	Calibration Standard	05	RA5	25.0	40.610	Not Executed	AS12A Anions
6		Seven Anion Standard II - 6	Calibration Standard	06	RB1	25.0	59.798	Not Executed	AS12A Anions
7		Drinking Water	Unknown		RB2	25.0	3.269	Passed	AS12A Anions
8		Tap Water	Unknown		RB3	25.0	12.887	Failed	AS12A Anions
9		Power Coolant Water	Unknown		RB4	25.0	n.a.	NA -> Passed	AS12A Anions
10		Power Coolant Water	Unknown		RB4	25.0	0.018	Passed	AS12A Anions

Click here to add a new injection

Name	Type	Date Modified	Comment
Anions in Water	View Settings	07-Oct-13 3:01 PM	
Anions in Water	Report Template	14-Mar-13 11:59 AM	
AS12A Anions in Water	Processing Method	07-Oct-13 11:53 AM	
AS12A Anions in Water	Instrument Method	22-Jul-10 2:03 PM	Instrument Method Anions in Water on AS12A column

Associated Items Custom Sequence Variables (0)

Sequence '20130311 Water Analysis' selected

CmServiceAMS: Full Access

## Electronic Signatures

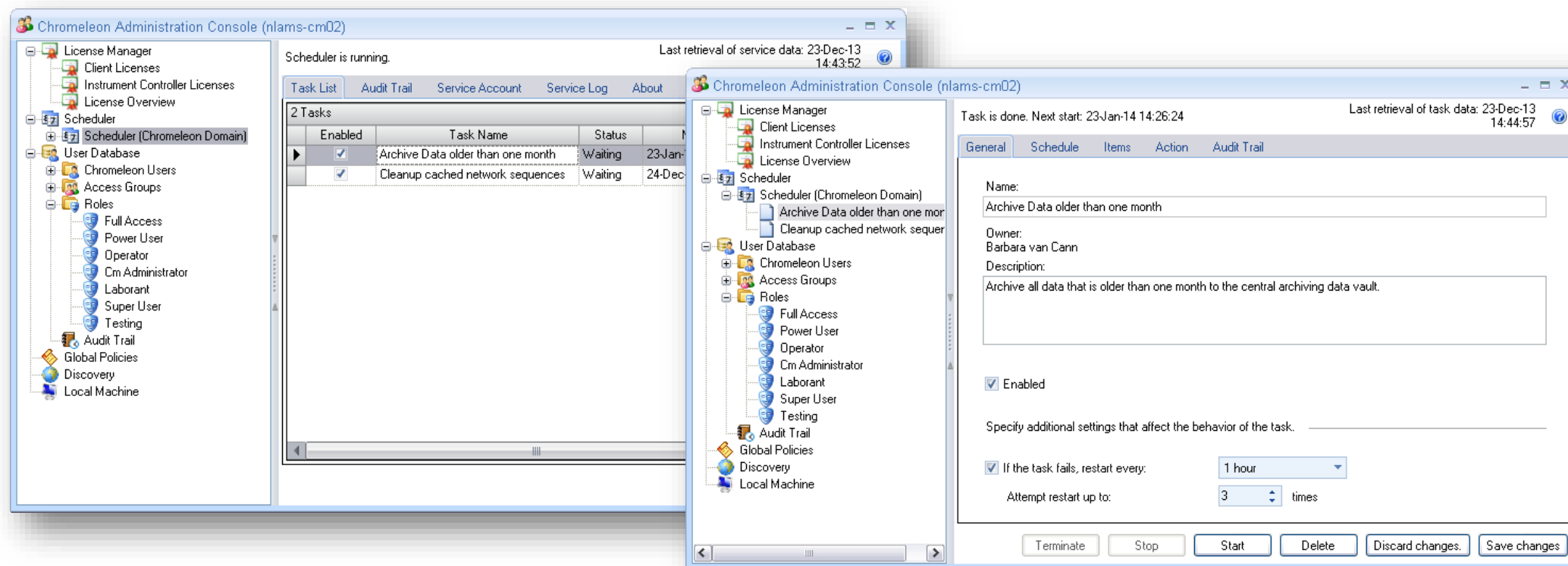
- 3 Levels of signature Submit, Review, Approve
- Applied to electronic report
- Complete sequence protected by checksums
- Controlled by privileges

The screenshot displays the Chromeleon 7 software interface. The main window shows the 'Electronic Report' for 'CmServiceAMS - RSLC Alkylphenone Linearity 2013-10-11 10-21-53 (Sequence)'. The 'Injections' list includes Equilibration, Linearity 1, Linearity 2, and Linearity 3. The 'Submit Signature' dialog box is open, prompting for the 'User Name' (CmServiceAMS), 'Signature Password', and 'Comment' (Submitting sequence). The background window shows a chromatogram and a table of injection results.

Injection	Peak Name	Retention Time (min)	Area (mV)	Height (mV)	Retention Time (min)	Area (mV)	Height (mV)	Amount (mg)
1	Unid	0.000	214.746	1.73	7.79	88.5000		
2	Acetaminophen	0.000	1.100	200.170	12.49	12.00	88.5000	
3	Propylphenone	0.000	1.000	200.170	14.50	10.52	88.5000	
4	Propylphenone	0.000	1.000	200.170	12.11	10.52	88.5000	
5	Propylphenone	0.000	1.000	200.170	10.50	10.52	88.5000	
6	Propylphenone	0.000	1.000	200.170	9.52	1.20	88.5000	
7	Propylphenone	0.000	1.000	200.170	9.52	1.20	88.5000	
8	Propylphenone	0.000	1.000	200.170	10.51	10.52	88.5000	
9	Propylphenone	0.000	1.000	200.170	10.51	10.52	88.5000	
10	Propylphenone	0.000	1.000	200.170	10.51	10.52	88.5000	

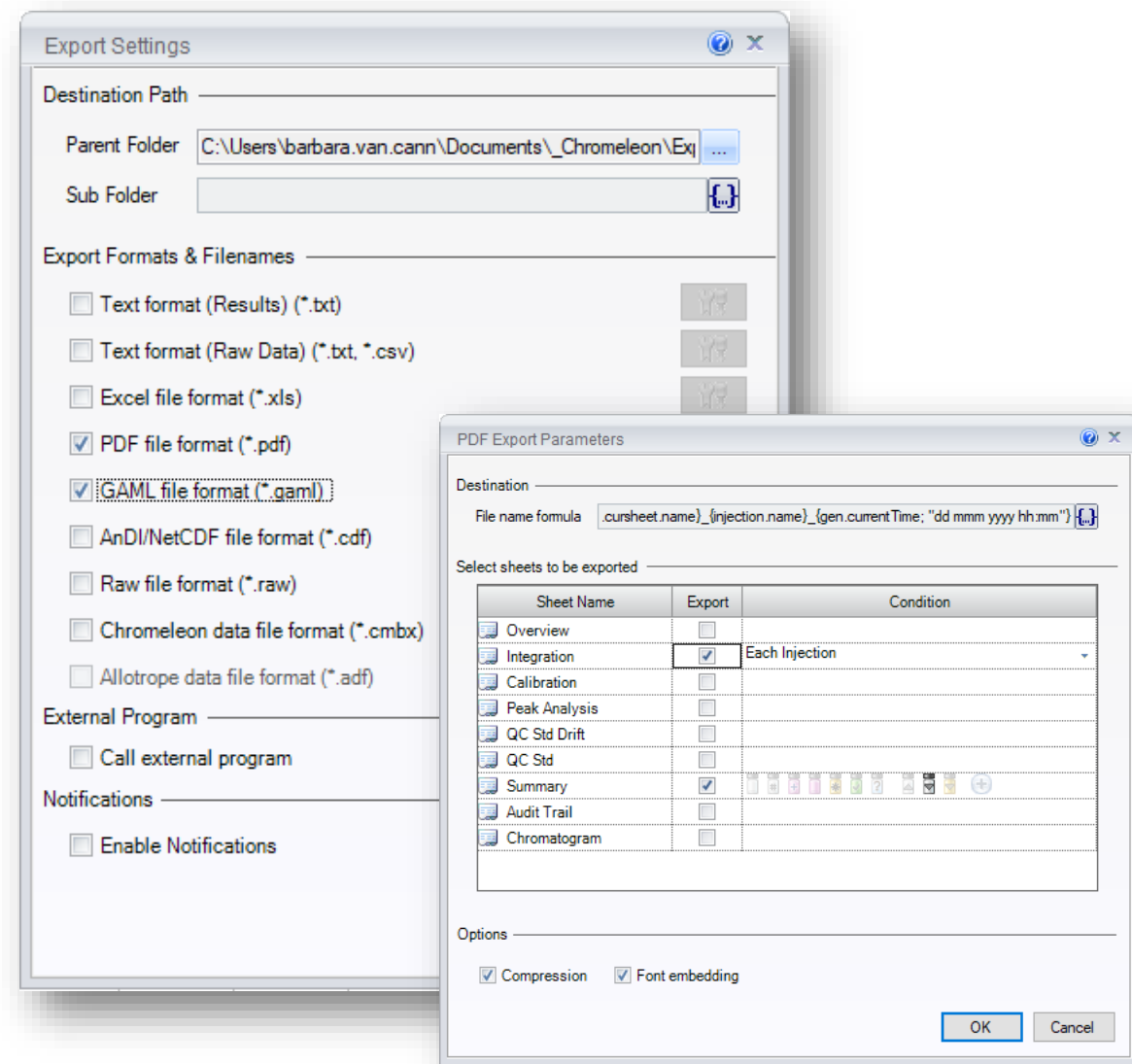
## Scheduler for Automatic Archiving

- Automatically move data by combining powerful injection queries with the Scheduler
- Easily organize your system



## Exporting

- Chromeleon CDS provides automatic printing or exporting of sequence results with just two clicks
- Print or export results in various formats, e.g.
  - PDF or spreadsheet for client
  - Result export as text or GAML file for LIMS
- Multiple output formats for all purposes
  - Text (TXT, CSV)
  - Excel (XLS)
  - Portable document format (PDF)
  - Generalized Analytical Markup Language (GAML)
  - AnDI/NetCDF (CDF)
  - Raw File (RAW)
  - Chromeleon Data File (CMBX)







- Qualification vs. validation
  - **Qualification** – prove and document that systems are properly installed, work correctly, and comply with specified requirements
    - Directly related to **equipment, systems or software**
  - **Validation** – document evidence that assures a process will consistently produce results within specifications
    - Directly related to the **process**
- Qualification is part of validation
  - Regulatory agencies take view that end-users of CDS are responsible for its qualification and validation



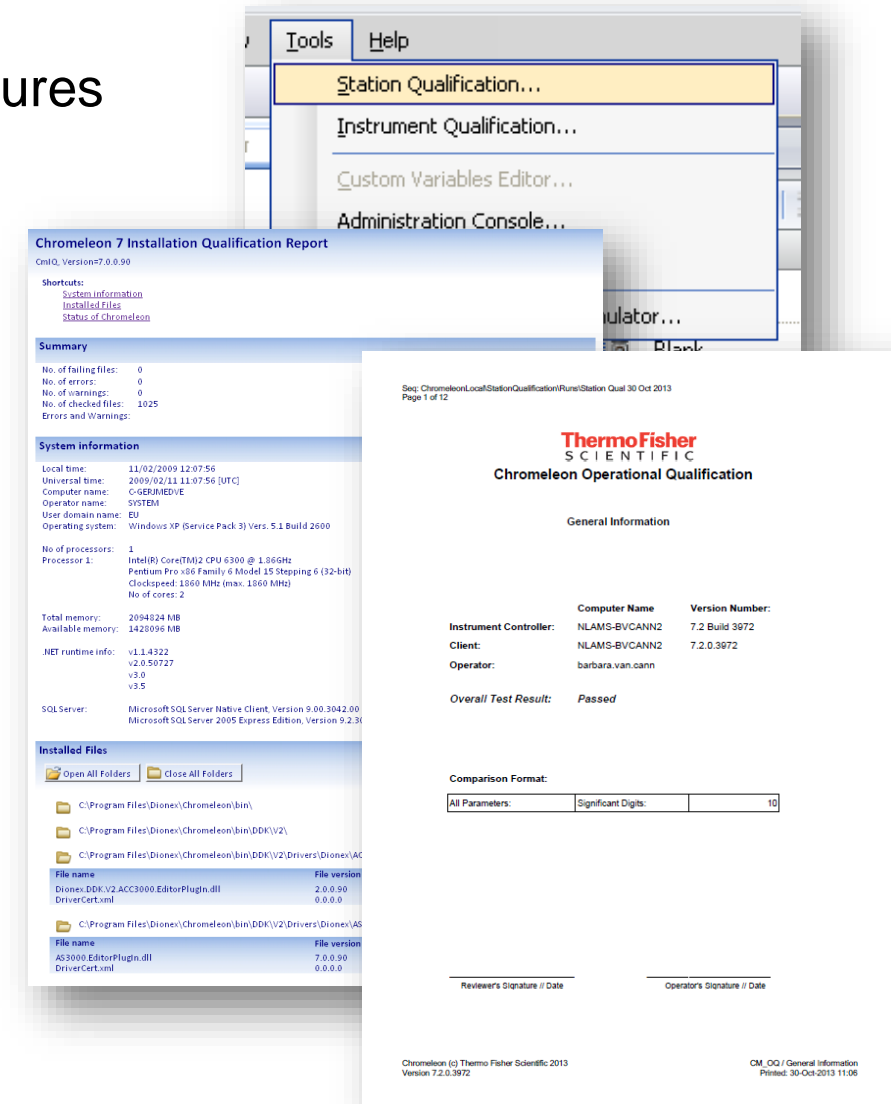
“QUALITY IS NOT AN ACT; IT IS A HABIT.”  
— Aristotle

• Deliverables

	Type	Responsibility		
<ul style="list-style-type: none"><li>• IQ plan, test scripts, report</li><li>• Functional Requirement Specifications</li><li>• System Configuration Document</li><li>• Project Plan</li><li>• Validation Plan</li><li>• OQ plan, test scripts (i.e. val kit), report</li><li>• User Requirement Specification</li><li>• PQ plan, tests, report</li><li>• Traceability Matrix</li><li>• Validation Report</li></ul>	<ul style="list-style-type: none"><li>Qualification</li><li>Validation</li><li>Validation</li><li>Validation</li><li>Validation</li><li>Qualification</li><li>Validation</li><li>Qualification</li><li>Validation</li><li>Validation</li></ul>	<div>Customer</div> <div>Supplier</div>	<ul style="list-style-type: none"><li>✓</li><li></li><li></li><li></li><li></li><li>✓</li><li></li><li>✓</li><li></li><li></li></ul>	<ul style="list-style-type: none"><li></li><li>✓</li><li>✓</li><li>✓</li><li></li><li></li><li>✓</li><li></li><li>✓</li><li></li></ul>

# Built for Compliance – Qualification

- Chromeleon CDS provides complete set of qualification procedures
  - Certificate of Validation
  - Automated Software IQ and OQ
  - Automated Instrument IQ, OQ and PQ
  - Automated System Suitability Testing
- Qualification processes are fully automated
  - Occasional, minor manual interaction for instrument IQ/OQ (e.g. pump priming)
  - Qualification can be performed in as short a time as possible
- All processes are available as standard
  - Requalification can be performed by the customer
  - Ensures down time and cost is kept to a minimum





Built for Compliance

Built for Data Integrity

Without compromise

- What is “data integrity”?
  - Completeness, consistency, and accuracy of data

## ALCOA+



### Attributable

- Who did what, when?



### Legible

- Readable throughout lifecycle



### Contemporaneous

- Recorded at time of activity



### Original

- Original record or certified copy



### Accurate

- Data with no errors or undocumented editing



### Complete

- All data including repeat or reanalysis



### Consistent

- Date/time stamped in expected sequence



### Enduring

- Recorded in enduring media throughout lifecycle

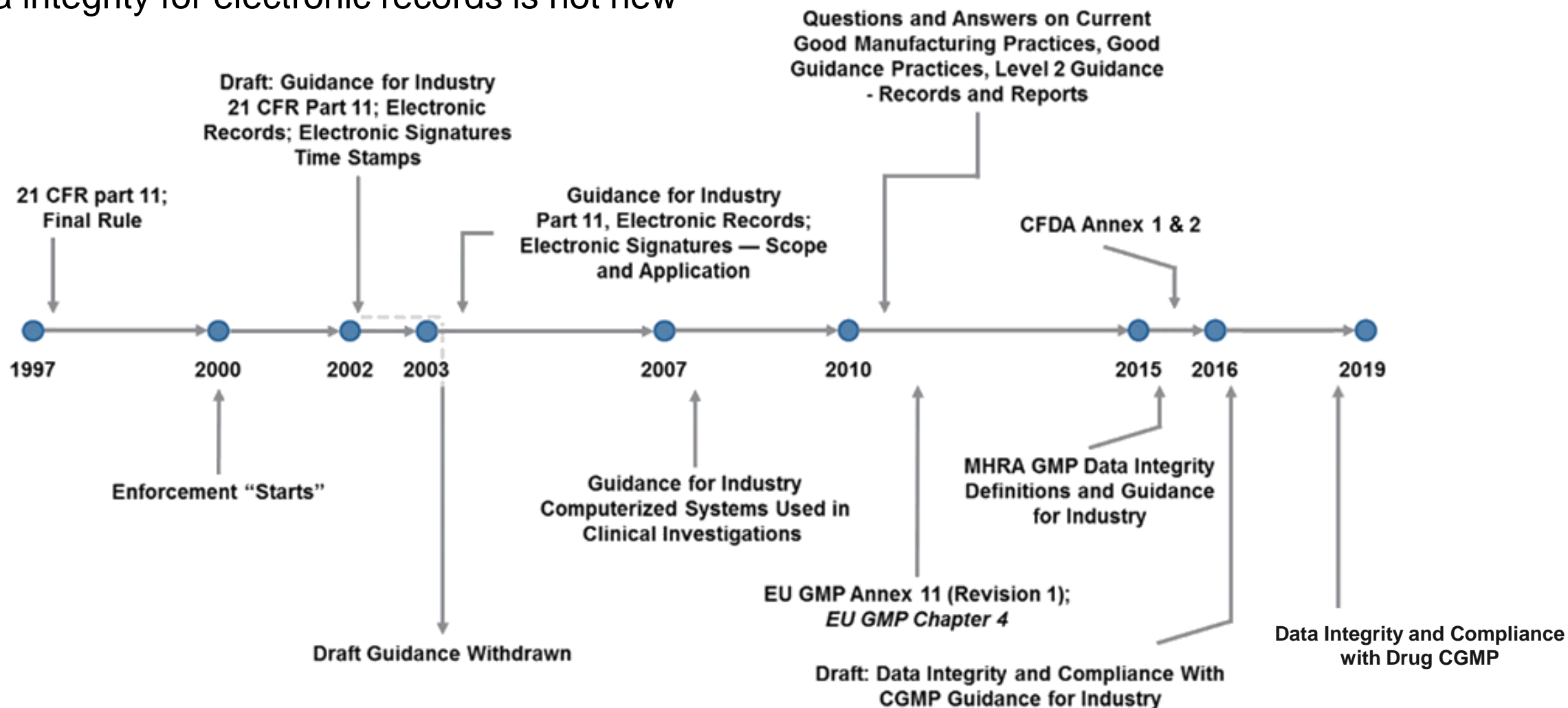


### Available

- Accessible for review/audit throughout lifecycle

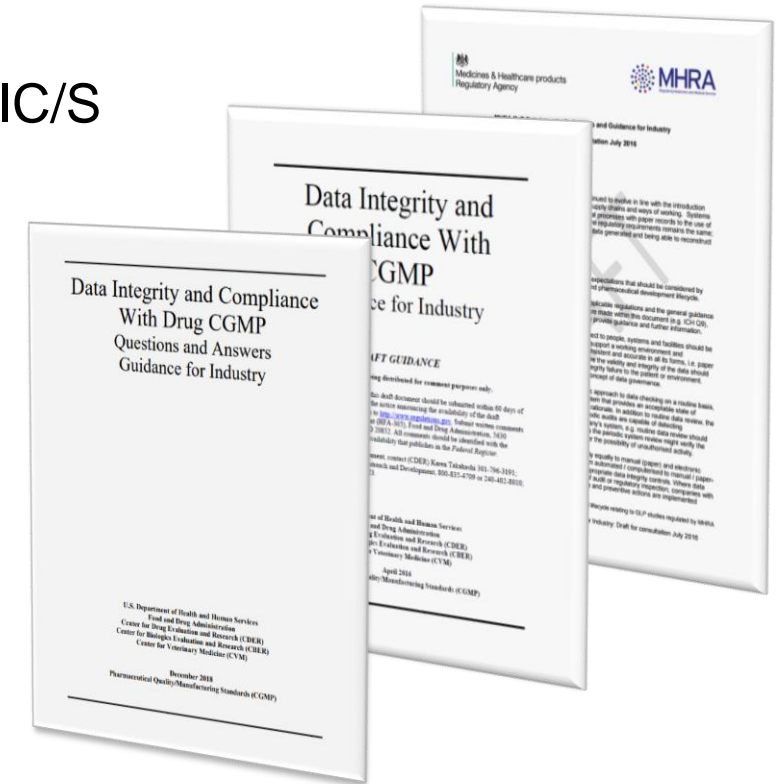


- Data integrity for electronic records is not new



- Data integrity guidelines 2015 & 2016 from FDA, MHRA, CFDA & PIC/S
- Clarifies role of data integrity in current good manufacturing practice (CGMP) for drugs
- Contains current thinking on creation and handling of data in accordance with CGMP requirements
- FDA data integrity guidelines Dec 2018
- Introduces need for regular audit trail reviews

- US Food & Drug Administration (FDA)
- International Society for Pharmaceutical Engineering (ISPE)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- European Medicines Agency
- China Food and Drug Administration (CFDA)
- World Health Organization (WHO)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)



## Audit Trails

- What is an audit trail?
  - “Secure, computer-generated, time-stamped electronic record that allows for reconstruction of events relating to creation, modification, or deletion of an electronic record.”
  - “Electronic audit trails include those that track creation, modification, or deletion of data **and** those that track actions at the record or system level.”

*The chronology of “who did what, when, and why” of a record*

- Audit trails are critical requirement of electronic record regulations
  - Enable detection of non-desirable activity
  - Provide tool that influences users’ behavior
  - Ensure data integrity
- Regulators use audit trails to review trustworthiness of presented data
- They are aware of available audit trails and expect to see them:
  - Enabled
  - Configured correctly
  - Part of data review or periodic review cycle

- Chromeleon CDS version 7.2 already introduced many compliance features to capture the 'who, what, when and why'
- 11 audit trailed areas
- Comprehensive user management
- Privileged Actions
- Version comparison with roll back
- Read-only Studio viewer

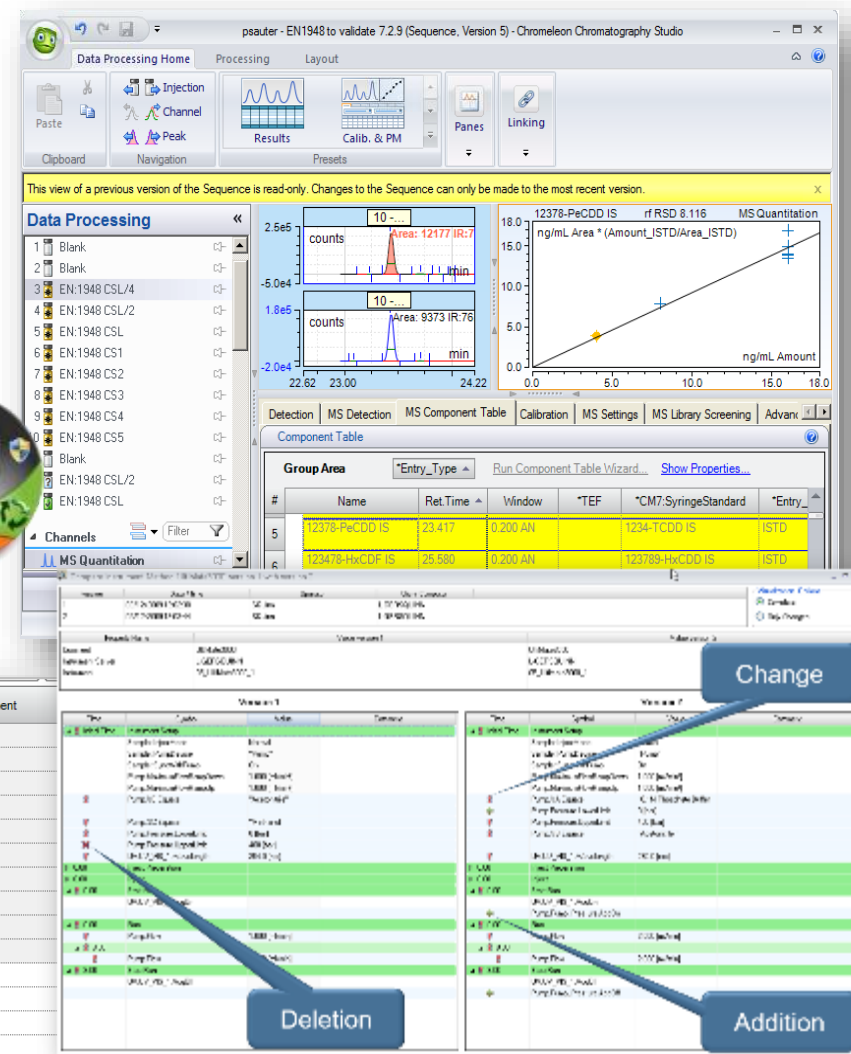


The screenshot displays the 'Privileged Actions' menu on the left, which includes options like Instrument Audit Trails, Detection Algorithm Version, User Templates Location, Watermark, UI Customizations, Privileged Actions (highlighted), Email Configuration, Station Audit, and Raw Data.

The main window shows a table of actions with columns for Action, Requires Authorization, Requires Comment, and Default Comment.

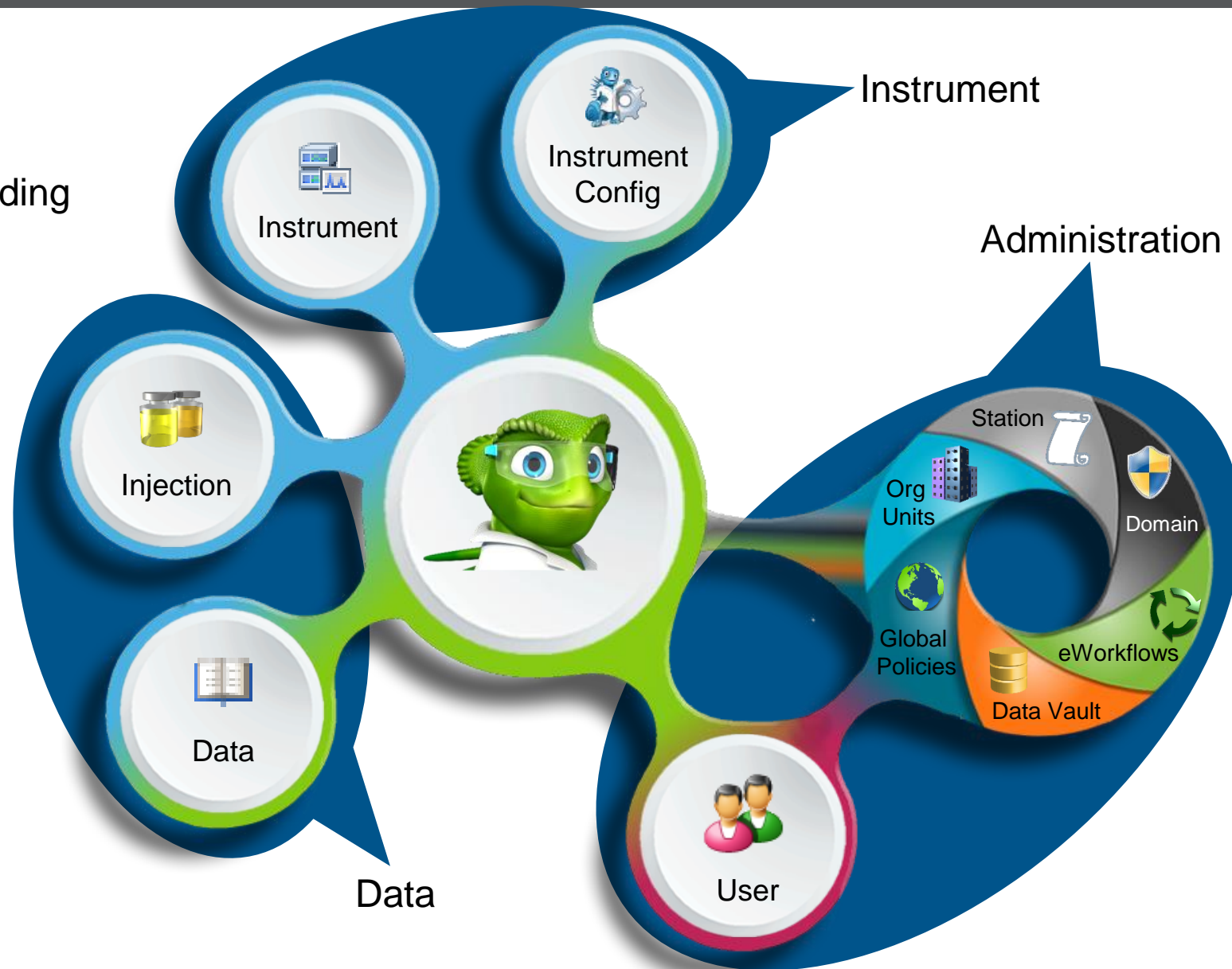
Action	Requires Authorization	Requires Comment	Default Comment
Instrument Configuration	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Instrument Method	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Instrument Audit Trail	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Data Vault	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Folder	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Query	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Sequence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Injection	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Manual Data Processing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
eWorkflow	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Create	<input type="checkbox"/>	<input checked="" type="checkbox"/>	created eWorkflow
Modify	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Rename	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Delete	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

Below the table, there are two panels showing a comparison of two versions of a workflow. The left panel is labeled 'Version 1' and the right panel is labeled 'Version 2'. Arrows point from the 'Change' button to the comparison panels, and from the 'Deletion' and 'Addition' buttons to specific changes in the workflow steps.



- Audit Trails

- Chromeleon CDS provides industry-leading audit trails
- 11 audit trailed areas
- 3 main audit trails
  - Instrument
  - Data
  - Administration
- All audit trails can be stored and managed centrally in Chromeleon CDS

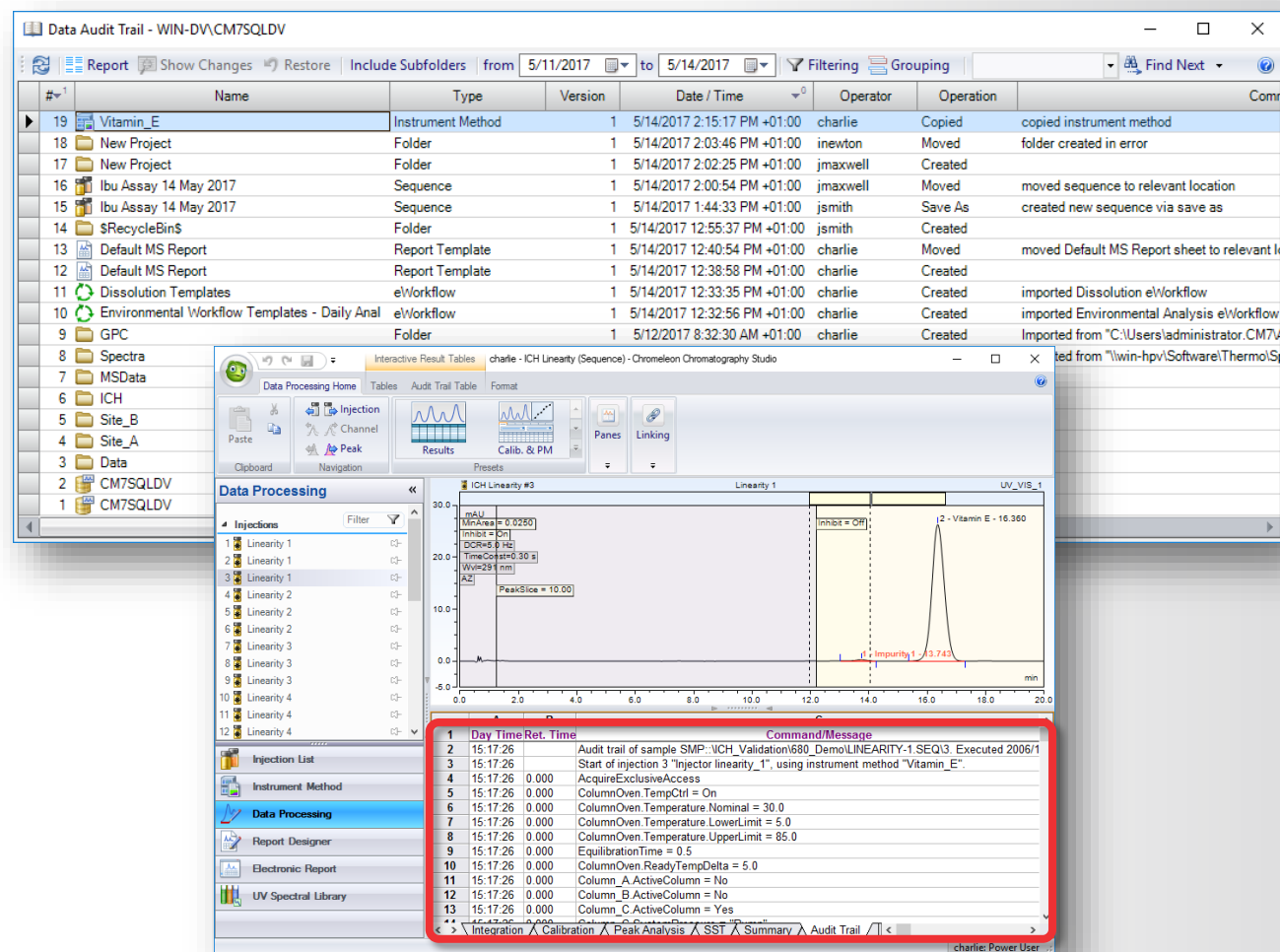




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  - 3 main audit trails
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    - Administration
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- Data Audit Trail
  - Log of all changes within Data Vault
  - Separate audit trail maintained per Data Vault and per data object, e.g., folder, sequence, injection, etc.
  - Injection audit trail logs all information recorded for a specific injection
    - Stored with & locked to raw data



- Instrument Audit Trail
  - Daily event log per instrument
  - Records all instrument operation events, e.g., system events, pre-run settings, commands and errors
  - Log of changes to instrument configuration

The screenshot displays the ThermoFisher Scientific software interface, specifically the 'Changes for category 'Instrument Configuration' and host 'WIN10-CM7'' window. The interface is divided into several panes:

- Left Pane:** A tree view showing the instrument configuration hierarchy. The 'WIN10-CM7' folder is expanded, showing sub-items like '10\_Vanquish', 'Vanquish Quaternary Pump', 'Used Pump', 'Flow Unit', 'Used Signals', 'Vanquish Binary Pump', 'Used Pump', 'Flow Unit', 'Flow/Pressure Limits', 'Used Solvents', 'Used Signals', and 'Pump\_Pressure'.
- Top Pane:** A table showing changes for the selected category and host. The table has columns: Date/Time, Operator, Operation, and Comment. The data row shows: 5/12/2017 1:31:30 PM +01:00, charlie, Changed, and an empty comment.
- Right Pane:** A table showing the 'Property' and 'New Value' for the selected instrument. The properties listed are: Device Name Pump Module (PumpModule), Simulation Mode (On), Used Relays, and Used.
- Bottom Pane:** A table showing the 'Audit Trail' for the selected instrument. The table has columns: Date, Time, Retention Time, Device, and Message. The data rows show a sequence of events from 5/14/2017 11:16:00 AM to 5/13/2017 12:48:31 AM, including messages like 'User charlie (from WIN10-CM7) has connected Chromeleon Instrument Configuration Manager to this controller.', 'Finished the sequence queue run.', 'Preparing the start of the next pending sequence (if there is any).', 'End of sequence "PQ\_STOP".', 'Vanquish Diode Array Detector @ USB -12345678 - VHD10-A - Serial # 12345678 - Firmware Version 0.00.01 UV Lamp on.', 'End of injection "Restore".', 'UV SetFactoryDefaults', 'Entered stage "Run"', 'Inject command ignored, because the injection is a blank run.', and 'Injection Volume is 1.00 ul'.

- Administrative Audit Trails
  - Domain Resources
  - Data Vault Manager
  - eWorkflow Tags
  - Station
  - Global Policies
  - Organizational Units

Chromeleon Administration Console (WIN-CMDC)

Report Show Changes From 7/ 1/2016 To 8/17/2017 Filtering Grouping

Date/Time	Operator	Additional Information	Computer Name
5/15/2017 11:16:22 AM +01:00	jsmith	The raw data file '2017/05/13/004740138.raw' failed an integrity check. It cannot be used.	WIN10-CM7
5/15/2017 11:16:35 AM +01:00	jsmith	The raw data file '2017/05/13/004740138.raw' failed an integrity check. It cannot be used.	WIN10-CM7
5/15/2017 11:16:39 AM +01:00	jsmith	The raw data file '2017/05/13/004740138.raw' failed an integrity check. It cannot be used.	WIN10-CM7
5/15/2017 11:16:41 AM +01:00	jsmith	The raw data file '2017/05/13/004740138.raw' failed an integrity check. It cannot be used.	WIN10-CM7

Chromeleon Administration Console (WIN-CMDC)

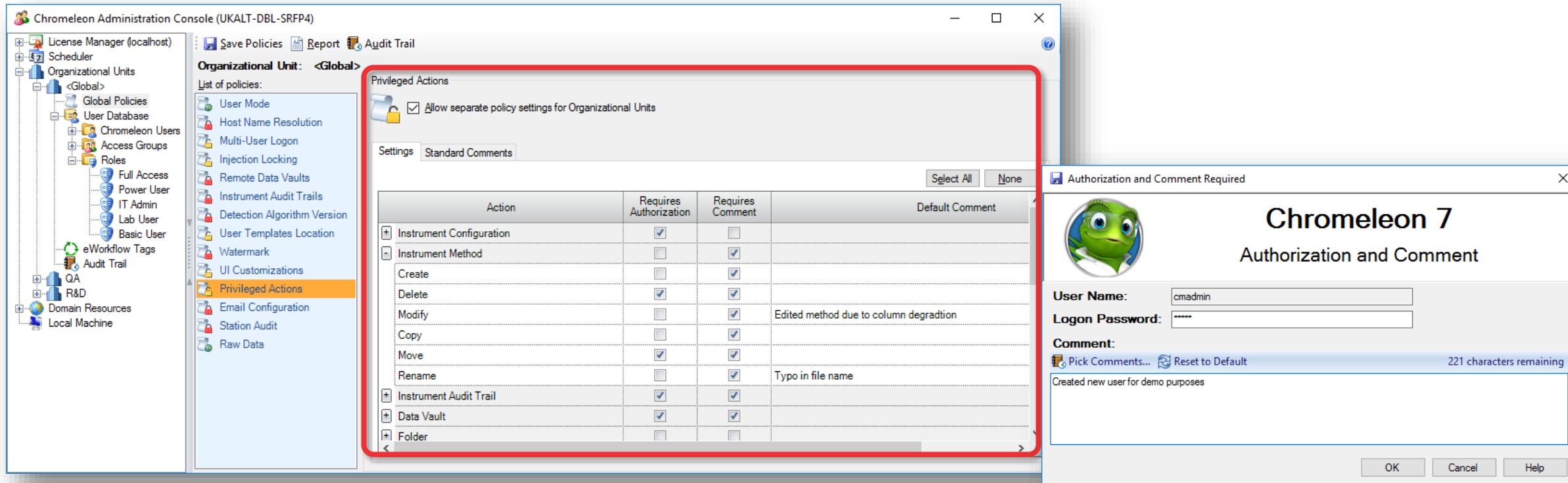
Report Show Changes From 8/15/2017 To 8/17/2017 Filtering Grouping

Date/Time	Operator	Operation	Computer Name	Category
8/16/2017 1:35:25 PM +01:00	jsmith	Changed User	WIN10-CM7	User Management
8/16/2017 1:12:20 PM +01:00	jmaxwell	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:13:10 PM +01:00	jmaxwell	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:17:11 PM +01:00	jmaxwell	Logoff	WIN10-CM7	Logon and Signature
8/16/2017 1:21:29 PM +01:00	jsmith	Logon Failed	WIN10-CM7	Logon and Signature
8/16/2017 1:21:50 PM +01:00	jsmith	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:35:39 PM +01:00	jmaxwell	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:35:55 PM +01:00	jmaxwell	Logoff	WIN10-CM7	Logon and Signature
8/16/2017 1:42:44 PM +01:00	charlie	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:43:59 PM +01:00	charlie	Logon	WIN10-CM7	Logon and Signature
8/16/2017 1:48:40 PM +01:00	inewton	Logon	WIN-CMDC	Logon and Signature
8/16/2017 8:54:56 AM -04:00	jsmith	Logon	WIN7-CM7	Logon and Signature
8/16/2017 8:56:21 AM -04:00	jsmith	Logoff	WIN7-CM7	Logon and Signature

Audit Trail

## Privileged Actions

- Require authorization for specified actions
- Ensure users add appropriate comments for specified actions – enforcing the “why?”
- Use standardized comments or free entry





## Version Comparison with Roll Back

- Show Changes
  - View two object versions side by side
  - Changes in objects easily identified by symbols
- Restore
  - In Data Audit Trail can roll back to previous object version
  - Restore is not permanent until saved
  - Save creates new version

Data Audit Trail - Demo Data\EN1948 to validate 7.2.9

Report Show Changes Restore Studio Include Subfolders

#	Name	Type	Version
1			
2			

Compare Instrument Method 'UltiMate3000' version 1 with version 2

Version	Date / Time	Operator	Client Computer
1	02/12/2009 13:02:38	SQuinn	L-GERSQUINN
2	02/12/2009 13:03:44	SQuinn	L-GERSQUINN

Property Name	Value version 1	Value version 2
Comment	UltiMate3000	UltiMate3000
Instrument Server	L-GERSQUINN	L-GERSQUINN
Instrument	05_UltiMate3000_1	05_UltiMate3000_1

Visualization Options: Complete

Time	Symbol	Value	Comment
Initial Time	Instrument Setup		
	Sampler.InjectMode	Normal	
	Sampler.PumpDevice	"Pump"	
	Sampler.SyncWithPump	On	
	Pump.MaximumFlowRampDown	1.000 [ml/min]	
	Pump.MaximumFlowRampUp	1.000 [ml/min]	
	Pump.%B.Equate	"Acetonitrile"	
	Pump.%C.Equate	"Methanol"	
	Pump.Pressure.LowerLimit	0 [bar]	
	Pump.Pressure.UpperLimit	400 [bar]	
	UV.UV_VIS_1.Wavelength	254.0 [nm]	
0.00	Inject Preparation		
0.00	Inject		
0.00	Start Run		
	UV.UV_VIS_1.AcqOn		
0.00	Flow	1.000 [ml/min]	
8.00	Pump.Flow	1.000 [ml/min]	
8.00	Stop Run		
	UV.UV_VIS_1.AcqOff		

Time	Symbol	Value	Comment
Initial Time	Instrument Setup		
	Sampler.InjectMode	Normal	
	Sampler.PumpDevice	"Pump"	
	Sampler.SyncWithPump	On	
	Pump.MaximumFlowRampDown	1.000 [ml/min]	
	Pump.MaximumFlowRampUp	1.000 [ml/min]	
	Pump.%A.Equate	"0.1M Phosphate Buffer"	
	Pump.Pressure.LowerLimit	0 [bar]	
	Pump.Pressure.UpperLimit	400 [bar]	
	Pump.%B.Equate	"Acetonitrile"	
	UV.UV_VIS_1.Wavelength	280.0 [nm]	
0.00	Inject Preparation		
0.00	Inject		
0.00	Start Run		
	UV.UV_VIS_1.AcqOn		
0.00	Run		
	Pump.Pump_Pressure.AcqOn		
0.00	Pump.Flow	2.000 [ml/min]	
8.00	Pump.Flow	2.000 [ml/min]	
	Stop Run		
	UV.UV_VIS_1.AcqOff		
	Pump.Pump_Pressure.AcqOff		

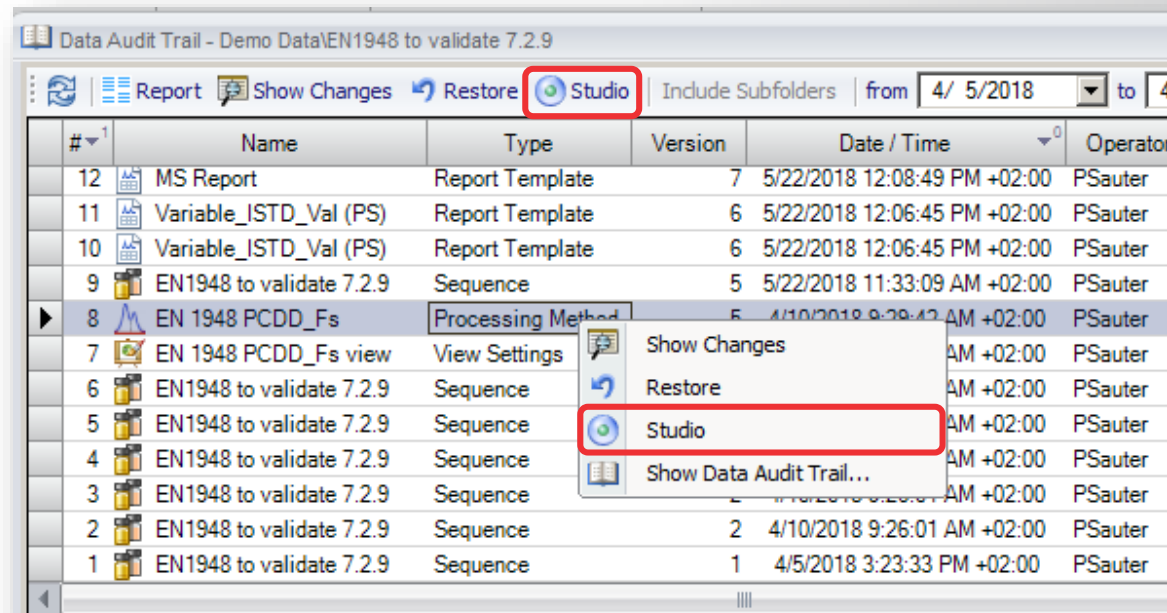
Change

Deletion

Addition

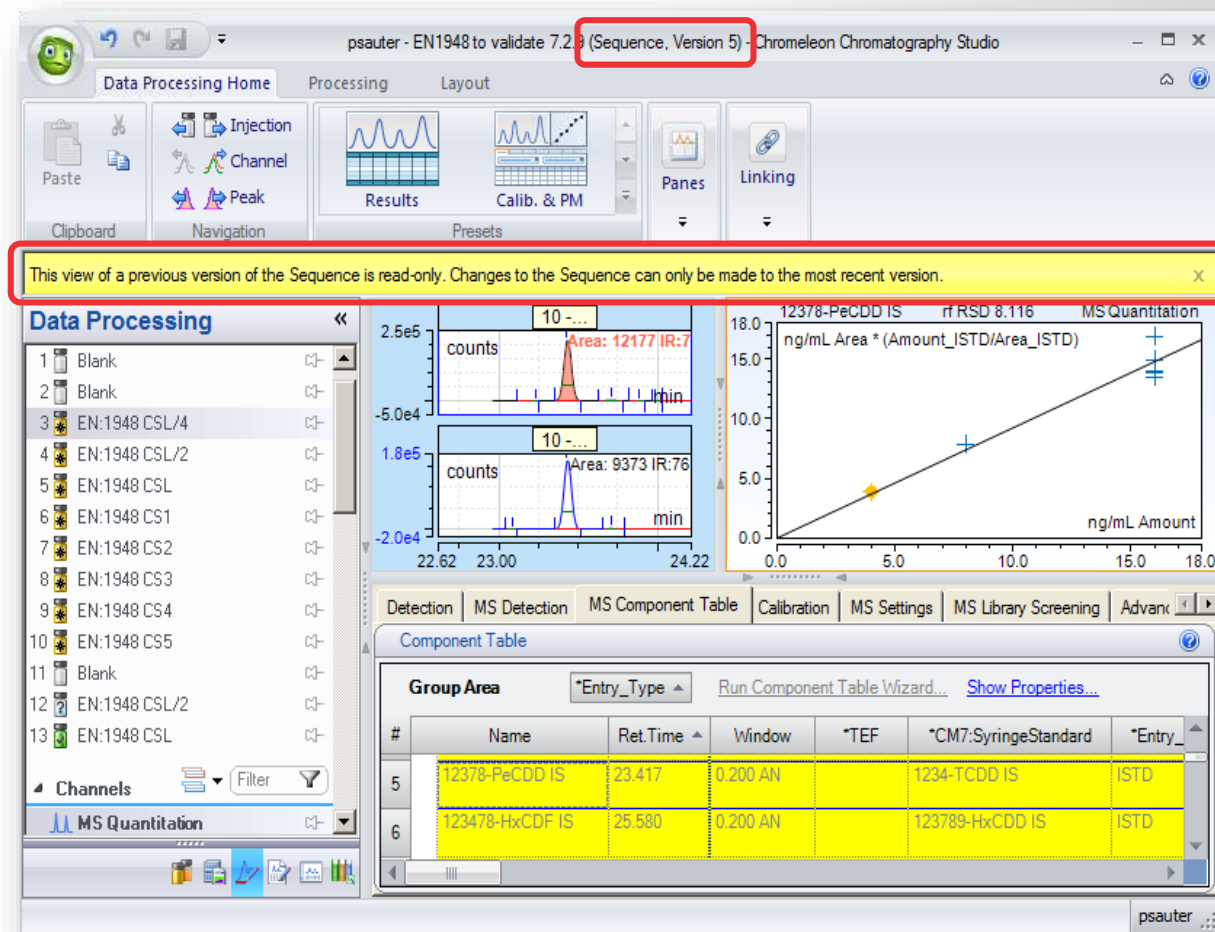
## Read-only Studio Viewer

- Studio
  - View object version in a read-only Chromatography Studio session
  - Selected item (e.g., injection, chromatogram, Processing Method, Instrument Method, Report Template, etc.) is automatically opened in a read-only Studio window

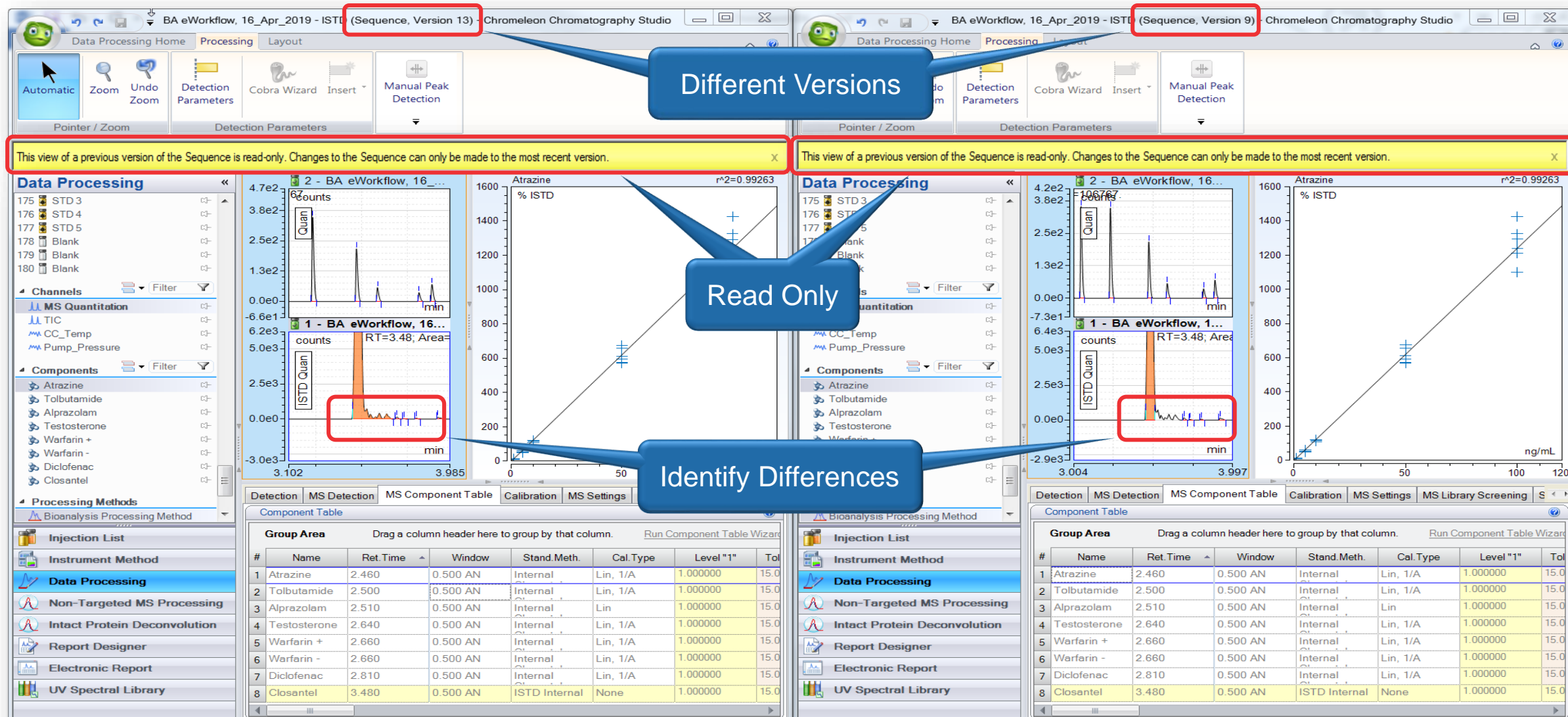


# Built for Data Integrity

- Selected version of sequence shown in caption
- Easy visual comparison of results
- All sequence objects are read-only except View Settings
  - View Settings can be changed but not saved
- Allows secure data review with zooming, changing panes, resizing, etc.



# Built for Data Integrity



- Open multiple read-only Studio sessions to compare different versions

- Compliant customers need to prove (regular) audit trail reviews
- Chromeleon 7.3 software provides framework
  - Configurable Audit Trail Events to highlight specific use cases
  - Connects Data, Instrument and Admin audit trails
  - Workflows to search and report Audit Trail Events





# Built for Data Integrity

- Audit Trail Events (ATE) configured in Admin Console (global policy)
- When new sequence created, ATE configuration is copied to sequence as read only. From that point, sequence defines which ATE are recorded and which not

Chromeleon Administration Console (DEGER-CMBETA)

License Manager (localhost) | Scheduler | Organizational Units

Organizational Units: <Global>

Global Policies

User Database

User Database Policies

Chromeleon Users

Access Groups

Roles

eWorkflow Tags

Audit Trail

Domain Resources

Local Machine

Save Policies | Report | Audit Trail

Organizational Unit: <Global>

List of policies:

- User Mode
- Host Name Resolution
- Multi-User Logon
- Injection Locking
- Remote Data Vaults
- Instrument Data
- Detection Algorithm Version
- User Templates Location
- Watermark
- UI Customizations
- Privileged Actions
- Email Configuration
- Station Audit
- License
- Raw Data
- Updater
- Audit Trail Events

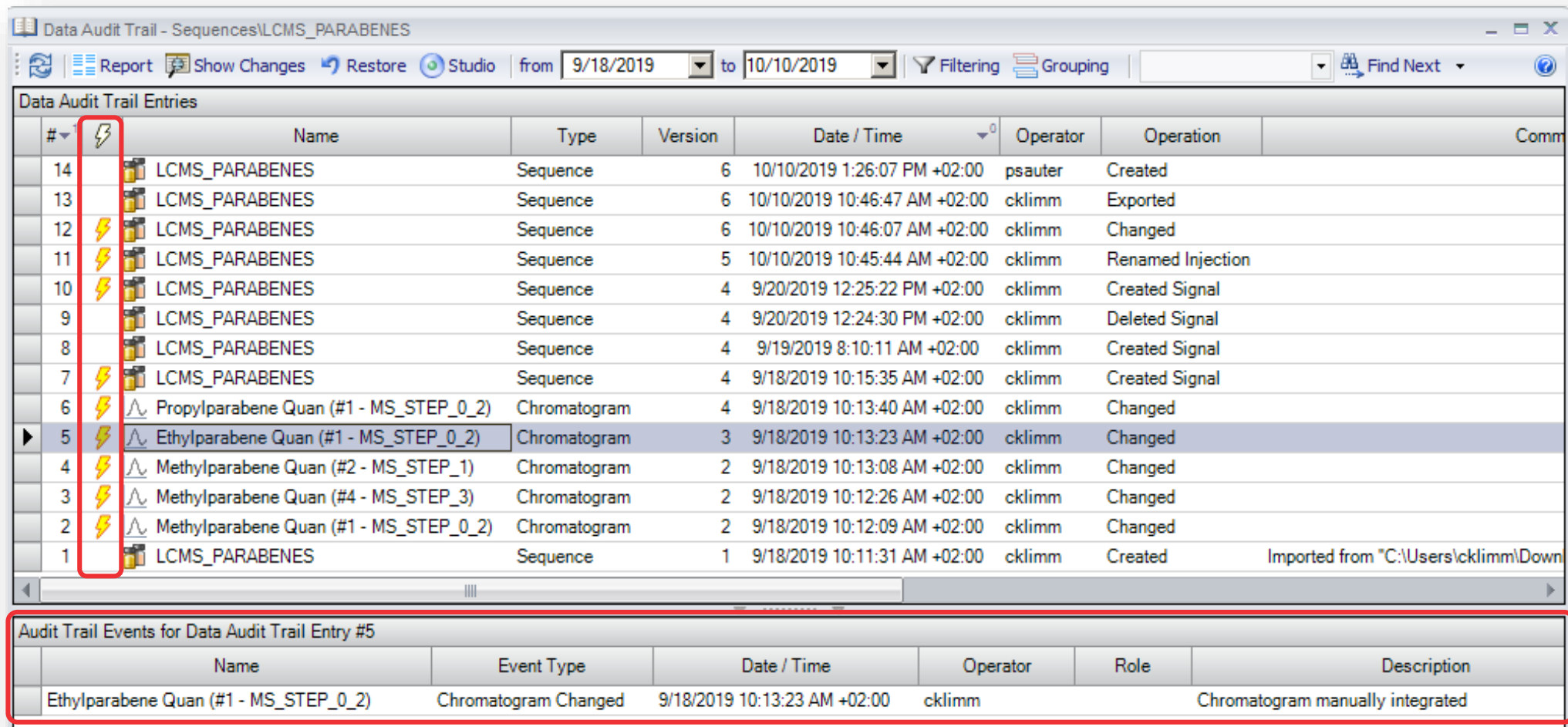
Audit Trail Events

☐ Allow separate policy settings for Organizational Units

Audit Trail Event	Description
<input checked="" type="checkbox"/> Ext. Report Template Changed	An external report template has been changed
<input checked="" type="checkbox"/> Ext. Spectral Library Changed	The external spectral libraries have been changed
<input checked="" type="checkbox"/> Manual Command Interference	A manual instrument command was executed while an injection was running
<input checked="" type="checkbox"/> Error During Injection Run	An instrument error occurred while an injection was running
<input checked="" type="checkbox"/> Processing Method Changed	A processing method has been changed
<input checked="" type="checkbox"/> Injection Changed	An injection has been changed
<input checked="" type="checkbox"/> Injection List Changed	An injection has been added or removed from the injection list
<input checked="" type="checkbox"/> Instrument Method Changed	An instrument method has been changed
<input checked="" type="checkbox"/> Report Template Changed	A report template has been changed
<input checked="" type="checkbox"/> Chromatogram Changed	A chromatogram has been changed manually

# Built for Data Integrity

- ATE recorded in Data Audit Trail of Sequence
- Every Data Audit Trail record may have one or more events



Data Audit Trail - Sequences\LCMS\_PARABENES

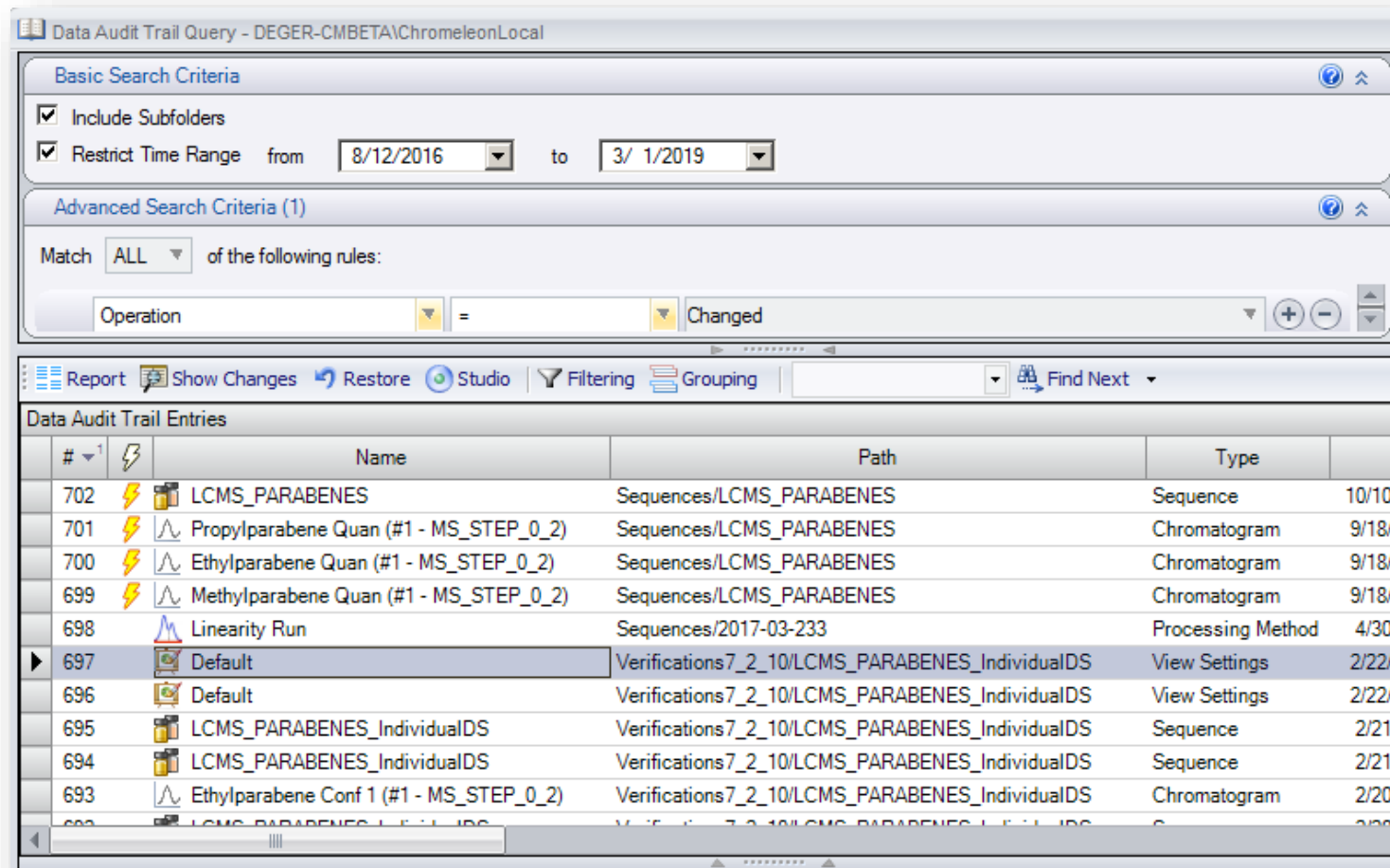
Report Show Changes Restore Studio from 9/18/2019 to 10/10/2019 Filtering Grouping Find Next

#	Name	Type	Version	Date / Time	Operator	Operation	Comm
14	LCMS_PARABENES	Sequence	6	10/10/2019 1:26:07 PM +02:00	psauter	Created	
13	LCMS_PARABENES	Sequence	6	10/10/2019 10:46:47 AM +02:00	cklimm	Exported	
12	LCMS_PARABENES	Sequence	6	10/10/2019 10:46:07 AM +02:00	cklimm	Changed	
11	LCMS_PARABENES	Sequence	5	10/10/2019 10:45:44 AM +02:00	cklimm	Renamed Injection	
10	LCMS_PARABENES	Sequence	4	9/20/2019 12:25:22 PM +02:00	cklimm	Created Signal	
9	LCMS_PARABENES	Sequence	4	9/20/2019 12:24:30 PM +02:00	cklimm	Deleted Signal	
8	LCMS_PARABENES	Sequence	4	9/19/2019 8:10:11 AM +02:00	cklimm	Created Signal	
7	LCMS_PARABENES	Sequence	4	9/18/2019 10:15:35 AM +02:00	cklimm	Created Signal	
6	Propylparabene Quan (#1 - MS_STEP_0_2)	Chromatogram	4	9/18/2019 10:13:40 AM +02:00	cklimm	Changed	
5	Ethylparabene Quan (#1 - MS_STEP_0_2)	Chromatogram	3	9/18/2019 10:13:23 AM +02:00	cklimm	Changed	
4	Methylparabene Quan (#2 - MS_STEP_1)	Chromatogram	2	9/18/2019 10:13:08 AM +02:00	cklimm	Changed	
3	Methylparabene Quan (#4 - MS_STEP_3)	Chromatogram	2	9/18/2019 10:12:26 AM +02:00	cklimm	Changed	
2	Methylparabene Quan (#1 - MS_STEP_0_2)	Chromatogram	2	9/18/2019 10:12:09 AM +02:00	cklimm	Changed	
1	LCMS_PARABENES	Sequence	1	9/18/2019 10:11:31 AM +02:00	cklimm	Created	Imported from "C:\Users\cklimm\Down

Audit Trail Events for Data Audit Trail Entry #5

Name	Event Type	Date / Time	Operator	Role	Description
Ethylparabene Quan (#1 - MS_STEP_0_2)	Chromatogram Changed	9/18/2019 10:13:23 AM +02:00	cklimm		Chromatogram manually integrated


- Audit Trail Query capability
- Executed via database Query
  - Faster than normal Query
- Will also search for ATE





- Two report tables
  - Configured ATE in sequence – shows which ATE were configured or not
  - Recorded ATE in sequence – shows which events did and did not occur
    - Option to show details of changes – old and new values
- Can be embedded in printouts / electronic reports


Audit Trail Events				
Sequence Details				
Name:	2020-02-11 13-55-31 Alkylphenone Linearity	Created On:	11-Feb-20 13:55:32	
Directory:	Data\2020\02_Feb	Created By:	barbara.van.cann	
Data Vault:	ChromeleonLocal	Updated On:	11-Feb-20 14:06:38	
No. of Injections:	21	Updated By:	barbara.van.cann	
Name	Event Type	Date/Time	Operator	Description
Sample 22 (#22)	Injection List Changed	11-Feb-20 1:58:30 PM +01:00	barbara.van.cann	The injection list has been changed
Sample 23 (#23)	Injection List Changed	11-Feb-20 1:58:30 PM +01:00	barbara.van.cann	The injection list has been changed
Sample 24 (#24)	Injection List Changed	11-Feb-20 1:58:30 PM +01:00	barbara.van.cann	The injection list has been changed
Sample 25 (#25)	Injection List Changed	11-Feb-20 1:58:30 PM +01:00	barbara.van.cann	The injection list has been changed
Sample 26 (#26)	Injection List Changed	11-Feb-20 1:58:30 PM +01:00	barbara.van.cann	The injection list has been changed
Linearity 2 (#7)	Injection List Changed	11-Feb-20 1:58:53 PM +01:00	barbara.van.cann	The injection list has been changed
2020-02-11 13-55-31 Alkylphenone	Additional Sequence Start	11-Feb-20 1:58:55 PM +01:00	barbara.van.cann	Additional start of sequence detected (#2). Previous sequence start was 3 minutes 17 seconds ago.
Linearity 2 (#7)	Injection List Changed	11-Feb-20 2:06:14 PM +01:00	barbara.van.cann	The injection list has been changed
UV_VIS_1 (#14 - Linearity 5)	Chromatogram Changed	11-Feb-20 2:06:38 PM +01:00	barbara.van.cann	Chromatogram manually integrated

Status and Audit

Audit Trail Table

Data Audit Trail Table

Audit Trail Events Table

Audit Trail Event Conf...



Built for Compliance  
Built for Data Integrity  
**Without compromise**



# Chromeleon CDS – Making Compliance Easier

## Technical Controls



### Comprehensive set of tools

Easy, centralized administration  
User Management with reduced admin settings  
Electronic Reports and Signatures

## Monitoring Adherence



### Effective monitoring to enhance behavior

Easy data review with sequence-centered structure  
Injection & audit trail queries to detect potential issues  
Login & logout auditing

## Demonstration of Compliance



### Easy demonstration of compliance during audits

Audit trails with Query  
Version comparison  
Audit Trail Events  
Advanced reporting tools

**Chromeleon CDS Delivers Ease of Compliance**

and Chromeleon CDS has passed 1000's of regulatory audits

For more information on Chromeleon CDS software visit:

[thermofisher.com/chromeleon](http://thermofisher.com/chromeleon)

Like Charlie Chromeleon on Facebook to follow his travels and get important updates on chromatography software!



[Facebook.com/CharlieLovesChromatography](https://Facebook.com/CharlieLovesChromatography)

Join the LinkedIn customer forum to discuss Chromeleon CDS with us and your industry peers.



[Chromeleon CDS User Group](#)

# Thank You!



Built for **Compliance.**

Built for **Data Integrity.**

Why compromise?

Chromeleon 7.3 CDS