



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)



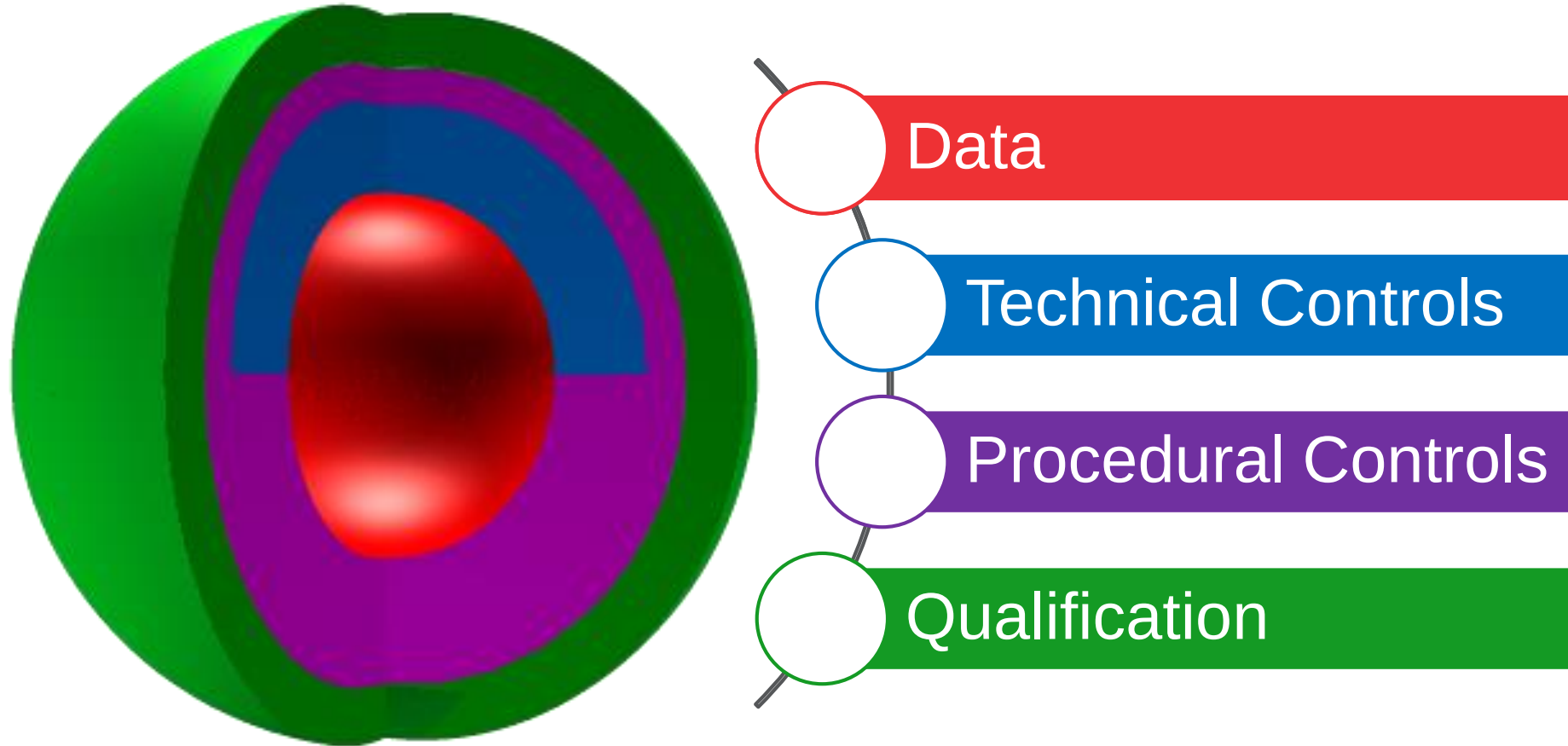
Built for **Compliance**

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Built for Compliance

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

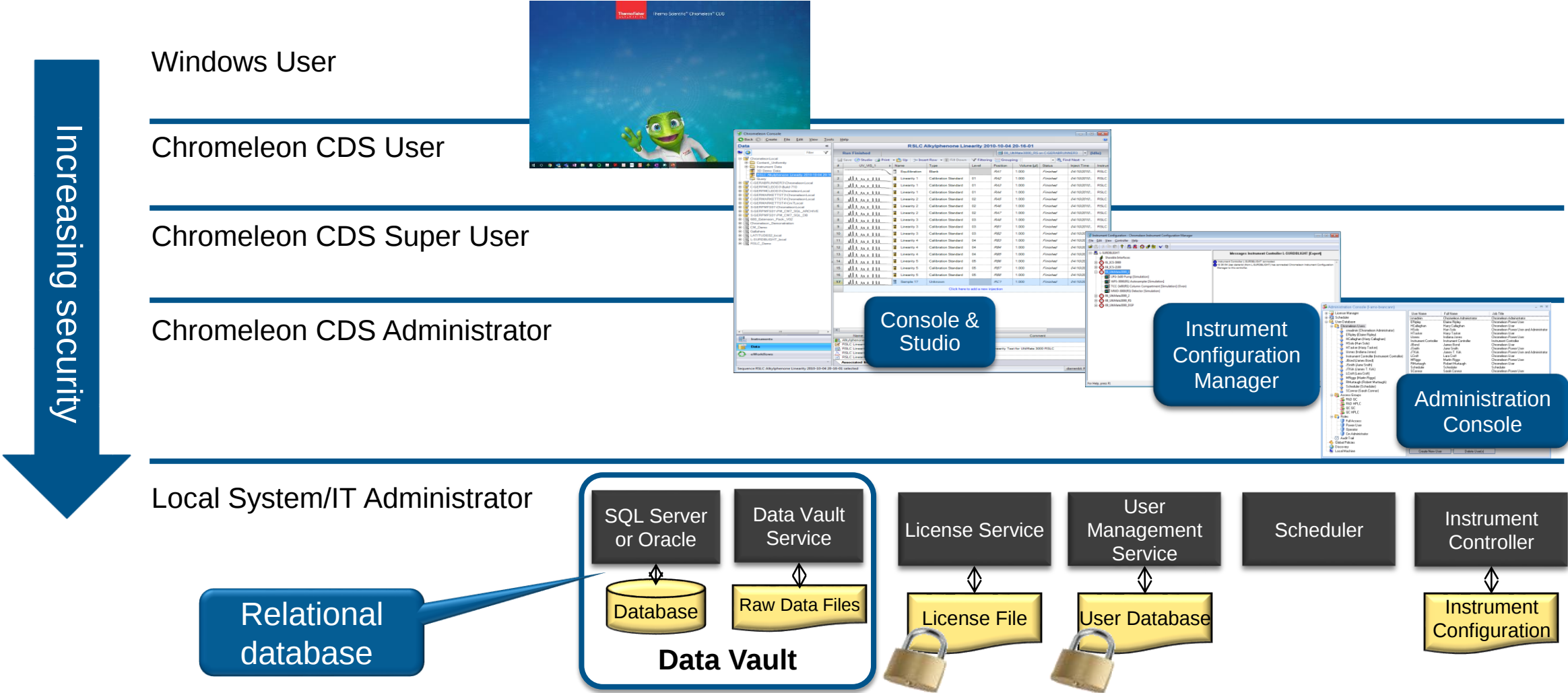


Built for Compliance

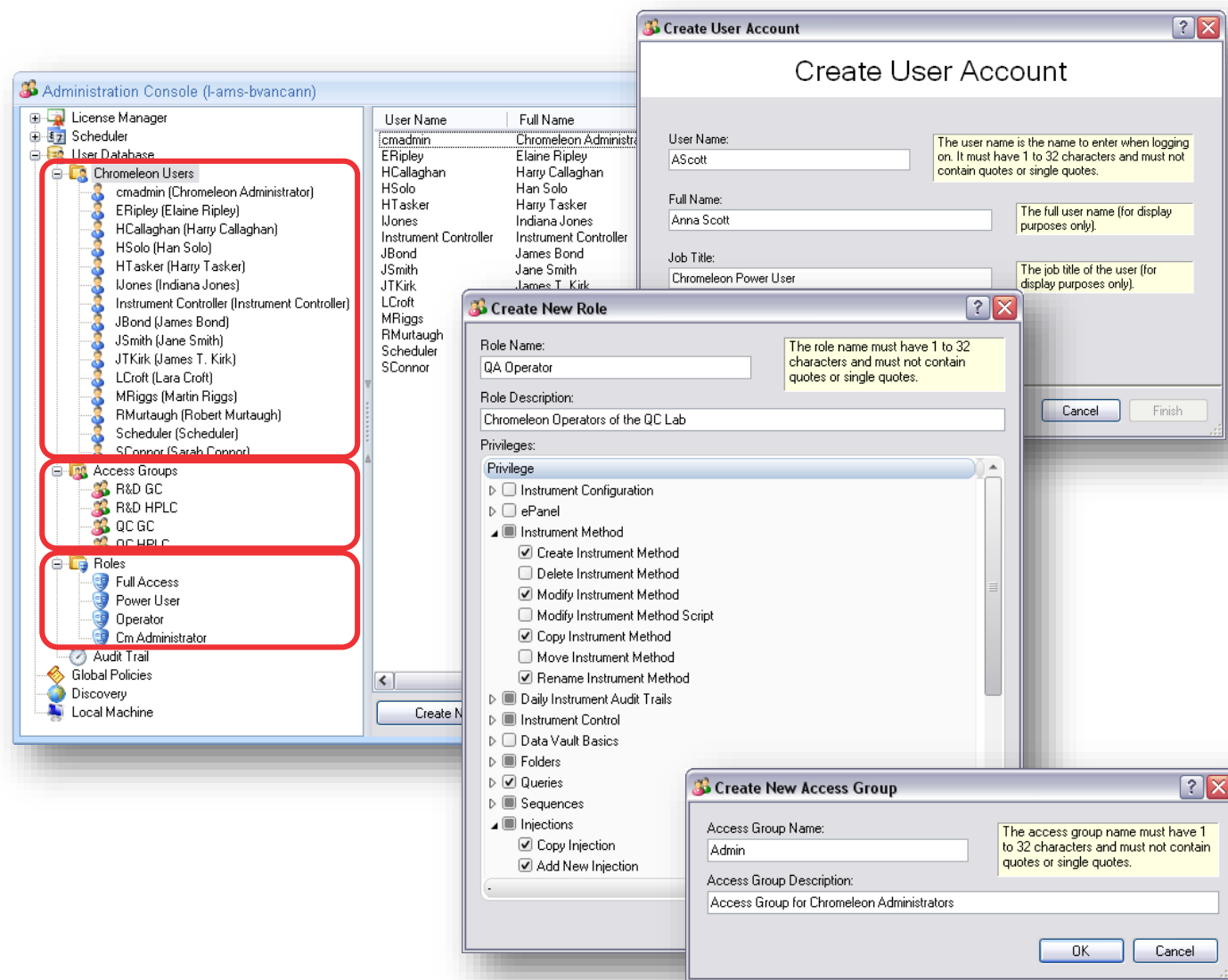
- Software must be capable of 21 CFR Part 11 compliance
- Compliance can be considered in four categories:
 - **Security**
 - Access control and data security
 - **Record Management**
 - All data stored, controlled and archived
 - **Audit Trails**
 - Traceability of all actions in CDS
 - No loss of productivity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



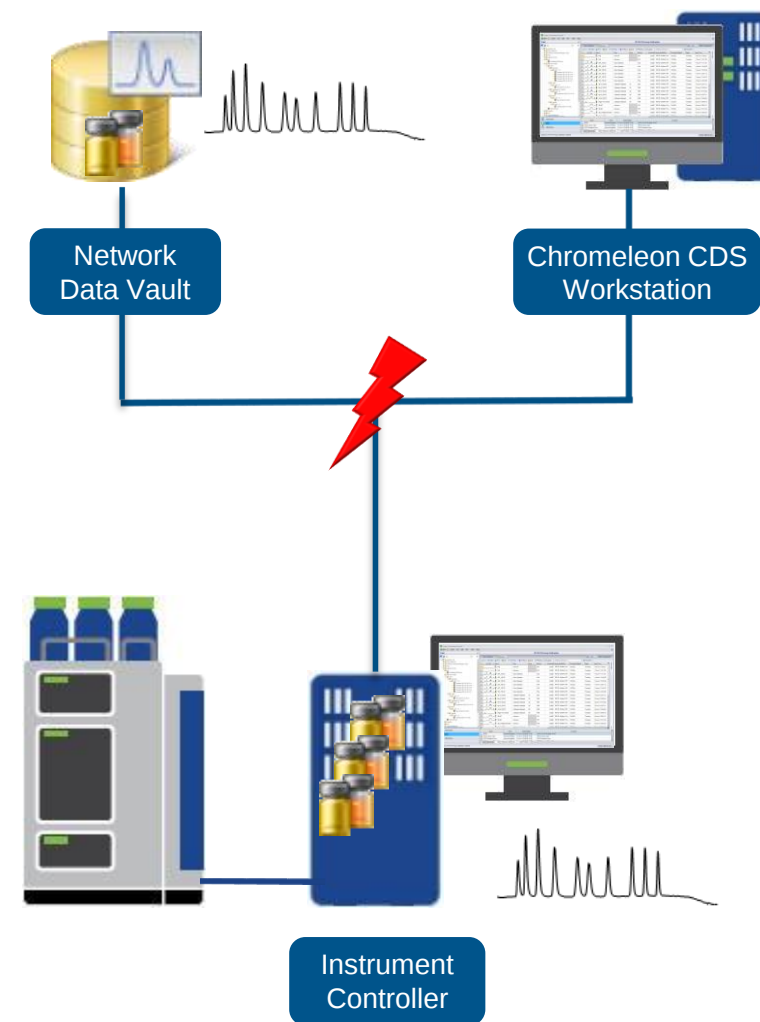
- Multiple levels of access security



- 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'. The 'Anions' folder is expanded, showing '20130311 Water Analysis' and 'AS12A Calibration and Samples'. A blue callout box with the text 'Flexible folder structure' points to this hierarchy.

The main pane shows a table titled '20130311 Water Analysis'. The table has columns: '#', 'ECD_1', 'Name', 'Type', 'Level', 'Position', 'Volume [µl]', '#Amount [mg/L] Chloride [ECD_1]', '#Chloride Amount Test [ECD_1]', and 'Processing Me'. The table contains 10 rows of data, including calibration standards and various water samples. The status of the tests is indicated in the 'Processing Me' column.

#	ECD_1	Name	Type	Level	Position	Volume [µl]	#Amount [mg/L] Chloride [ECD_1]	#Chloride Amount Test [ECD_1]	Processing Me
1		Seven Anion Standard II - 1	Calibration Standard	01	RA1	25.0	9.141	Not Executed	AS12A Anions
2		Seven Anion Standard II - 2	Calibration Standard	02	RA2	25.0	19.639	Not Executed	AS12A Anions
3		Seven Anion Standard II - 3	Calibration Standard	03	RA3	25.0	40.610	Not Executed	AS12A Anions
4		Seven Anion Standard II - 4	Calibration Standard	04	RA4	25.0	59.798	Not Executed	AS12A Anions
5		Seven Anion Standard II - 5	Calibration Standard	05	RA5	25.0	12.887	Not Executed	AS12A Anions
6		Seven Anion Standard II - 6	Calibration Standard	06	RB1	25.0	n.a.	Not Executed	AS12A Anions
7		Drinking Water	Unknown		RB2	25.0	0.018	Passed	AS12A Anions
8		Tap Water	Unknown		RB3	25.0		Failed	AS12A Anions
9		Power Coolant Water	Unknown		RB4	25.0		NA -> Passed	AS12A Anions
10		Power Coolant Water	Unknown		RB4	25.0		Passed	AS12A Anions

At the bottom of the interface, there is a section for 'Associated Items' which lists various items like 'Anions in Water', 'AS12A Anions in Water', and 'Instrument Method Anions in Water on AS12A column'.

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 is titled 'CmServiceAMS - RSLC Alkylphenone Linearity 2013-10-11 10:21:53 (Sequence) - Chromeleon Chromatogram...'. The 'Electronic Report' window is open, showing a list of injections and a chromatogram. The 'Submit Signature' dialog box is overlaid on the report, prompting the user to enter their username and signature password. The dialog box includes fields for 'User Name', 'Signature Password', and 'Comment'. The 'User Name' field is populated with 'CmServiceAMS'. The 'Signature Password' field is masked with asterisks. The 'Comment' field contains the text 'Submitting sequence'. The 'Submit' button is highlighted with a red box in the main window's toolbar.

Electronic Report

Chromatogram and Results

Injection Details

Injection Name	Injection Number	Injection Volume	Injection Date	Injection Time	Injection Status
Linearity 1	1	1.00	2013-10-11 10:21:53	10:21:53	Success
Linearity 2	2	1.00	2013-10-11 10:21:53	10:21:53	Success
Linearity 3	3	1.00	2013-10-11 10:21:53	10:21:53	Success

Submit Signature

User Name: CmServiceAMS

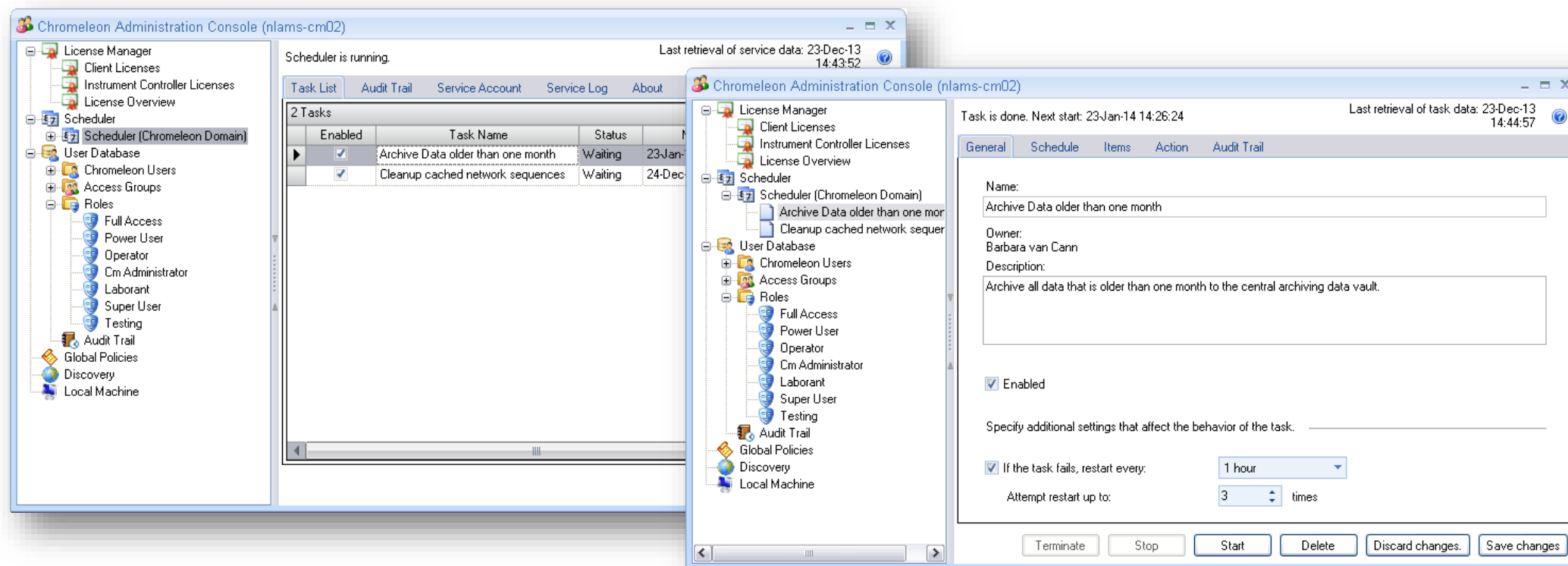
Signature Password: [Masked]

Comment: Submitting sequence

OK Cancel Help

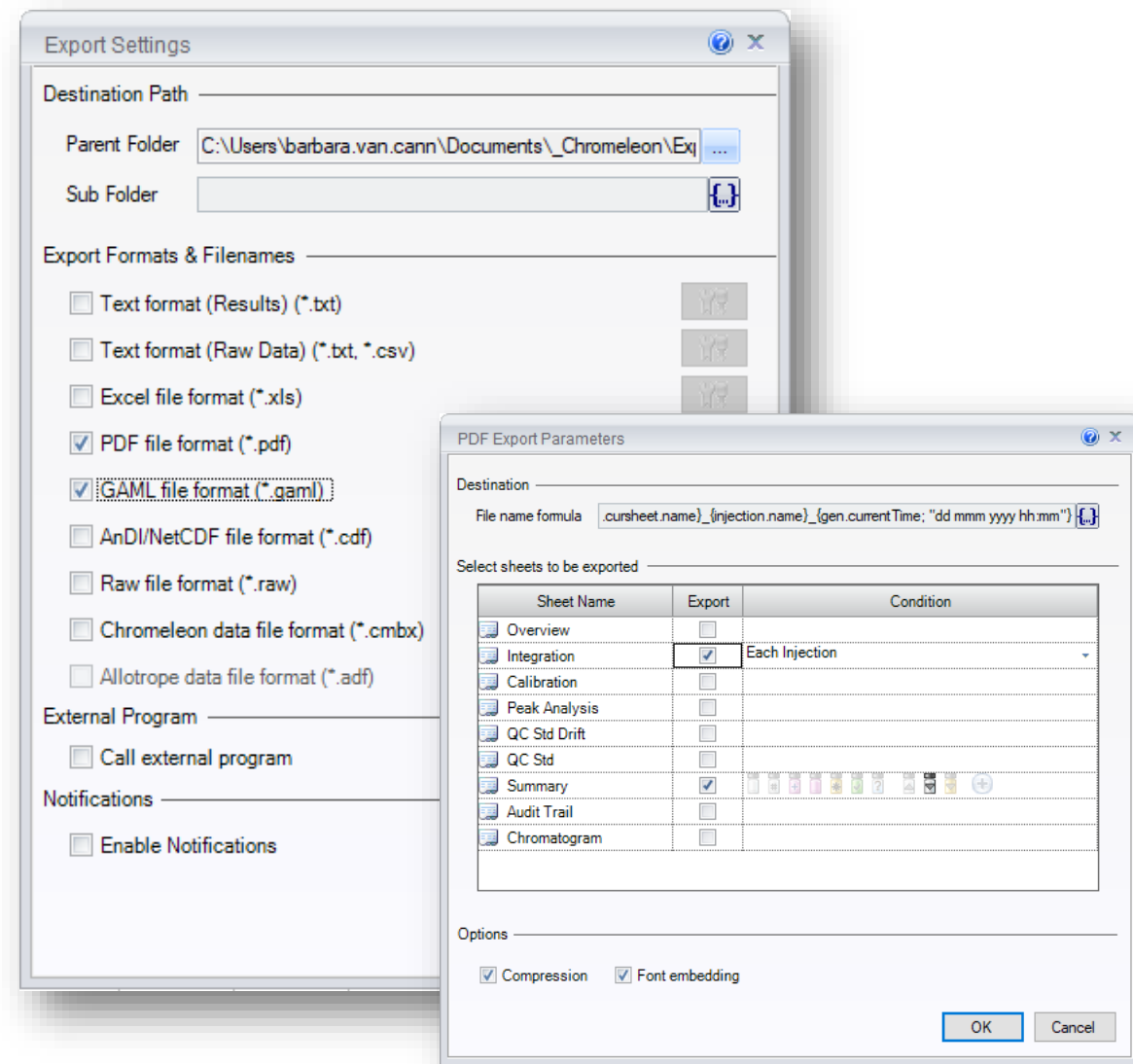
Scheduler for Automatic Archiving

- 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



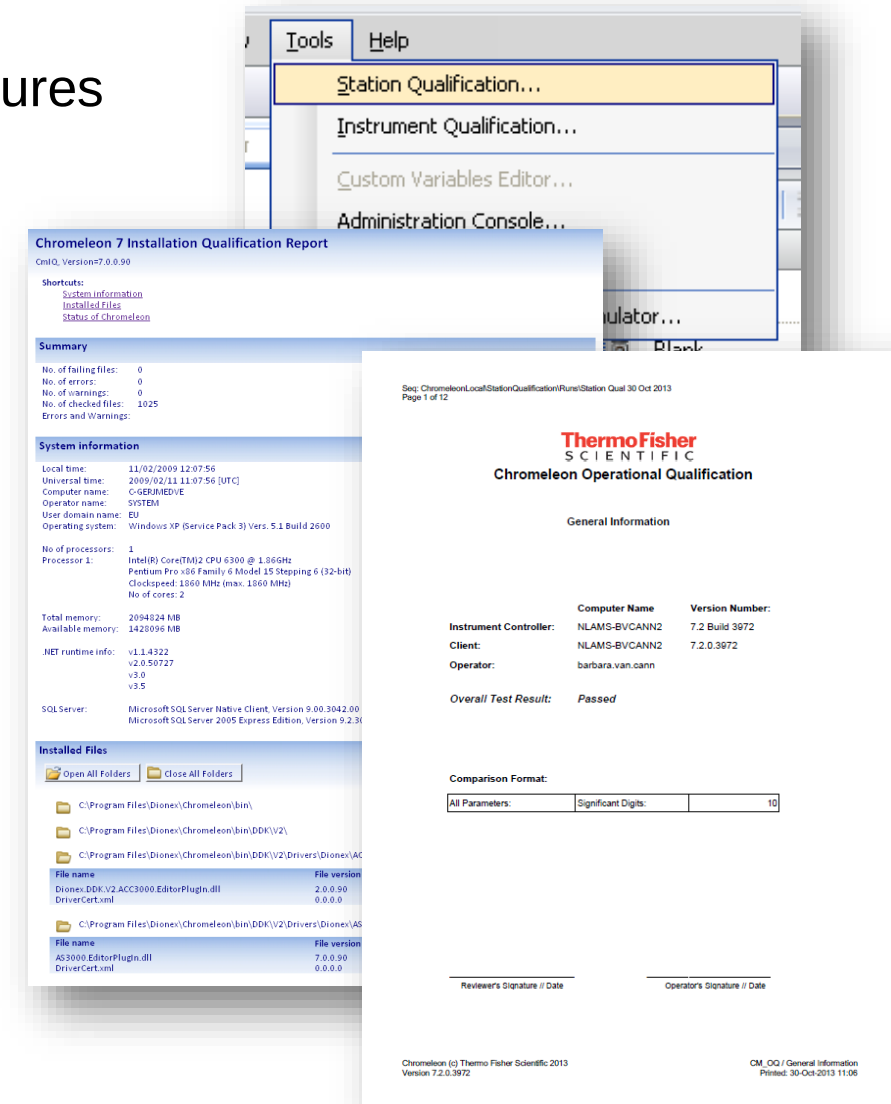
“QUALITY IS NOT AN ACT; IT IS A HABIT.”
— Aristotle

• Deliverables

	Type	Responsibility		
• IQ plan, test scripts, report • Functional Requirement Specifications • System Configuration Document • Project Plan • Validation Plan • OQ plan, test scripts (i.e. val kit), report • User Requirement Specification • PQ plan, tests, report • Traceability Matrix • Validation Report	- Qualification - Validation - Validation - Validation - Validation - Qualification - Validation - Qualification - Validation - Validation	Customer Supplier	✓ ✓ ✓	✓ ✓ ✓ ✓ ✓

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

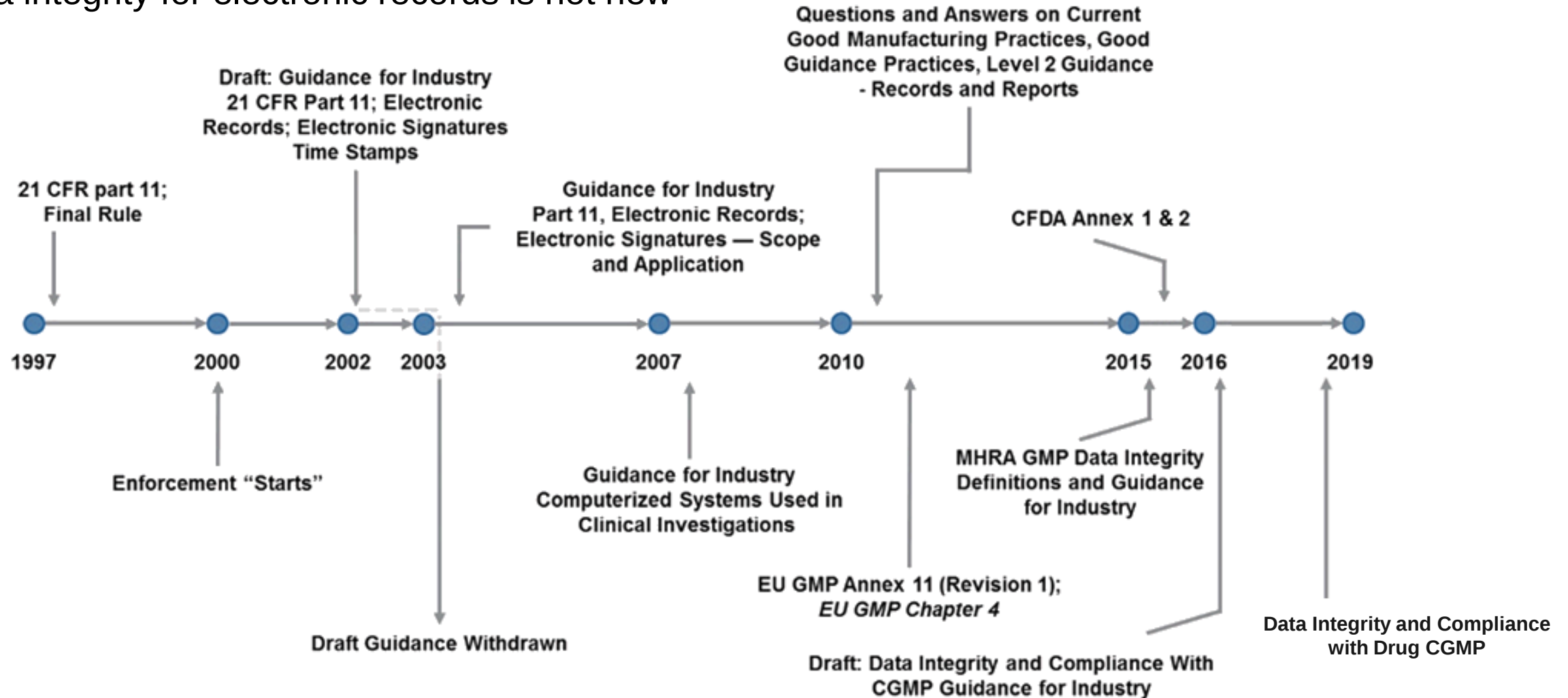
- Recorded in enduring media throughout lifecycle



Available

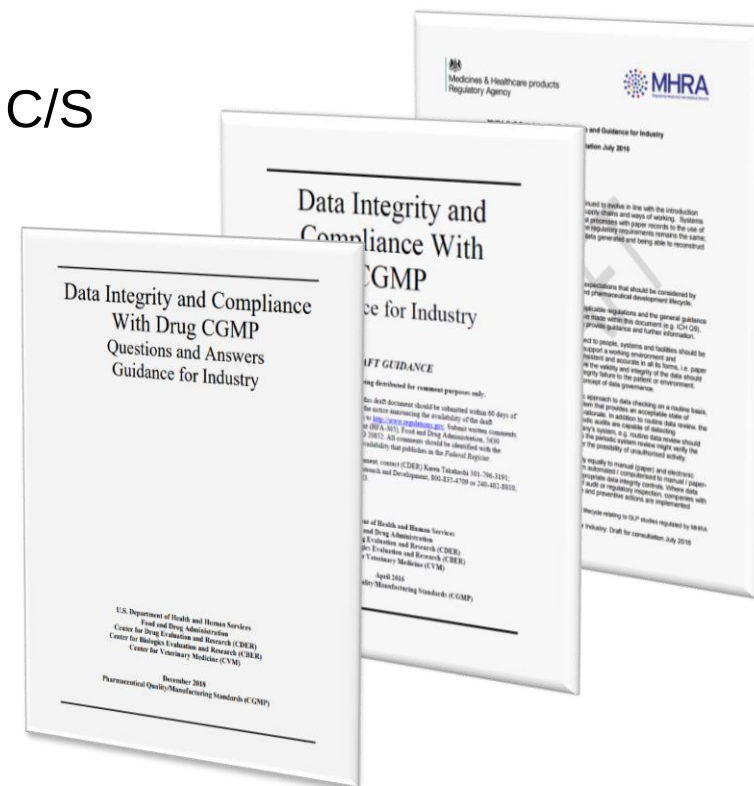
- Accessible for review/audit throughout lifecycle

- 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



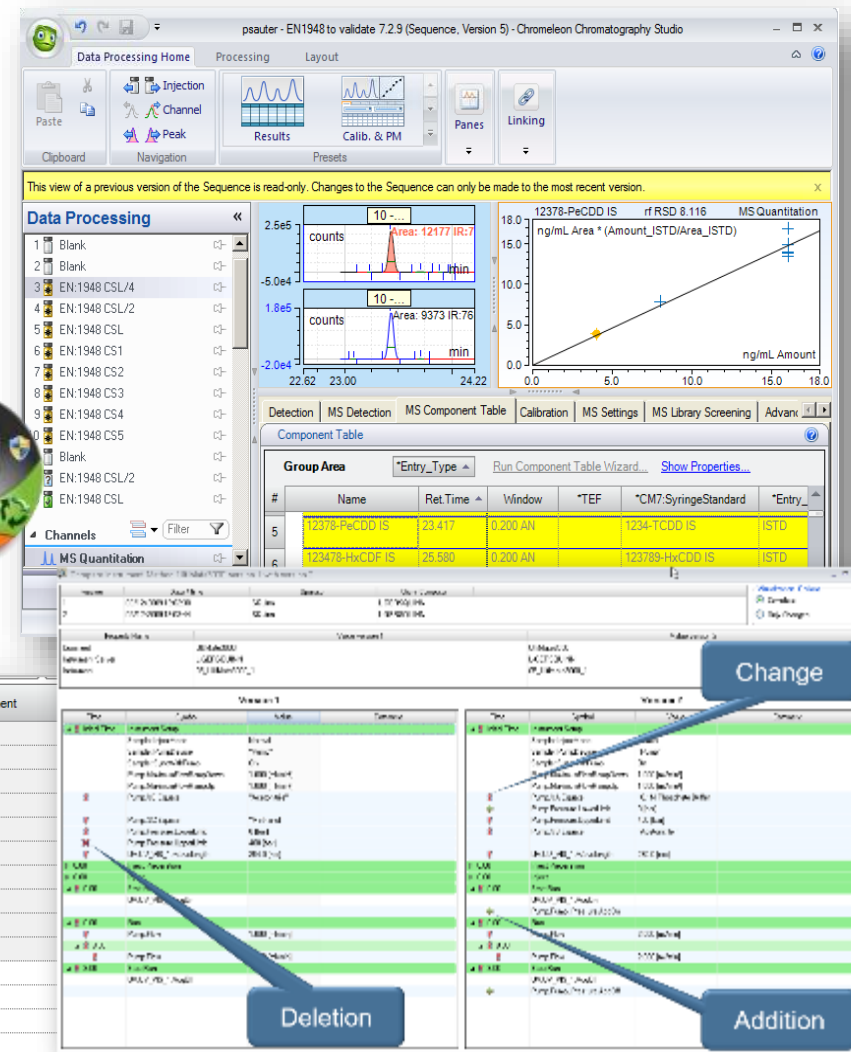
Privileged Actions

Action	Requires Authorization	Requires Comment	Default Comment
Instrument Configuration	☐	☒	
Instrument Method	☐	☒	
Instrument Audit Trail	☐	☒	
Data Vault	☐	☒	
Folder	☐	☒	
Query	☐	☒	
Sequence	☐	☒	
Injection	☐	☒	
Manual Data Processing	☒	☒	
eWorkflow	☐	☒	
Create	☐	☒	created eWorkflow
Modify	☐	☒	
Rename	☐	☒	
Delete	☐	☒	

Change

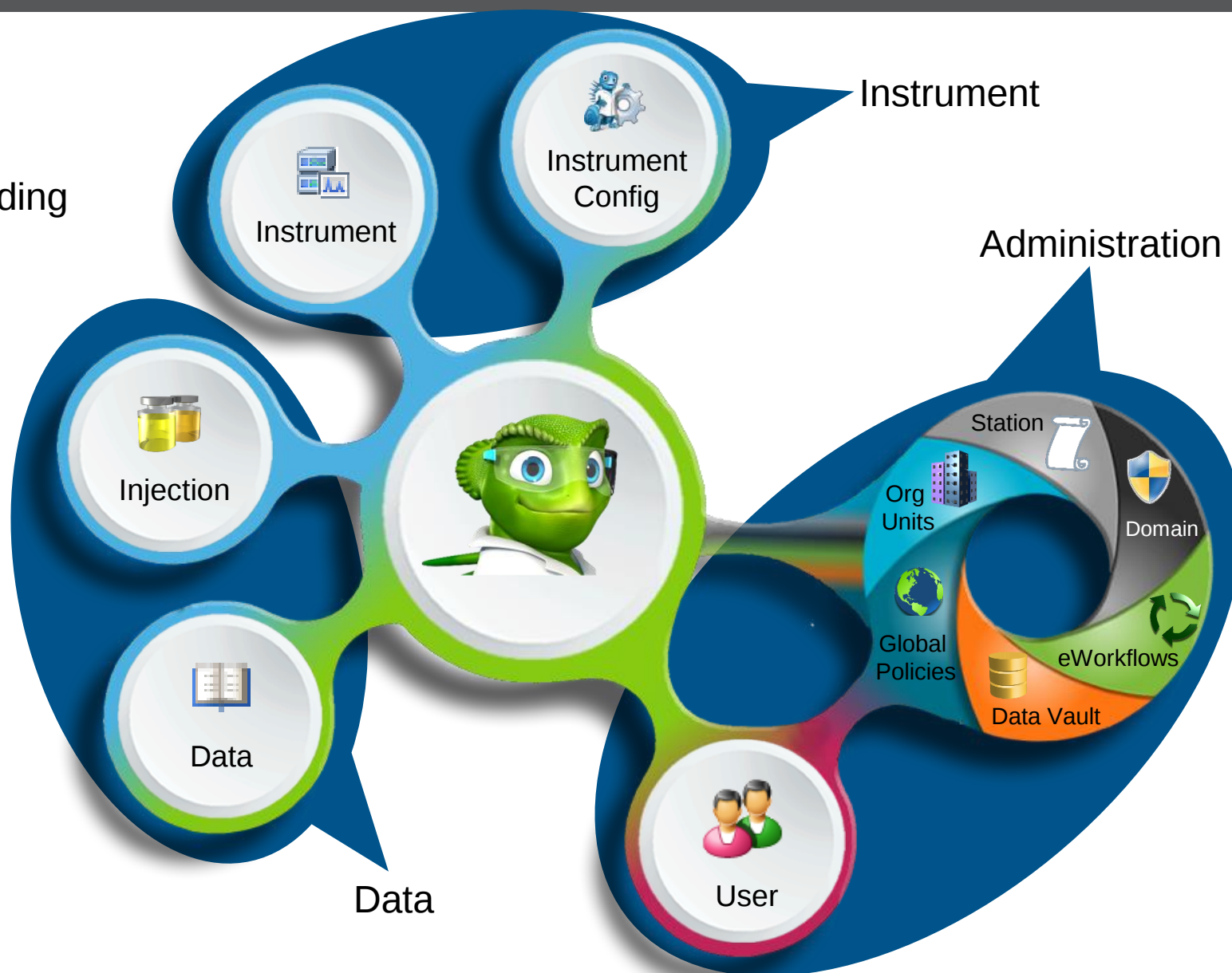
Deletion

Addition



- Audit Trails

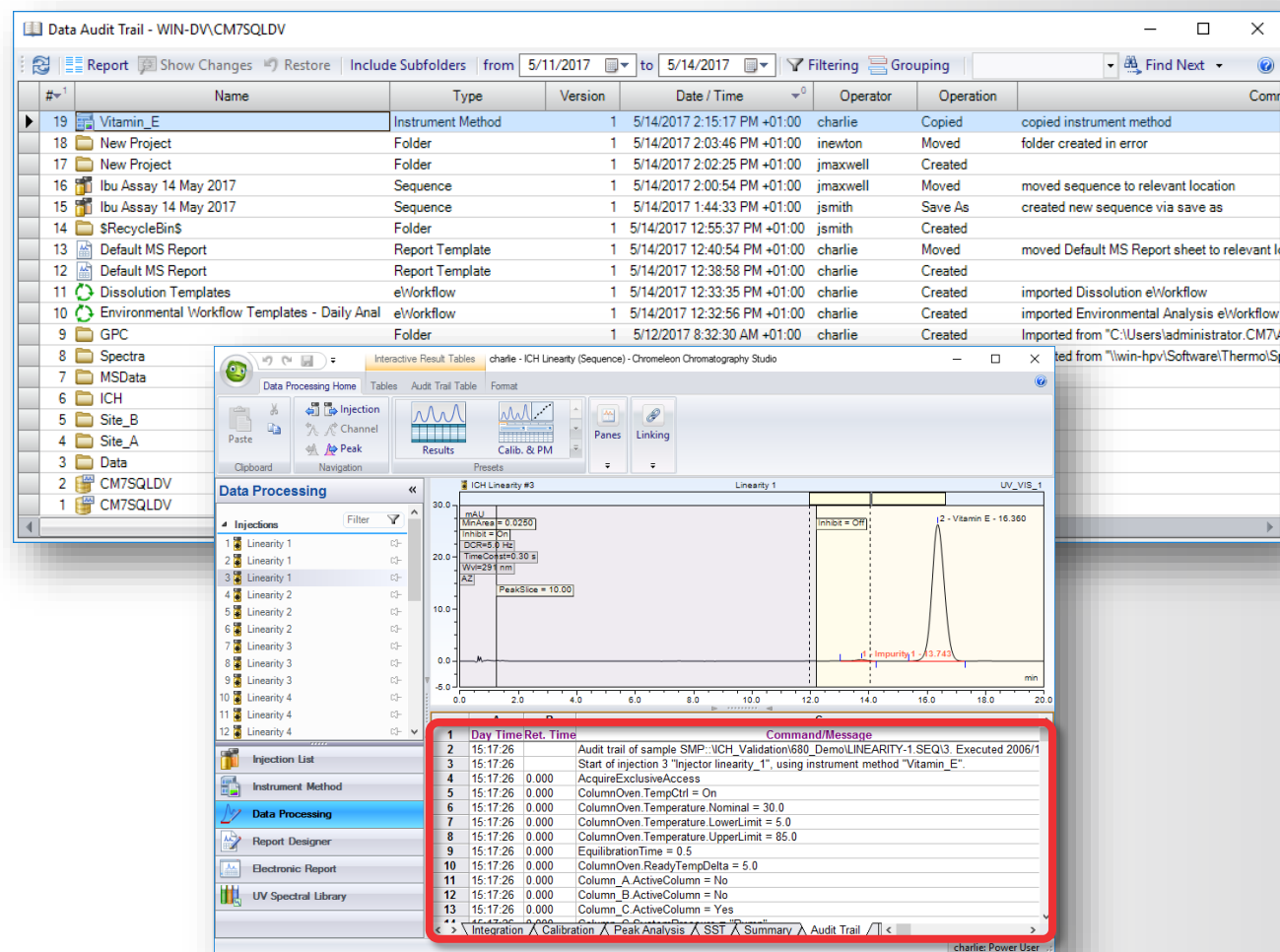
- Chromeleon CDS provides industry-leading audit trails
- 11 audit trailed areas
- 3 main audit trails
 - Instrument
 - Data
 - Administration
- All audit trails can be stored and managed centrally in Chromeleon CDS



- Audit Trails
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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 three overlapping windows from the ThermoFisher Scientific software interface.

Top Window: Changes for category 'Instrument Configuration' and host 'WIN10-CM7'

Date/Time	Operator	Operation	Comment
5/12/2017 1:31:30 PM +01:00	charlie	Changed	

Left Window: Instrument Configuration Tree

- WIN10-CM7
 - 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
 - Pump_Pressure

Right Window: Audit Trail

	Date	Time	Retention Time	Device	Message
1	5/14/2017	11:16:00 AM +01:00			User charlie (from WIN10-CM7) has connected Chromeleon Instrument Configuration Manager to this controller.
2	5/14/2017	11:14:50 AM +01:00			User charlie has disconnected Chromeleon Instrument Configuration Manager from this controller.
3	5/13/2017	10:55:50 AM +01:00			User charlie (from WIN10-CM7) has connected Chromeleon Instrument Configuration Manager to this controller.
4	5/13/2017	12:49:34 AM +01:00			Finished the sequence queue run.
5	5/13/2017	12:49:33 AM +01:00			Preparing the start of the next pending sequence (if there is any).
6	5/13/2017	12:49:33 AM +01:00			End of sequence "PQ_STOP".
7	5/13/2017	12:49:31 AM +01:00		UV	Vanquish Diode Array Detector @ USB -12345678 - V#D10-A - Serial # 12345678 - Firmware Version 0.00.01
8	5/13/2017	12:49:31 AM +01:00		UV	UV Lamp on.
9	5/13/2017	12:49:31 AM +01:00			End of injection "Restore".
10	5/13/2017	12:49:31 AM +01:00	1.000	UV	UV SetFactoryDefaults
11	5/13/2017	12:48:31 AM +01:00	0.000		Entered stage "Run"
12	5/13/2017	12:48:31 AM +01:00	0.000	SamplerModule Sampler	Inject command ignored, because the injection is a blank run.
	5/13/2017	12:48:31 AM +01:00	0.000	SamplerModule Sampler	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)

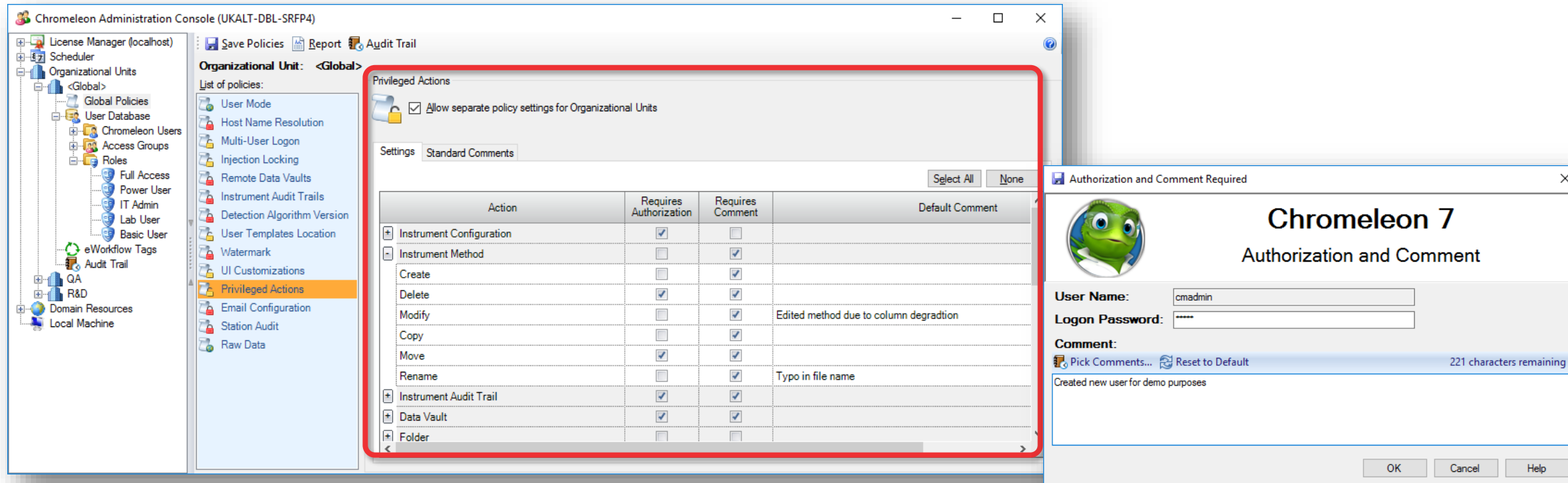
Report Show Changes From 8/15/2017 To 8/17/2017 Filtering Grouping

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

Version 1				Version 2			
Time	Symbol	Value	Comment	Time	Symbol	Value	Comment
Initial Time	Instrument Setup			Initial Time	Instrument Setup		
	Sampler.InjectMode	Normal			Sampler.InjectMode	Normal	
	Sampler.PumpDevice	"Pump"			Sampler.PumpDevice	"Pump"	
	Sampler.SyncWithPump	On			Sampler.SyncWithPump	On	
	Pump.MaximumFlowRampDown	1.000 [ml/min]			Pump.MaximumFlowRampDown	1.000 [ml/min]	
	Pump.MaximumFlowRampUp	1.000 [ml/min]			Pump.MaximumFlowRampUp	1.000 [ml/min]	
	Pump.%B.Equate	"Acetonitrile"			Pump.%A.Equate	"0.1M Phosphate Buffer"	
	Pump.%C.Equate	"Methanol"			Pump.Pressure.LowerLimit	0 [bar]	
	Pump.Pressure.LowerLimit	0 [bar]			Pump.Pressure.UpperLimit	400 [bar]	
	Pump.Pressure.UpperLimit	400 [bar]			Pump.%B.Equate	"Acetonitrile"	
	UV.UV_VIS_1.Wavelength	254.0 [nm]			UV.UV_VIS_1.Wavelength	280.0 [nm]	
0.00	Inject Preparation			0.00	Inject Preparation		
0.00	Inject			0.00	Inject		
0.00	Start Run			0.00	Start Run		
	UV.UV_VIS_1.AcqOn				UV.UV_VIS_1.AcqOn		
0.00	Run			0.00	Run		
	Pump.Flow	1.000 [ml/min]			Pump.Flow	2.000 [ml/min]	
8.00	Stop Run			8.00	Stop Run		
	Pump.Flow	1.000 [ml/min]			Pump.Flow	2.000 [ml/min]	
8.00	Stop Run			8.00	Stop Run		
	UV.UV_VIS_1.AcqOff				UV.UV_VIS_1.AcqOff		
	Pump.Pump_Pressure.AcqOff				Pump.Pump_Pressure.AcqOff		

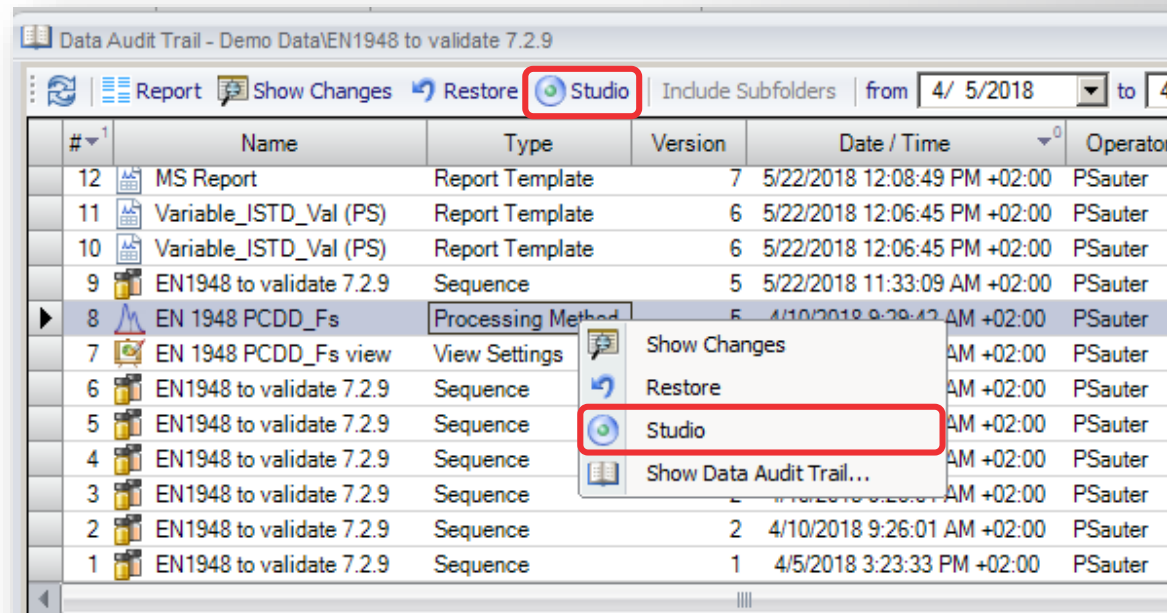
Change

Deletion

Addition

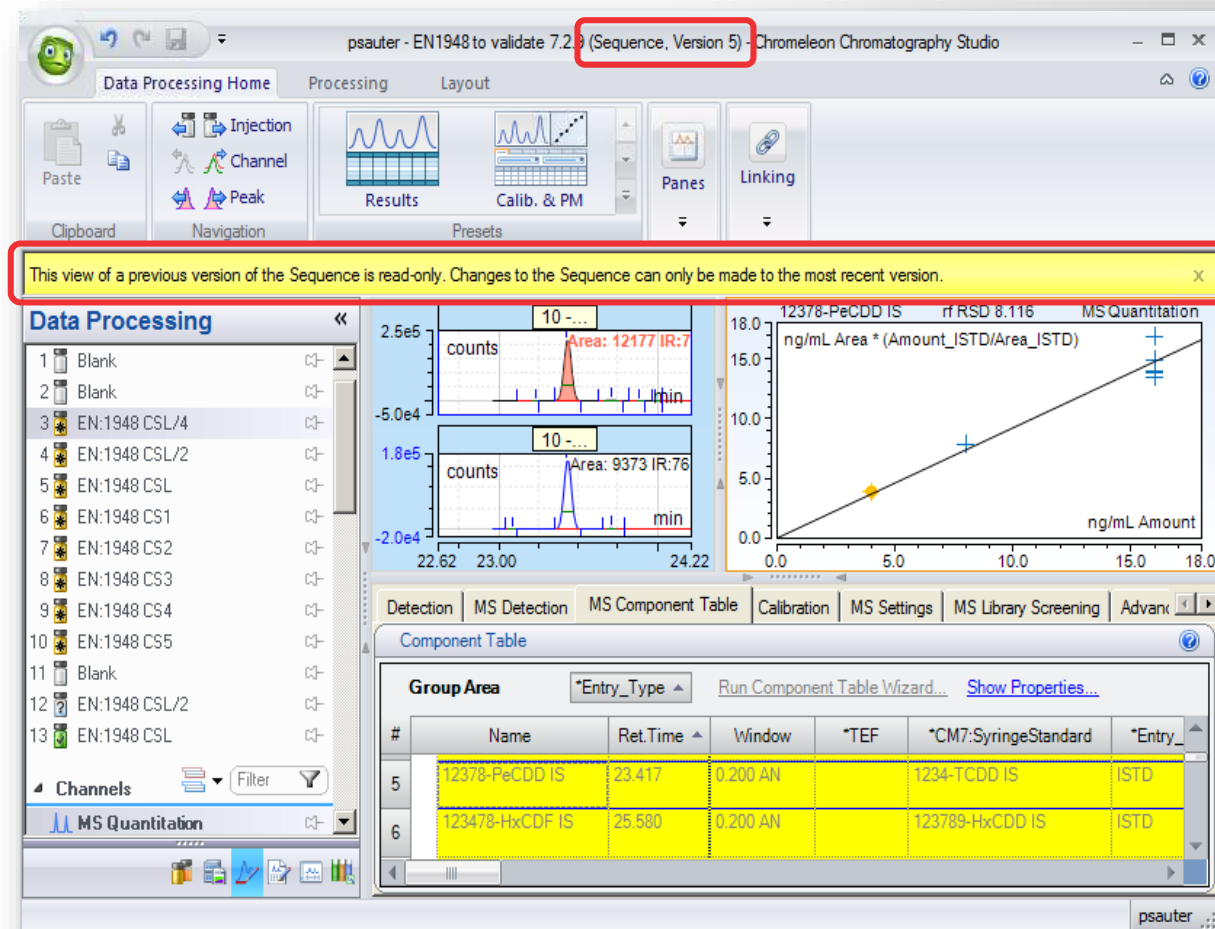
Read-only Studio Viewer

- 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

The image displays two side-by-side windows of the Chromeleon Chromatography Studio. Both windows show the same data processing workflow for a sequence named 'BA eWorkflow, 16_Apr_2019 - ISTD'. The left window is labeled '(Sequence, Version 13)' and the right window is labeled '(Sequence, Version 9)'. A blue callout box labeled 'Different Versions' points to the version labels in the window titles. A yellow banner at the top of each window states: 'This view of a previous version of the Sequence is read-only. Changes to the Sequence can only be made to the most recent version.' A blue callout box labeled 'Read Only' points to this banner. The main data area of each window contains three plots: a chromatogram (counts vs. time), a peak table (RT=3.48, Area=106767), and a calibration curve (Atrazine % ISTD vs. ng/mL). A red box in the chromatogram of the left window is labeled 'Identify Differences'. Below the plots is a 'Component Table' with the following data:

#	Name	Ret. Time	Window	Stand. Meth.	Cal. Type	Level "1"	Tol
1	Atrazine	2.460	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
2	Tolbutamide	2.500	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
3	Alprazolam	2.510	0.500 AN	Internal	Lin	1.000000	15.0
4	Testosterone	2.640	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
5	Warfarin +	2.660	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
6	Warfarin -	2.660	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
7	Diclofenac	2.810	0.500 AN	Internal	Lin, 1/A	1.000000	15.0
8	Closetel	3.480	0.500 AN	ISTD Internal	None	1.000000	15.0

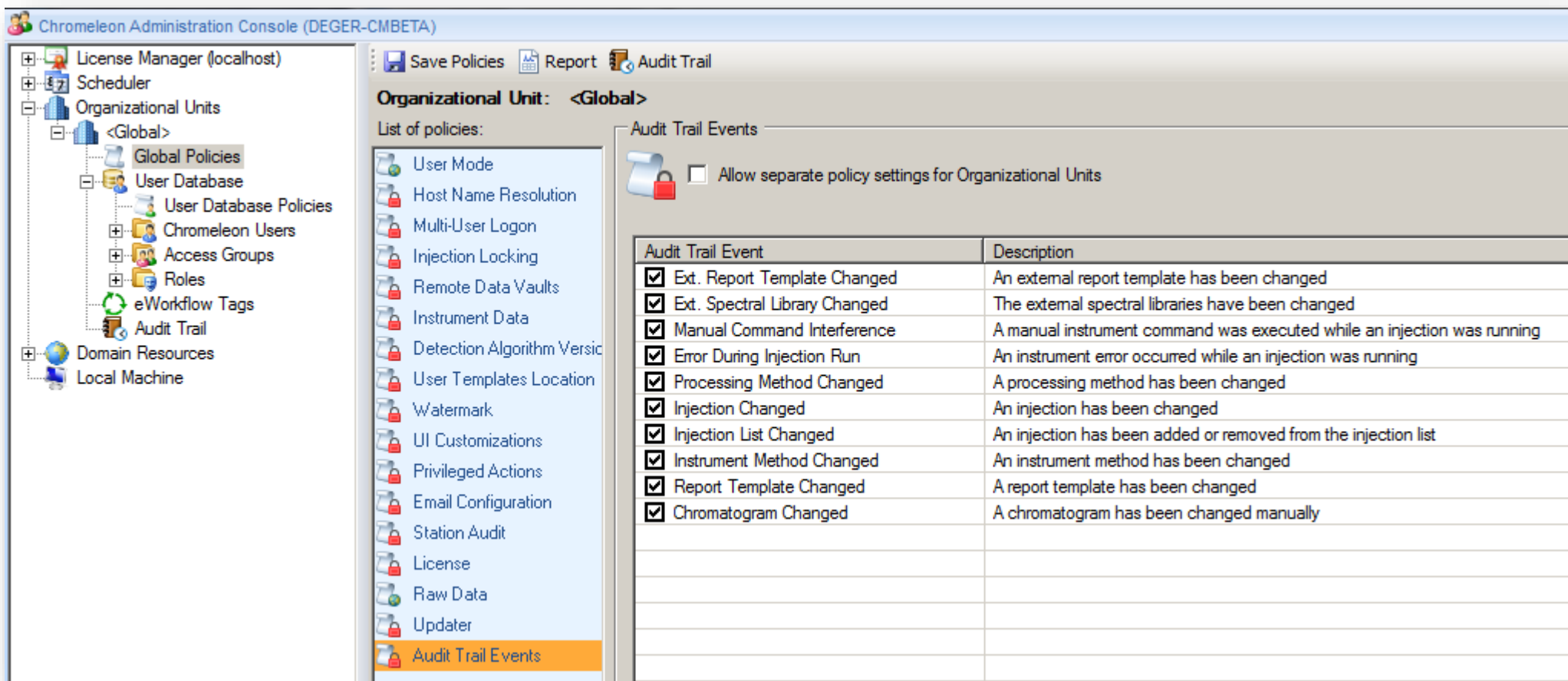
- Open multiple read-only Studio sessions to compare different versions

- 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



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

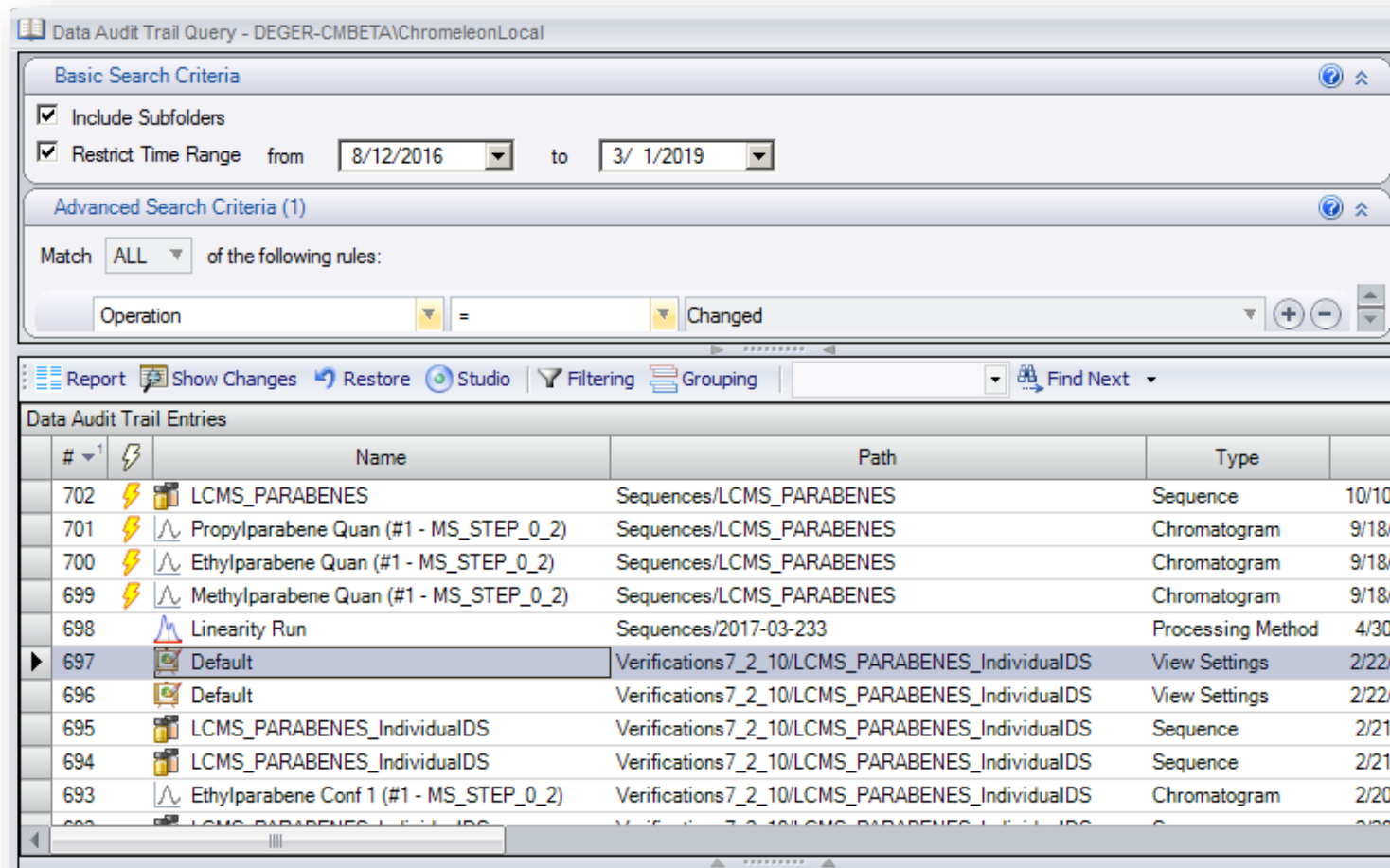
Report Show Changes Restore Studio from 9/18/2019 to 10/10/2019 Filtering Grouping Find Next

#	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

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Thank You!



Built for **Compliance.**

Built for **Data Integrity.**

Why compromise?

Chromeleon 7.3 CDS