

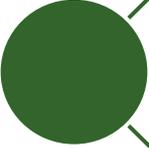
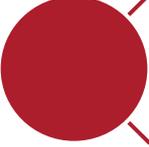
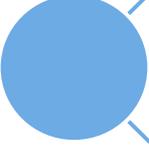
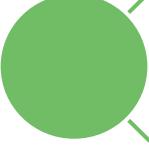
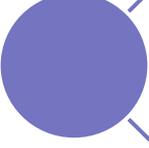


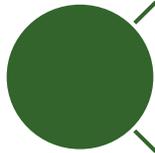
ThermoFisher
S C I E N T I F I C

Comply with Data Integrity Regulations with Chromeleon CDS Software

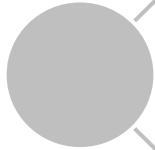
Darren Barrington-Light
Product Marketing Specialist
Chromatography Software

The world leader in serving science

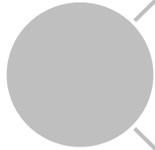
-  Introduction
-  Data Integrity
-  Audit Trails
-  Record Management
-  Summary
-  Q & A



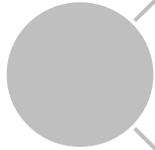
Introduction



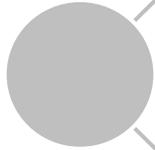
Data Integrity



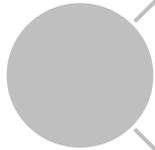
Audit Trails



Record Management



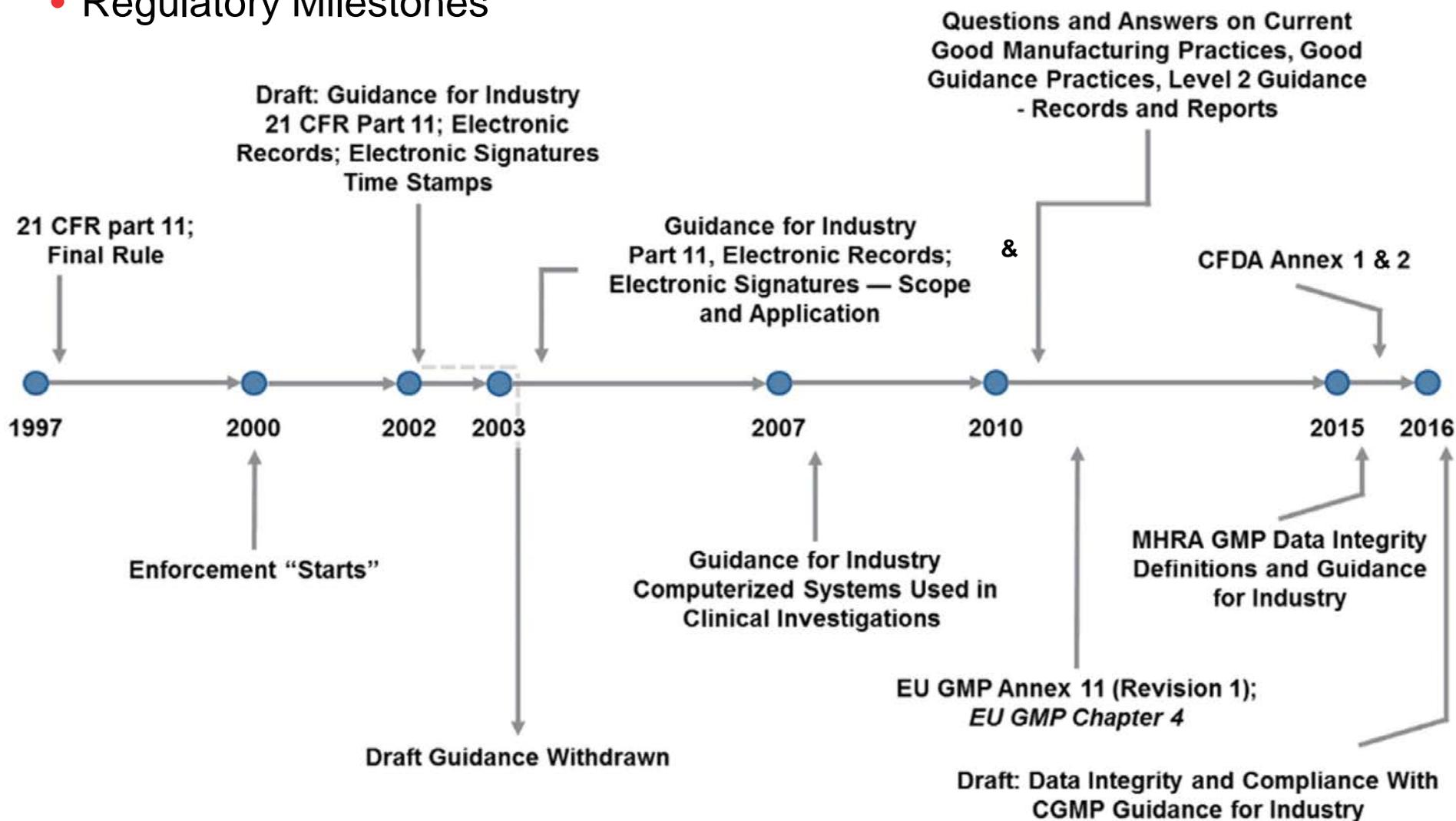
Summary



Q & A

Introduction

- Regulatory Milestones



Introduction

- Data integrity requirements
 - New guidelines in 2015 & 2016 from MHRA, CFDA and FDA
 - Covers authenticity and security of data
 - 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
- Software needs to meet regulatory requirements.
 - Includes requirements for 21 CFR Part 11 compliance



- In recent years, FDA and MHRA have increased focus on data integrity during CGMP inspections.
- Observed CGMP violations involving data integrity during inspections
- Ensuring data integrity is important
 - Industry's responsibility to ensure safety, efficacy, and quality of drugs
 - Regulatory responsibility to protect the public health
- How can Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) software help?

- Introduction
- **Data Integrity**
- Audit Trails
- Record Management
- Summary
- Q & A

Data Integrity

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

Attributable

Who performed an action & when?

Legible

Can you read the data file & written entries throughout the life cycle?

Contemporaneous

Documented at the time of the activity.

Original

Original record or a certified copy

Accurate

No errors or editing without documented amendments

Use ALCOA+ Criteria for Data Integrity



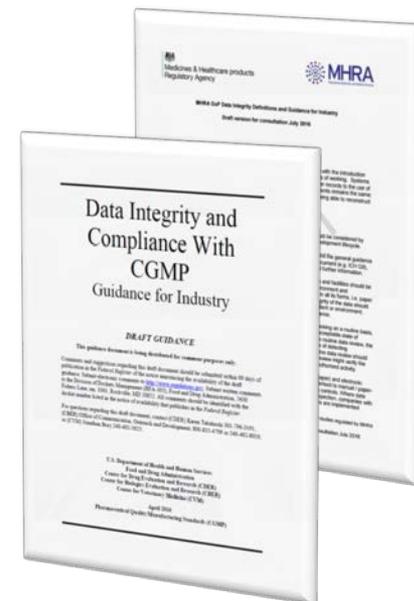
- What is “data”?
 - Any recorded information. 2 types:
 - **Static** - fixed-data document such as paper record or electronic image
 - **Dynamic** - record format that allows interaction between user and record content
 - E.g. chromatogram allowing user to change baseline or reprocess data so peaks may change size; user modifiable formulas or entries in spreadsheet

- What is “metadata”?
 - Metadata is data about data
 - Contextual information required to understand data
 - A data value is meaningless by itself without additional information
 - Metadata can describe a single piece of data, a data set or collection



- Introduction
- Data Integrity
- **Audit Trails**
- Record Management
- Summary
- Q & A

- 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.
 - CGMP-compliant record-keeping practices prevent data from being lost or obscured. Electronic record-keeping systems, which include audit trails, **can** fulfil these CGMP requirements.



Chronology of the “who, what, when, and why” of a record

- Is it acceptable to only save final results from reprocessed laboratory chromatography?
 - No. Analytical methods should be capable and stable
 - For most lab analyses, reprocessing data should not be regularly needed
 - If chromatography is reprocessed, written procedures must be established and followed and each result retained for review
 - Must have complete data in lab records, which includes raw data, graphs, charts, and spectra from lab instruments
- Predicated rules show this refers to reprocessing of **samples**, not **data**.
 - Must keep all data (and metadata) relating to each analysis
 - Versioning helps track changes to objects

Audit Trails in Chromeleon CDS

Chromeleon CDS provides industry-leading audit trails

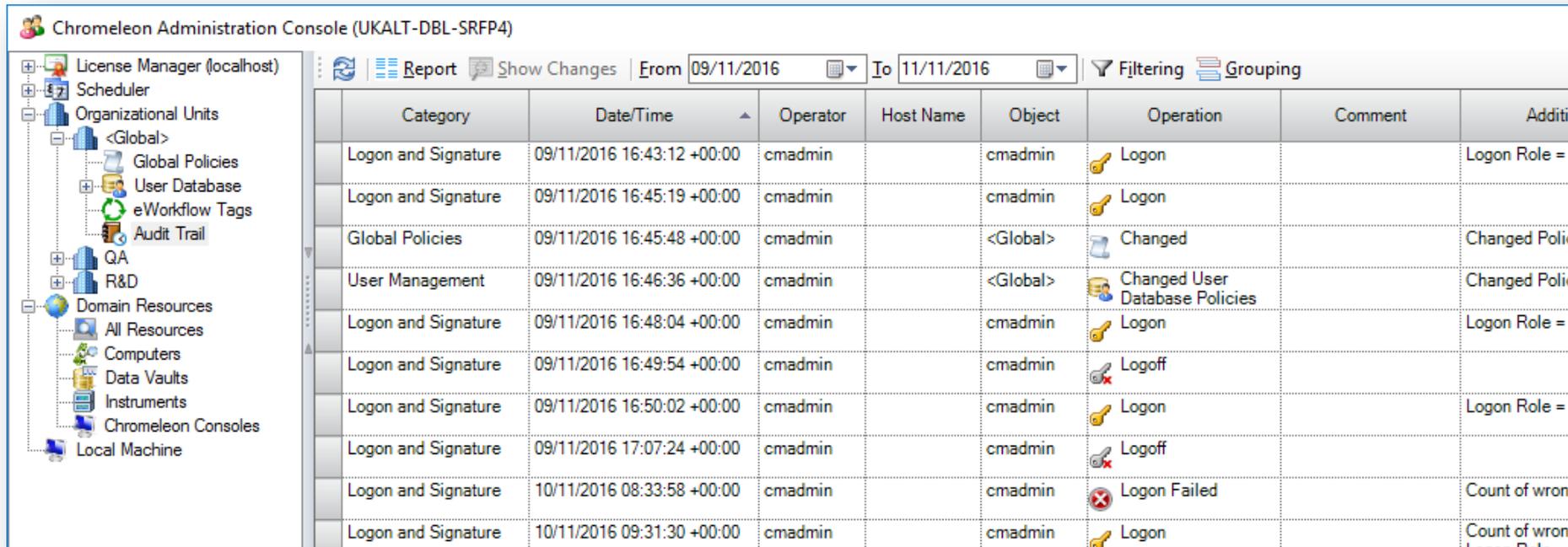
- Detailed audit trails for:
 - Chromeleon Console & Chromatography Studio
 - Administration Console, Instrument Configuration Manager, Data Vault Manager
 - Chromeleon Station
- Logs all user, instrument & system actions
 - E.g. user logon/logoff, instrument setup, sequence start/stop, data processing, admin changes, services startup/shutdown, etc.

Name	Type	Version	Date / Time	Operator	Operation	Comment	Additional Information
ChromeleonLocal	Data Vault	1	10/11/2016 12:32:43 +00:00	cmadmin	Changed	Lockout other users	Access control changed
ChromeleonLocal	Data Vault	1	10/11/2016 10:09:57 +00:00	cmadmin	Changed		Enable versioning and data audit trails.
Instrument Utilization	Folder	1	12/09/2016 14:04:39 +01:00	cmadmin	Created		Imported from C:\Users\darrenb\Desktop

Category	Date/Time	Operator	Host Name	Object	Operation
User Management	10/11/2016 09:53:46 +00:00	cmadmin		Full Access	Changed Role
Logon and Signature	10/11/2016 09:54:04 +00:00	cmadmin		cmadmin	Logoff
Logon and Signature	10/11/2016 09:54:14 +00:00	cmadmin		cmadmin	Logon

Audit Trails in Chromeleon CDS

- Chromeleon CDS consolidated audit trail viewer
 - Combines all Audit Trails within Organizational Unit
 - Events are categorized for filtering and grouping
 - Entries contain significant detail



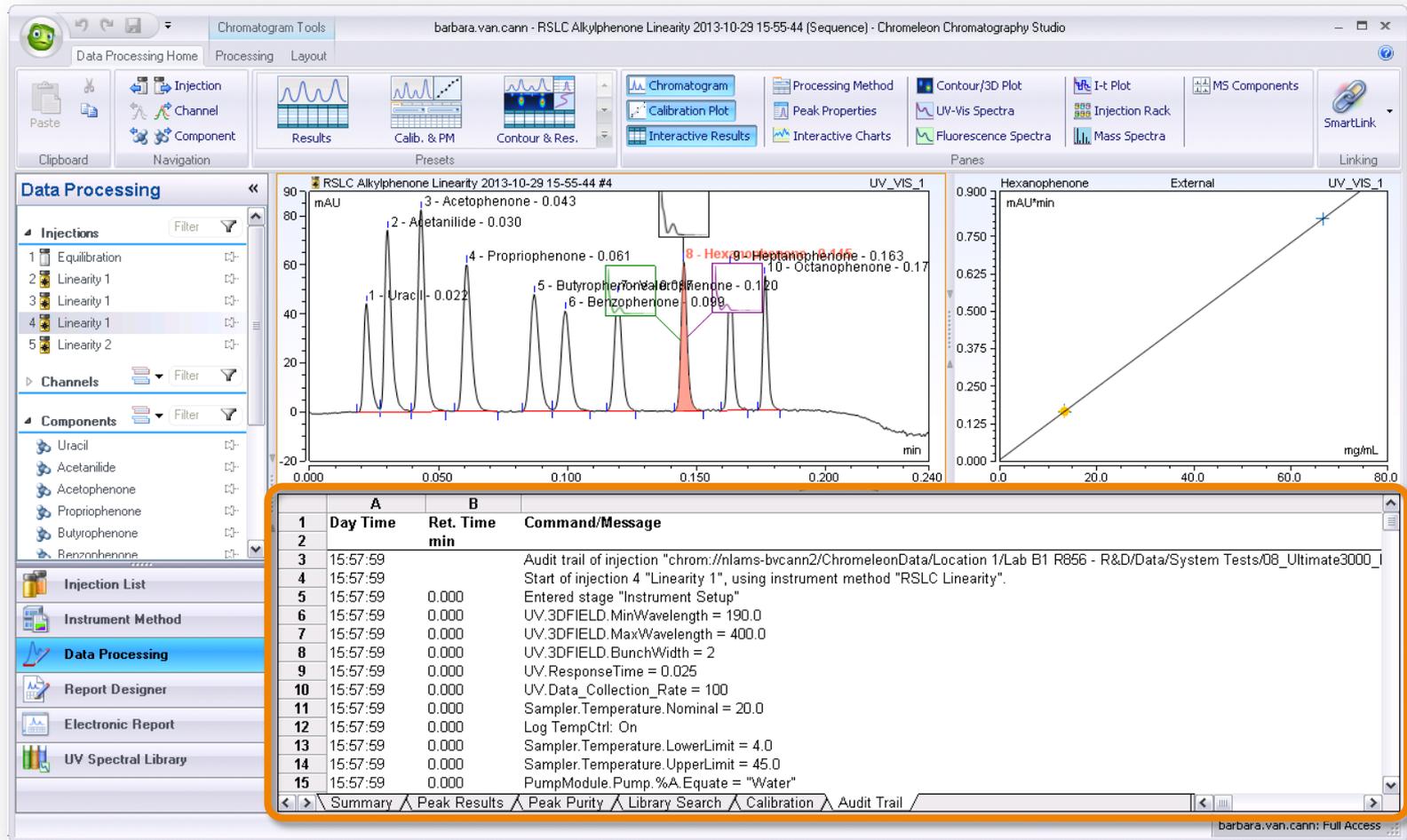
Chromeleon Administration Console (UKALT-DBL-SRFP4)

Report Show Changes From 09/11/2016 To 11/11/2016 Filtering Grouping

Category	Date/Time	Operator	Host Name	Object	Operation	Comment	Additi
Logon and Signature	09/11/2016 16:43:12 +00:00	cmadmin		cmadmin	Logon		Logon Role =
Logon and Signature	09/11/2016 16:45:19 +00:00	cmadmin		cmadmin	Logon		
Global Policies	09/11/2016 16:45:48 +00:00	cmadmin		<Global>	Changed		Changed Poli
User Management	09/11/2016 16:46:36 +00:00	cmadmin		<Global>	Changed User Database Policies		Changed Poli
Logon and Signature	09/11/2016 16:48:04 +00:00	cmadmin		cmadmin	Logon		Logon Role =
Logon and Signature	09/11/2016 16:49:54 +00:00	cmadmin		cmadmin	Logoff		
Logon and Signature	09/11/2016 16:50:02 +00:00	cmadmin		cmadmin	Logon		Logon Role =
Logon and Signature	09/11/2016 17:07:24 +00:00	cmadmin		cmadmin	Logoff		
Logon and Signature	10/11/2016 08:33:58 +00:00	cmadmin		cmadmin	Logon Failed		Count of wron
Logon and Signature	10/11/2016 09:31:30 +00:00	cmadmin		cmadmin	Logon		Count of wron

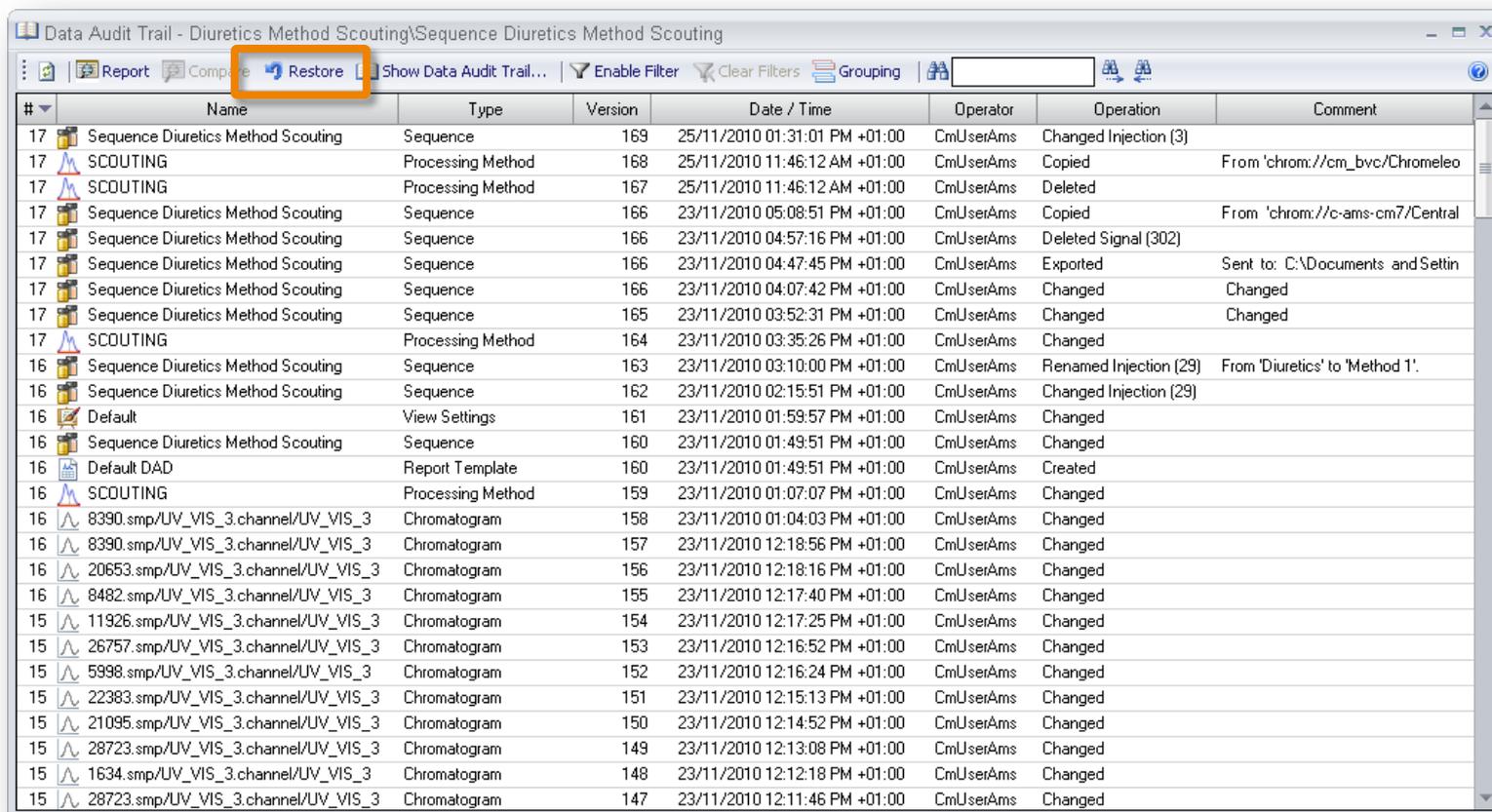
Audit Trails in Chromeleon CDS

- Instrument daily event audit trail for each injection



Audit Trails in Chromeleon CDS

- Modification history audit trail
 - Displays complete change history of each object (versions)
 - Can roll back (restore) a previous version



#	Name	Type	Version	Date / Time	Operator	Operation	Comment
17	Sequence Diuretics Method Scouting	Sequence	169	25/11/2010 01:31:01 PM +01:00	CmUserAms	Changed Injection (3)	
17	SCOUTING	Processing Method	168	25/11/2010 11:46:12 AM +01:00	CmUserAms	Copied	From 'chrom://cm_bvc/Chromeleo
17	SCOUTING	Processing Method	167	25/11/2010 11:46:12 AM +01:00	CmUserAms	Deleted	
17	Sequence Diuretics Method Scouting	Sequence	166	23/11/2010 05:08:51 PM +01:00	CmUserAms	Copied	From 'chrom://c-ams-cm7/Central
17	Sequence Diuretics Method Scouting	Sequence	166	23/11/2010 04:57:16 PM +01:00	CmUserAms	Deleted Signal (302)	
17	Sequence Diuretics Method Scouting	Sequence	166	23/11/2010 04:47:45 PM +01:00	CmUserAms	Exported	Sent to: C:\Documents and Settin
17	Sequence Diuretics Method Scouting	Sequence	166	23/11/2010 04:07:42 PM +01:00	CmUserAms	Changed	Changed
17	Sequence Diuretics Method Scouting	Sequence	165	23/11/2010 03:52:31 PM +01:00	CmUserAms	Changed	Changed
17	SCOUTING	Processing Method	164	23/11/2010 03:35:26 PM +01:00	CmUserAms	Changed	
16	Sequence Diuretics Method Scouting	Sequence	163	23/11/2010 03:10:00 PM +01:00	CmUserAms	Renamed Injection (29)	From 'Diuretics' to 'Method 1'.
16	Sequence Diuretics Method Scouting	Sequence	162	23/11/2010 02:15:51 PM +01:00	CmUserAms	Changed Injection (29)	
16	Default	View Settings	161	23/11/2010 01:59:57 PM +01:00	CmUserAms	Changed	
16	Sequence Diuretics Method Scouting	Sequence	160	23/11/2010 01:49:51 PM +01:00	CmUserAms	Changed	
16	Default DAD	Report Template	160	23/11/2010 01:49:51 PM +01:00	CmUserAms	Created	
16	SCOUTING	Processing Method	159	23/11/2010 01:07:07 PM +01:00	CmUserAms	Changed	
16	8390.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	158	23/11/2010 01:04:03 PM +01:00	CmUserAms	Changed	
16	8390.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	157	23/11/2010 12:18:56 PM +01:00	CmUserAms	Changed	
16	20653.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	156	23/11/2010 12:18:16 PM +01:00	CmUserAms	Changed	
16	8482.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	155	23/11/2010 12:17:40 PM +01:00	CmUserAms	Changed	
15	11926.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	154	23/11/2010 12:17:25 PM +01:00	CmUserAms	Changed	
15	26757.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	153	23/11/2010 12:16:52 PM +01:00	CmUserAms	Changed	
15	5998.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	152	23/11/2010 12:16:24 PM +01:00	CmUserAms	Changed	
15	22383.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	151	23/11/2010 12:15:13 PM +01:00	CmUserAms	Changed	
15	21095.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	150	23/11/2010 12:14:52 PM +01:00	CmUserAms	Changed	
15	28723.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	149	23/11/2010 12:13:08 PM +01:00	CmUserAms	Changed	
15	1634.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	148	23/11/2010 12:12:18 PM +01:00	CmUserAms	Changed	
15	28723.smp/UUV_VIS_3.channel/UUV_VIS_3	Chromatogram	147	23/11/2010 12:11:46 PM +01:00	CmUserAms	Changed	

Audit Trails in Chromeleon CDS

- Version comparison tool

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

Visualization Options
 Complete
 Only Changes

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

Version 1

Time	Symbol	Value	Comment
Initial Time	Instrument Setup		
	Sampler.InjectMode	Normal	
	Sampler.PumpDevice	"Pump"	
	Sampler.SyncWithPump	On	
	Pump.MaximumFlowRampDown	1.000 [ml/min ²]	
	Pump.MaximumFlowRampUp	1.000 [ml/min ²]	
	Pump.%B.Equate	"Acetonitrile"	
	Pump.%C.Equate	"Methanol"	
	Pump.Pressure.UpperLimit	400 [bar]	
0.00	Inject Preparation		
0.00	Inject		
0.00	Start Run		
	UV.UV_VIS_1.AcqOn		
0.00	Run		
	Pump.Flow	1.000 [ml/min]	
8.00	Pump.Flow	2.000 [ml/min]	
8.00	Stop Run		
	UV.UV_VIS_1.AcqOff		

Change (points to Pump.Pressure.UpperLimit)

Deletion (points to Pump.Pressure.UpperLimit)

Version 2

Time	Symbol	Value	Comment
Initial Time	Instrument Setup		
	Sampler.InjectMode	Normal	
	Sampler.PumpDevice	"Pump"	
	Sampler.SyncWithPump	On	
	Pump.MaximumFlowRampDown	1.000 [ml/min ²]	
	Pump.MaximumFlowRampUp	1.000 [ml/min ²]	
	Pump.%A.Equate	"0.1M Phosphate Buffer"	
	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		
	Pump.Pump_Pressure.AcqOff		
0.00	Run		
	Pump.Flow	2.000 [ml/min]	
8.00	Pump.Flow	2.000 [ml/min]	
8.00	Stop Run		
	UV.UV_VIS_1.AcqOff		
	Pump.Pump_Pressure.AcqOff		

Addition (points to Pump.Pump_Pressure.AcqOff)

Audit Trails in Chromeleon CDS

- File section in injection list and folder view shows current version

cmadmin - Chromeleon Console

Back Create File Edit View Tools Help

Data

Name	Type	Date Modified	Version	Comment
Station Qual 2016-11-10	Sequence	10/11/2016 09:49:51 +00:00	1	Sequence for Station Operational Qualification

Folder 'Runs' selected

cmadmin - Chromeleon Console

Back Create File Edit View Tools Help

Data

Station Qual 2016-11-10

Run Finished <CM_OQ> (Not Connected)

Save Studio Print Up Insert Row Fill Down Lock Filtering Grouping

#	UV_VIS_1	Name	Type	Level	Position	Volume [µl]	Instrument Method
1		Alkylphenones 1	Calibration Standard	01	RA1	2.000	CM_OQ
2		Alkylphenones 2	Calibration Standard	01	RA1	4.000	CM_OQ
3		Alkylphenones 3	Calibration Standard	01	RA1	8.000	CM_OQ
4		Alkylphenones 4	Calibration Standard	01	RA1	12.000	CM_OQ
5		Alkylphenones 5	Calibration Standard	01	RA1	16.000	CM_OQ
6		Alkylphenones 6	Calibration Standard	01	RA1	20.000	CM_OQ
7		Alkylphenones 7	Unknown		RA2	4.000	CM_OQ

Click here to add a new injection

Name	Type	Date Modified	Version	Comment
CM_OQ	Processing Method	10/11/2016 09:49:19 +00:00	1	
CM_OQ	Instrument Method	10/11/2016 09:49:51 +00:00	1	
CM_OQ	Report Template	10/11/2016 09:49:19 +00:00	1	
CM_OQ	View Settings	10/11/2016 09:49:19 +00:00	1	

Associated Items Custom Sequence Variables (0) Custom Formulas

Sequence 'Station Qual 2016-11-10' selected cmadmin: Full Access

Audit Trails in Chromeleon CDS

- Privileged Actions
 - Require authorization for specified actions
 - Ensure users add appropriate comments for specified actions
 - Use standardized comments or free entry

The screenshot displays the Chromeleon Administration Console (UKALT-DBL-SRFP4) interface. The left sidebar shows a tree view of organizational units, with 'Privileged Actions' selected. The main window shows the 'Privileged Actions' configuration page for the '<Global>' organizational unit. A table lists various actions, including 'Instrument Configuration', 'Instrument Method', 'Create', 'Delete', 'Modify', 'Copy', 'Move', 'Rename', 'Instrument Audit Trail', 'Data Vault', and 'Folder'. An 'Authorization and Comment Required' dialog box is overlaid on the right, featuring the Chromeleon 7 logo and the title 'Authorization and Comment'. The dialog contains fields for 'User Name' (cmadmin), 'Logon Password' (masked), and a 'Comment' field with the text 'Created new user for demo purposes'. The dialog also includes buttons for 'Pick Comments...', 'Reset to Default', and '221 characters remaining'.

Chromeleon Administration Console (UKALT-DBL-SRFP4)

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 Audit Trails
- Detection Algorithm Version
- User Templates Location
- Watermark
- UI Customizations
- Privileged Actions
- Email Configuration
- Station Audit
- Raw Data

Privileged Actions

Settings Standard Comments

Allow separate policy settings for Organizational Units

Action
Instrument Configuration
Instrument Method
Create
Delete
Modify
Copy
Move
Rename
Instrument Audit Trail
Data Vault
Folder

Authorization and Comment Required

Chromeleon 7
Authorization and Comment

User Name: cmadmin

Logon Password: *****

Comment: Pick Comments... Reset to Default 221 characters remaining

Created new user for demo purposes

OK Cancel Help

- Introduction
- Data Integrity
- Audit Trails
- **Record Management**
- Summary
- Q & A

All data should be stored, controlled and archived correctly

- When does electronic data become a CGMP record?
 - When generated to satisfy any CGMP requirement, all data becomes a CGMP record
 - Must document, or save, data at time of performance (contemporaneous)
 - E.g. chromatograms should be sent to long-term storage upon run completion
 - Not acceptable to record data on paper that will be discarded after data are transcribed to permanent laboratory notebook
 - Not acceptable to store data electronically in temporary memory, in manner that allows for manipulation, before creating permanent record

All data should be stored, controlled and archived correctly

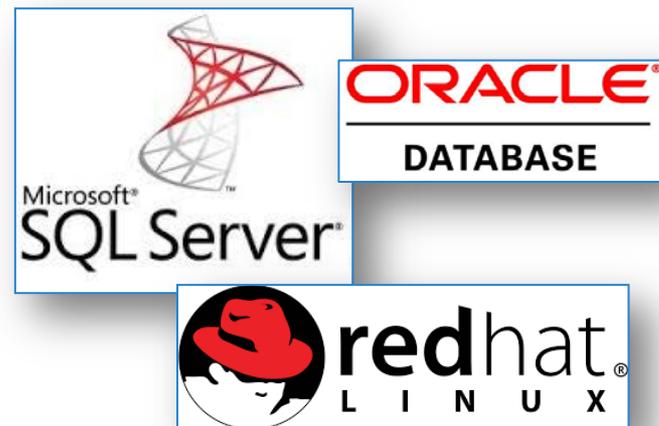
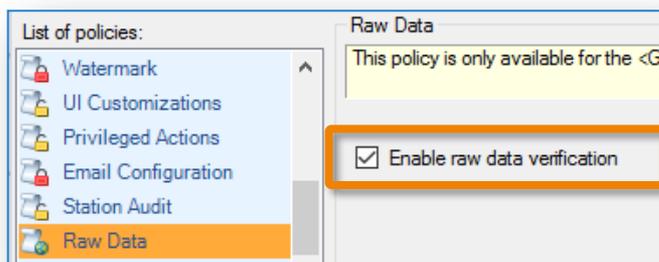
- How do regulatory bodies use the term “backup”?
 - A true copy of original data that is maintained securely throughout records retention period.
 - Backup file should contain data (with associated metadata) in original format or in format compatible with original format.
- Must not be confused with backup copies!
 - Created during normal computer use and temporarily maintained for disaster recovery (e.g. in case of a computer crash or other interruption)
- How does Chromeleon CDS help?



Record Management – Data Storage

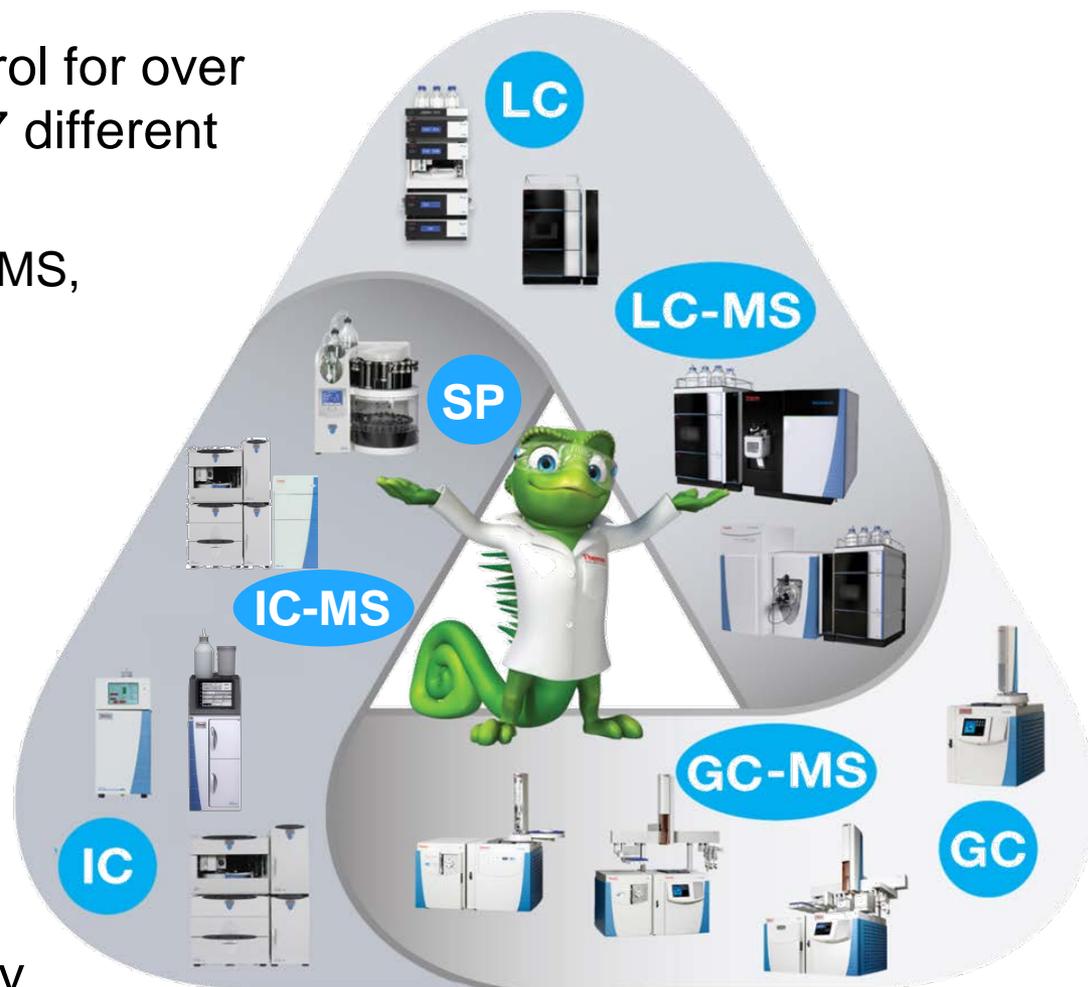
Immediate transfer to long-term storage

- Chromeleon CDS uses relational database
 - Microsoft® SQL® Server Express (2005 SP3, 2008 R2 SP2 & 2014 SP2)
 - Microsoft® SQL® Server (2008 R2, 2012 & 2014 SP2)
 - Oracle® Database 11g & 12c
 - Oracle® Database 12c on Red Hat® Enterprise Linux® 7
- Detect changes to raw files
 - Automatic detection of raw files being manipulated outside Chromeleon CDS



Record Management – Data Storage

- Bi-directional instrument control for over 450 different modules from 17 different manufacturers including:
 - Thermo Scientific (LC, IC, GC, MS, Sample Prep)
 - Agilent (LC, GC)
 - Waters (LC)
 - Shimadzu (LC, GC)
 - Varian (LC, GC)
 - Perkin Elmer (LC, GC)
 - Gilson (LC)
 - CTC PAL (Sample Prep)
- Highest data transport security
 - Communication secured using latest standards



Record Management – Data Control

The screenshot displays the Chromeleon 7 software interface. The main window shows an 'Electronic Report' for a sequence named 'CmServiceAMS - RSLC Alkylphenone Linearity 2013-10-11 10-21-53 (Sequence) - Chromeleon Chromatogr...'. The report includes a 'Chromatogram and Results' section with a chromatogram plot and a table of peak data. A 'Review Signature' dialog box is overlaid on the report, prompting the user to enter their name and password for signature verification.

Chromatogram and Results

Injection Details

Injection Name	Run Time (min)	Injection Volume
Linearity 2	0.20	0.10

Chromatogram

Injection Results

No.	Peak Name	Retention Time (min)	Area (mAU*min)	Height (mAU)	Relative Area (%)	Relative Height (%)	Amount (mg)
1	Urad	0.022	0.020	214.748	7.12	7.19	20.0000
2	Acetophenone	0.280	1.100	320.170	12.49	12.50	20.0000
3	Alkylphenone	0.290	1.200	320.291	14.21	14.28	20.0000
4	Phenolphthalein	0.291	0.911	252.219	12.17	10.52	20.0000
5	Stylyphenone	0.2817	0.380	251.265	10.51	3.38	20.0000
6	Diethylphenone	0.280	0.200	251.010	0.52	7.28	20.0000
7	Chlorophenone	0.120	0.200	250.261	0.52	0.51	20.0000
8	Hexachlorophenone	0.140	0.210	250.265	0.53	10.51	20.0000
9	Phenolphthalein	0.140	0.140	250.265	0.53	10.51	20.0000
10	Chlorophenone	0.140	0.140	250.265	0.53	10.51	20.0000

- Electronic Report
 - Snapshot in time of sequence
 - Any changes tracked
 - Can be sent for review
- Electronic Signatures
 - 3 Levels of signature Submit, Review, Approve
 - Applied to electronic report
 - Complete sequence protected by checksums
 - Controlled by privileges

Record Management – Data Control

The screenshot displays a software interface for record management. The main window shows a navigation pane on the left with 'Electronic Report' and 'Injections' (Equilibration, Linearity 1). The 'Submit' button is highlighted with a red box. A dialog box titled 'Enter Chromeleon User Name And Signature Password' is open, showing 'User Name: CmServiceAMS' and 'Signature Password: *****'. A 'Submitting Results' dialog box is also open, listing submitted items:

- Sequence Layouts
 - 'SequenceLayout' submitted
- Sequence Definitions
 - 'SequenceDefinition' submitted
- eWorkflows
 - 'RSLC Alkylphenone Linearity' submitted
- View Settings
 - 'RSLC Linearity' submitted
- Electronic Reports
 - 'RSLC Alkylphenone Linearity 2013-10-11 10-21-53' submitted
- Sequences
 - 'RSLC Alkylphenone Linearity 2013-10-11 10-21-53' submitted

A yellow box at the bottom contains the text: "The sequence is signed. Modifications to the sequence are not possible."

Record Management – Archive/Backup

- Chromeleon Scheduler – automatically archive/backup data using powerful Injection Queries
 - Transfer to another Data Vault – direct access with full metadata
- Export to cmbx or other format (e.g. PDF, GAML, XLS, etc.)

The image displays two screenshots of the Chromeleon Administration Console (nlams-cm02) interface.

Left Screenshot: The Scheduler is running. The last retrieval of service data was on 23-Dec-13 at 14:43:52. A table shows 2 tasks:

Enabled	Task Name	Status
<input checked="" type="checkbox"/>	Archive Data older than one month	Waiting
<input checked="" type="checkbox"/>	Cleanup cached network sequences	Waiting

Right Screenshot: The configuration for the task "Archive Data older than one month" is shown. The task is done, and the next start is on 23-Jan-14 at 14:26:24. The last retrieval of task data was on 23-Dec-13 at 14:44:57. The configuration includes:

- Name: Archive Data older than one month
- Owner: Barbara van Cann
- Description: Archive all data that is older than one month to the central archiving data vault.
- Enabled
- Specify additional settings that affect the behavior of the task: _____
- If the task fails, restart every: 1 hour
- Attempt restart up to: 3 times

Buttons at the bottom include Terminate, Stop, Start, Delete, Discard changes, and Save changes.

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Summary

- Data integrity and compliance go hand-in-hand
 - Subject to elevated scrutiny by regulatory bodies
- Chromeleon CDS meets all of your data integrity needs:
 - Ensures completeness, consistency, and accuracy of data
 - ALCOA+
 - Comprehensive audit trails
 - Who, what, when and why of data
 - Maintains record authenticity
 - Contemporaneous collection
 - Automated long-term data retention with easy accessibility

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Thank you

For more information about Chromeleon 7.2 CDS or to request an informational 'demo' CD, visit:

thermofisher.com/Chromeleon

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



facebook.com/CharlieLovesChromatography

Any questions?



**Do you have additional questions
or do you want to talk to an expert from
Thermo Fisher Scientific?**

**Please send an E-Mail to
analyze.eu@thermofisher.com
and we will get back to you.**

