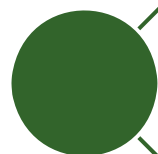


ThermoFisher
S C I E N T I F I C

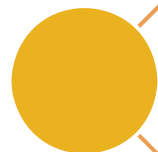
CDS, SDMS and LIMS considerations for Compliance, Data Integrity and Data Security

Darren Barrington-Light
Senior Manager - Product Marketing
Chromatography & Mass Spectrometry Software

The world leader in serving science



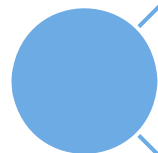
Introduction



Data Security



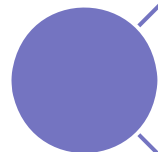
Enterprise Software



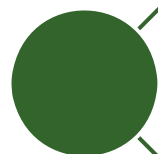
Audit Trails



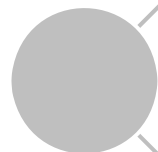
Record Management



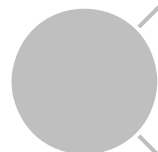
Summary



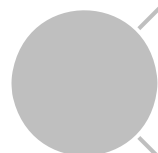
Introduction



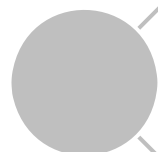
Data Security



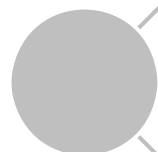
Enterprise Software



Audit Trails



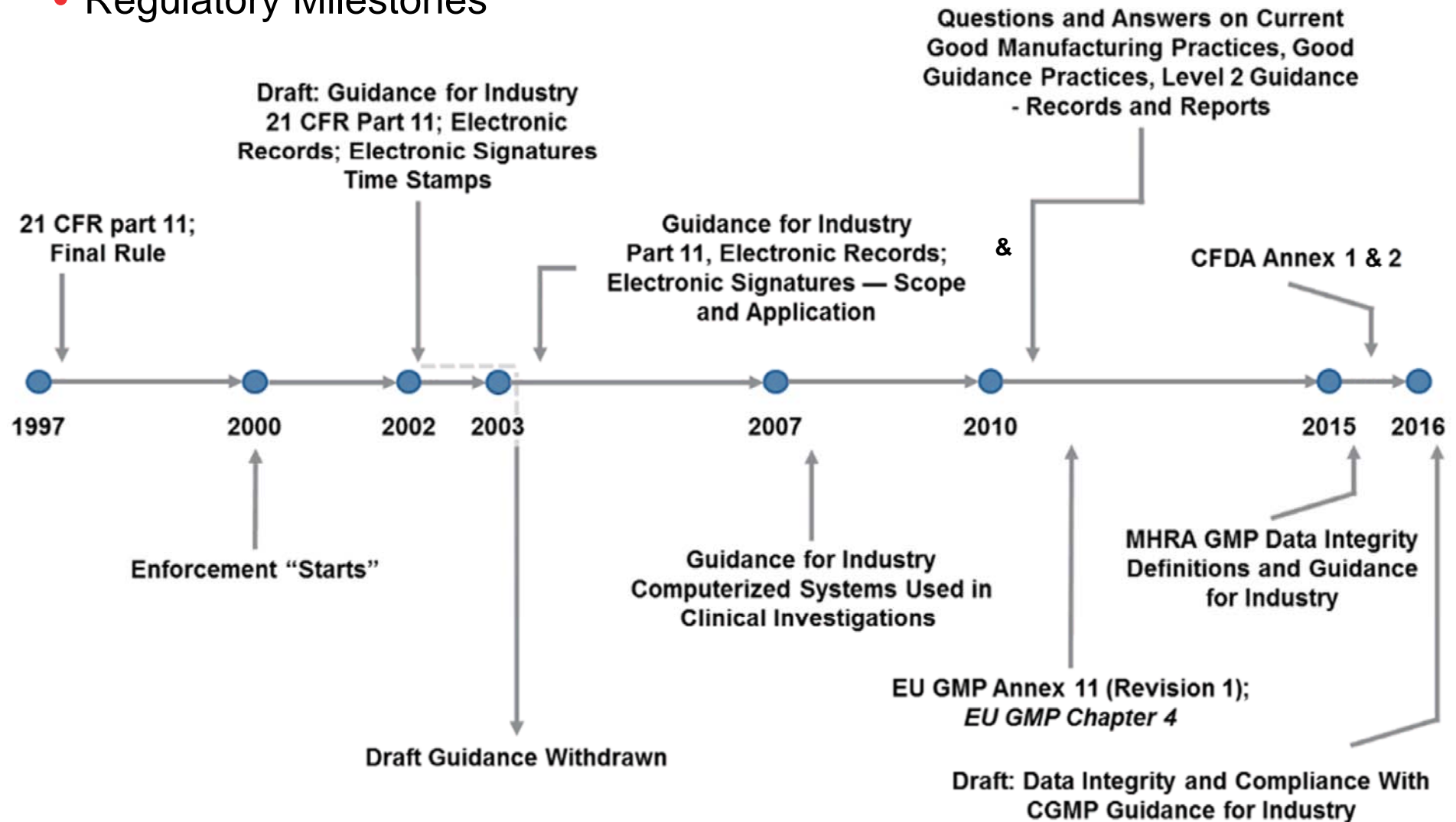
Record Management



Summary

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



FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

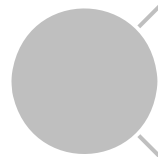


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

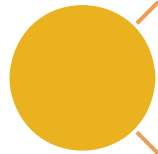
ICH
harmonisation for better health

MHRA
Regulating Medicines and Medical Devices

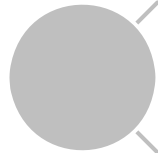
CFDA China Food and Drug Administration



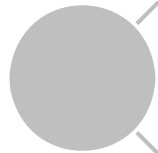
Introduction



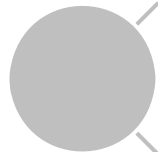
Data Security



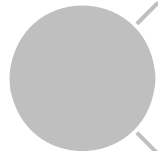
Enterprise Software



Audit Trails



Record Management



Summary

Data Security

- 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+

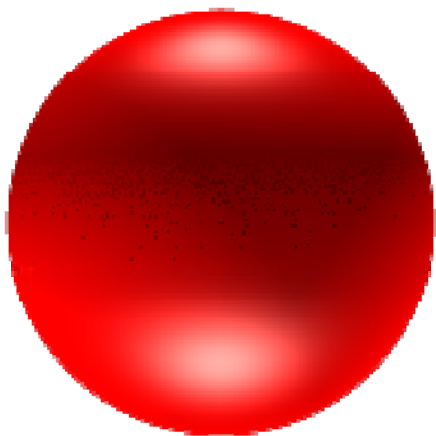
**Criteria for
Data Integrity**



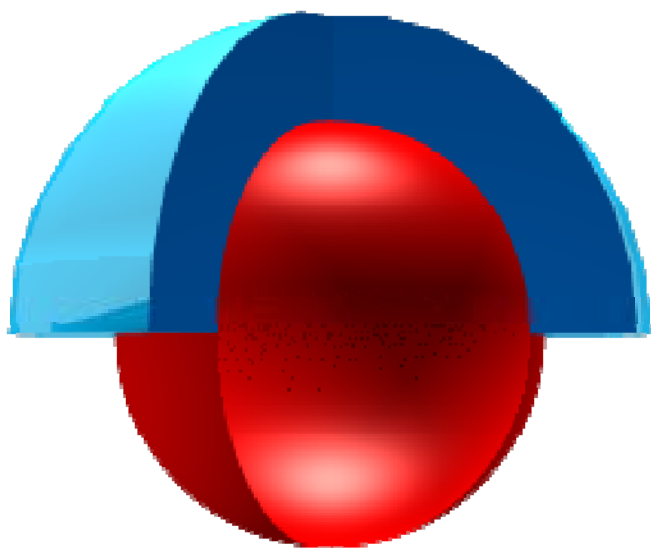
Data Security

-

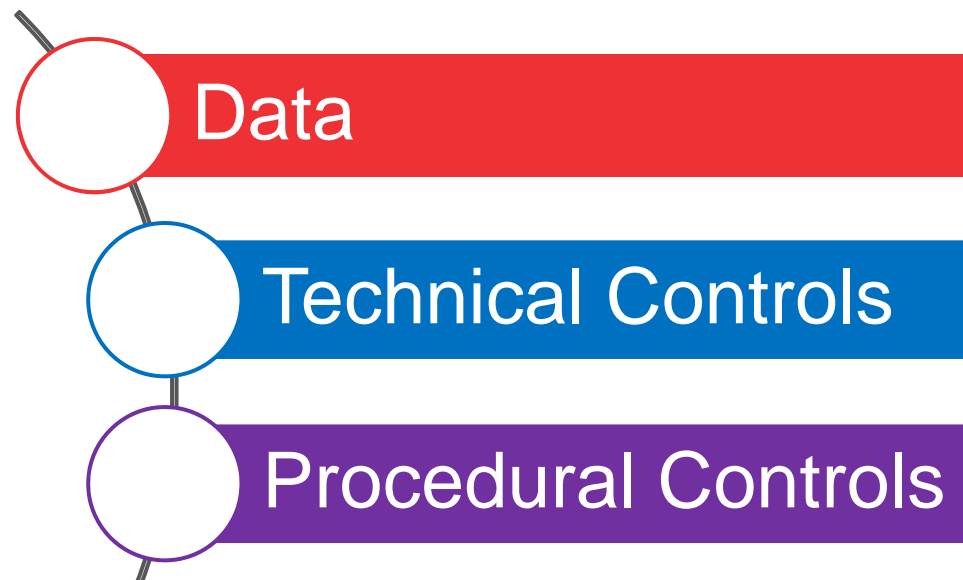
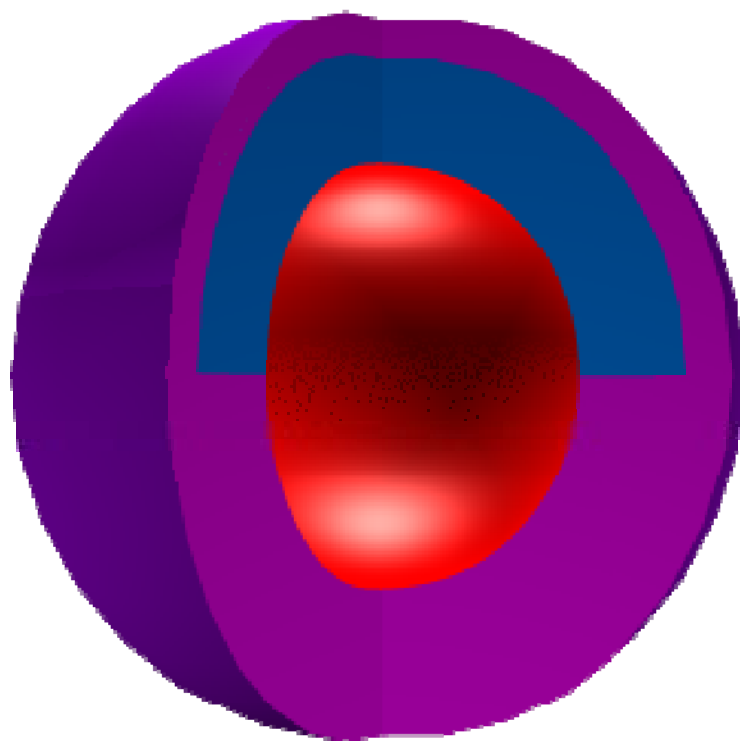
Data Security Layers



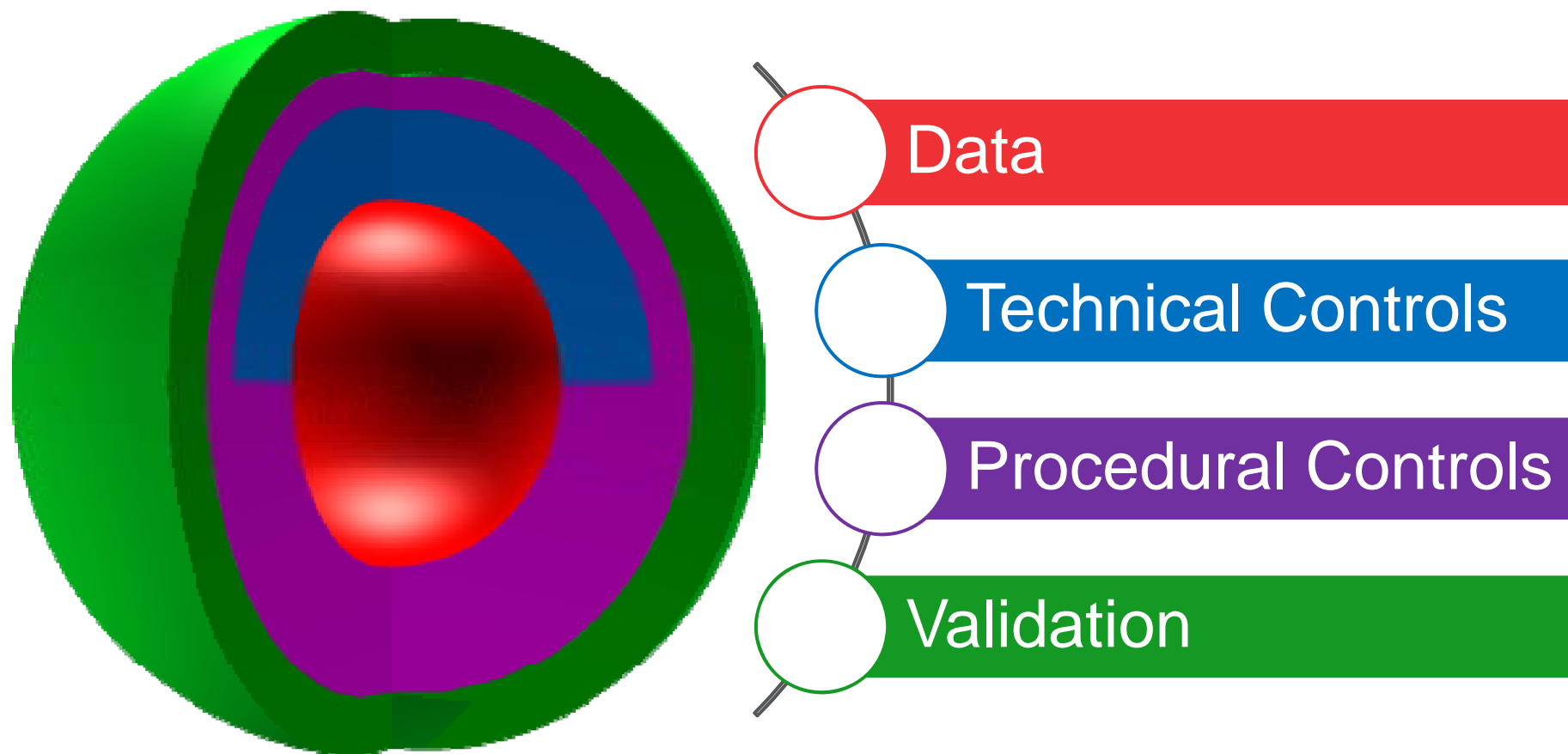
Data Security Layers

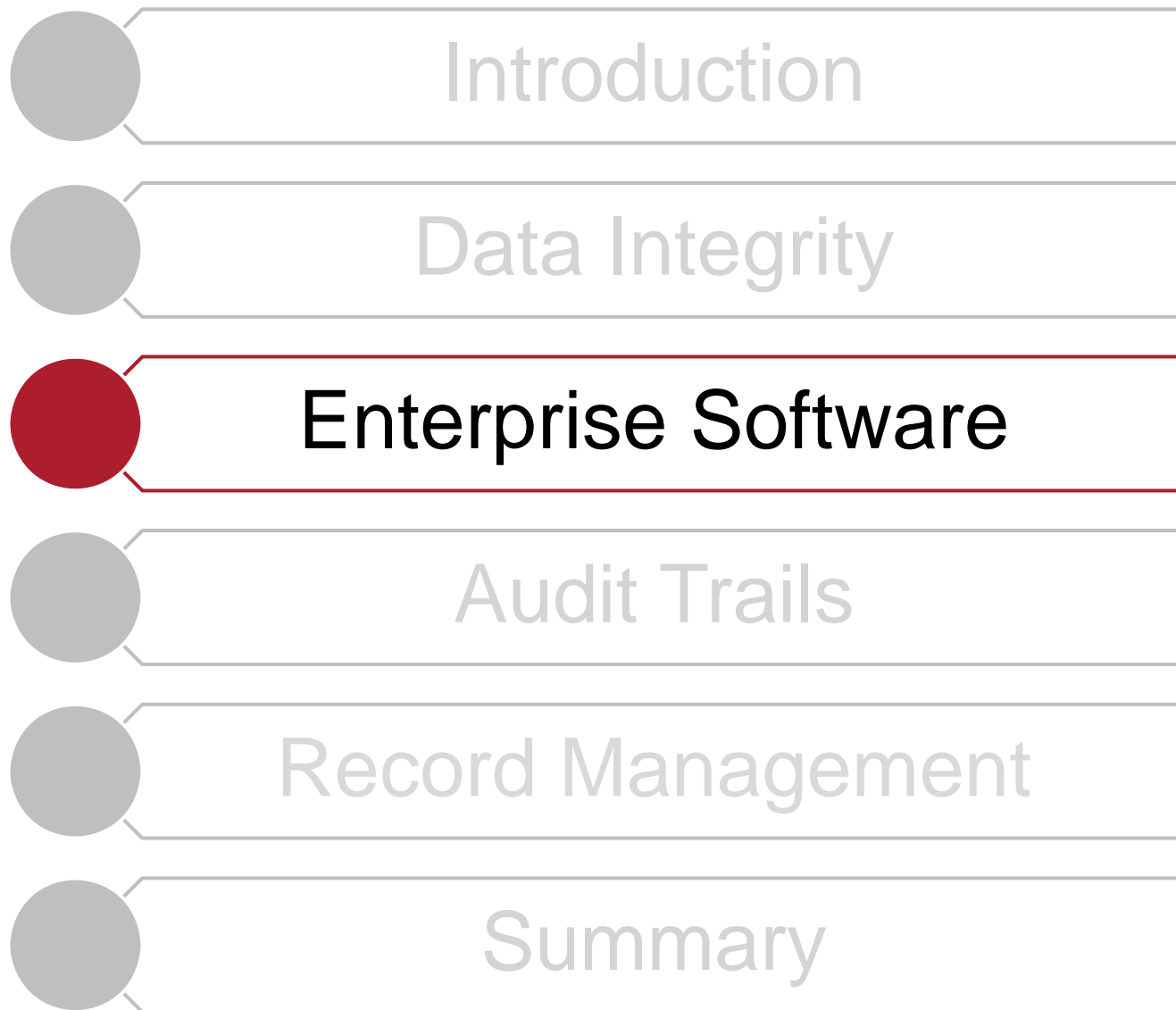


Data Security Layers

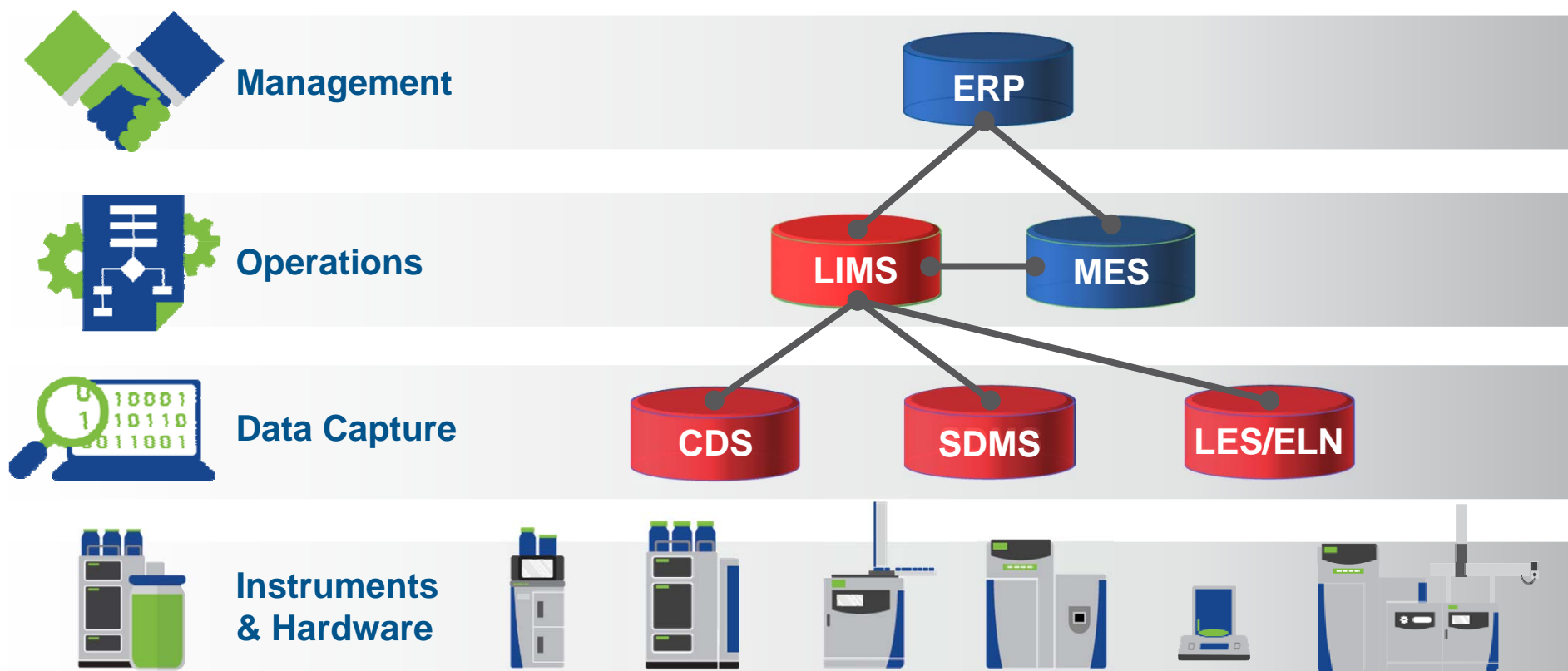


Data Security Layers





Is your data flow delivering knowledge while ensuring compliance and data security?



Thermo Fisher Scientific Enterprise Software

- Complete enterprise software portfolio delivering compliance and data security from sample to knowledge



CDS

Streamline your chromatography and routine mass spectrometry workflow with one CDS.



LIMS

Manage the data, resources, and workflows of your laboratory, turning your data into actionable business intelligence.



SDMS

Visualize and securely share data across your organization across multiple techniques and vendors.



LES & ELN

Simplify the execution of your methods and SOPs by driving analysts step by step through the process.



Integration

Integrate your laboratory from instruments through to enterprise systems to achieve end to end data management.

Thermo Scientific Chromeleon 7.2 Chromatography Data System

Industry-leading!

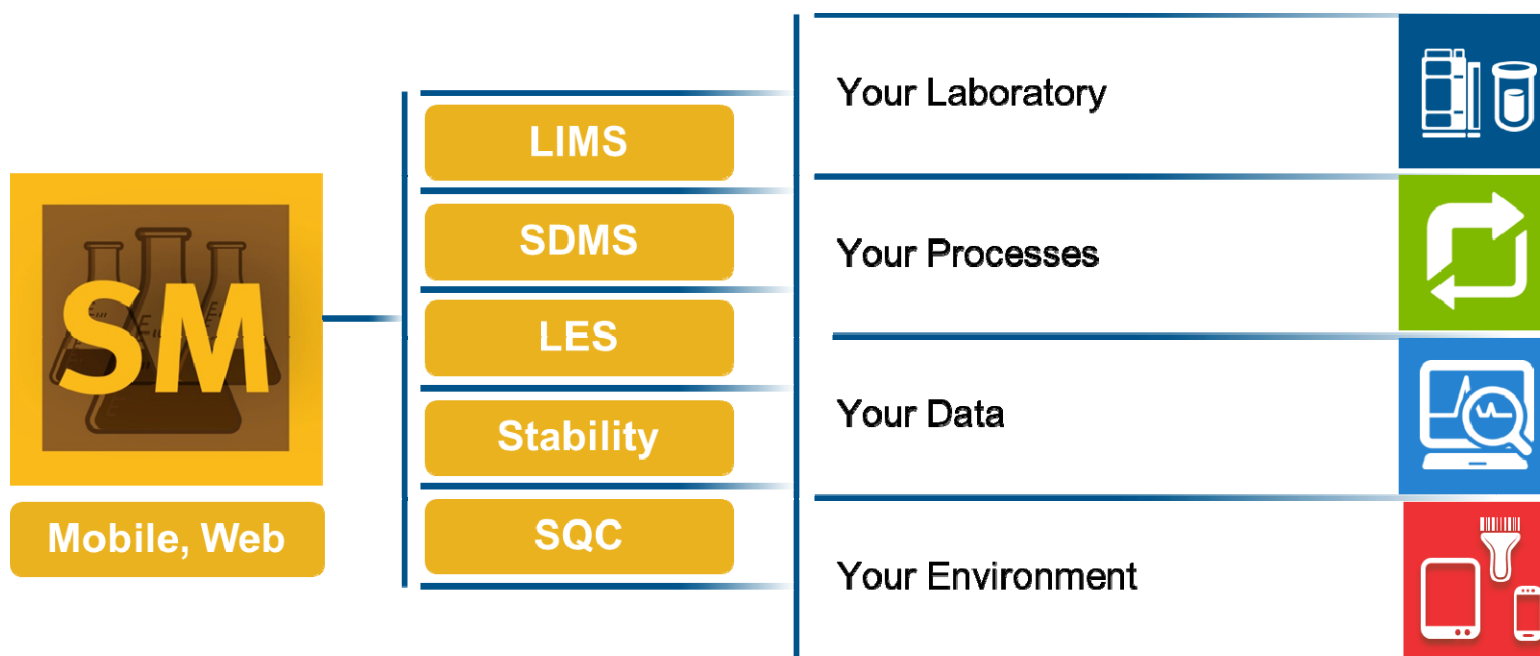
- ✓ Compliance and data security
- ✓ Ease of use
- ✓ Network Failure Protection (24/7 operation)
- ✓ Network MS control & processing
- ✓ Instrument control (>450 from 18 vendors)



Thermo Fisher SampleManager LIMS Software

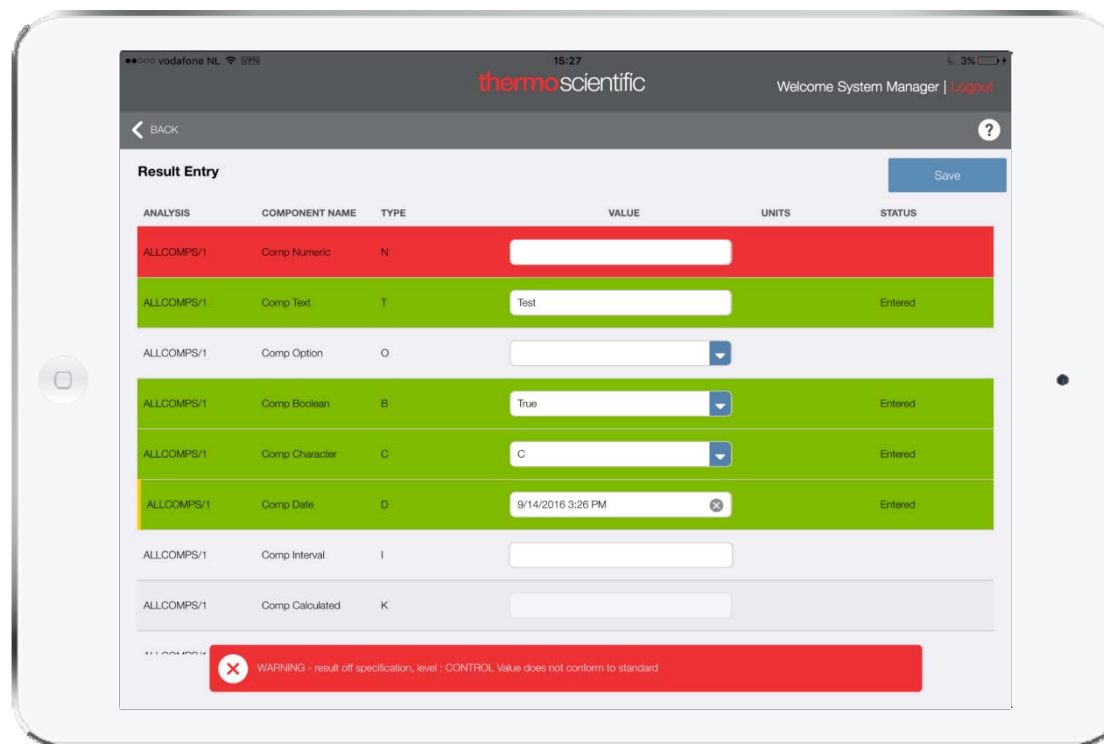
More than a LIMS!

- ✓ Manages the entire laboratory
- ✓ Ensures adherence to processes
- ✓ Maintains data integrity
- ✓ Facilitates complete regulatory compliance



Thermo Fisher SampleManager LES – Procedural ELN

Execute lab work anytime, anywhere



thermoFisher Scientific

Welcome System Manager | Logout

BACK

Result Entry

Save

ANALYSIS	COMPONENT NAME	TYPE	VALUE	UNITS	STATUS
ALLCOMPS/1	Comp Numeric	N	<input type="text"/>		
ALLCOMPS/1	Comp Text	T	<input type="text" value="Test"/>		Entered
ALLCOMPS/1	Comp Option	O	<input type="text"/>		
ALLCOMPS/1	Comp Boolean	B	<input type="text" value="True"/>		Entered
ALLCOMPS/1	Comp Character	C	<input type="text" value="C"/>		Entered
ALLCOMPS/1	Comp Date	D	<input type="text" value="9/14/2016 3:26 PM"/>		Entered
ALLCOMPS/1	Comp Interval	I	<input type="text"/>		
ALLCOMPS/1	Comp Calculated	K	<input type="text"/>		

WARNING - result off specification, level : CONTROL Value does not conform to standard

Thermo Fisher SampleManager SDMS

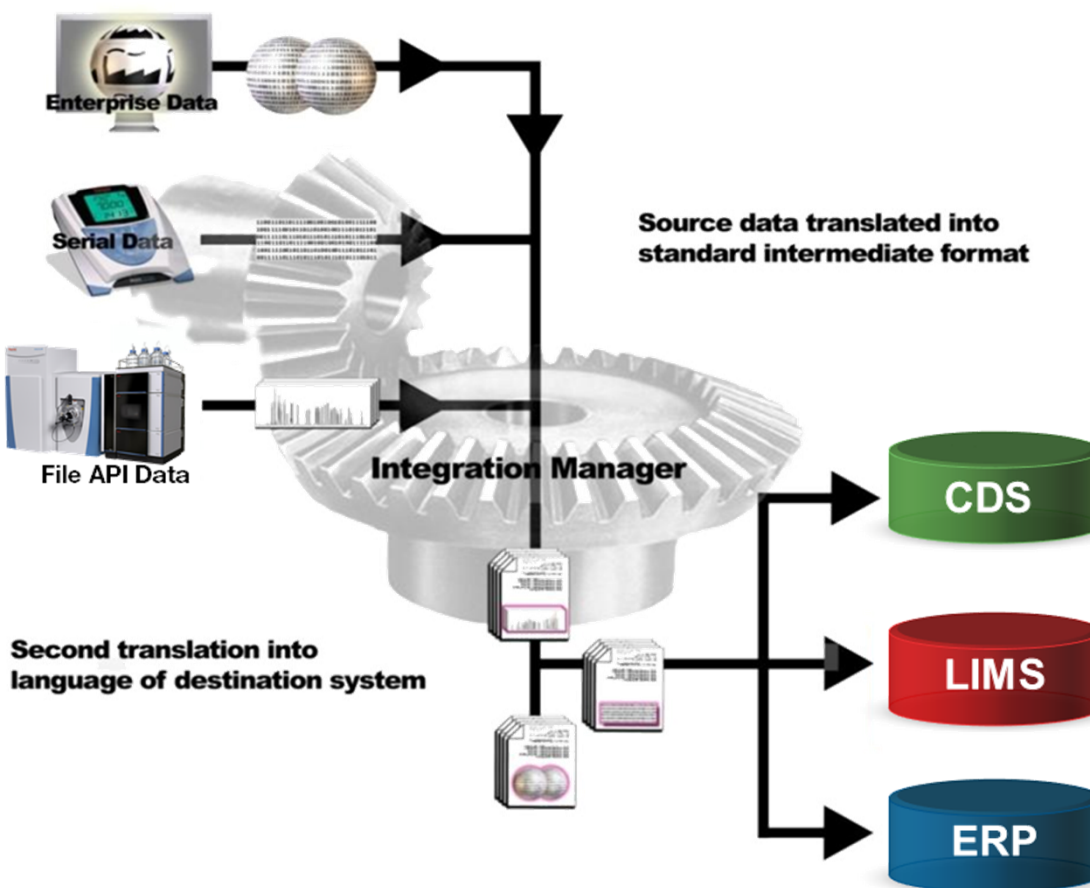
Provides secure, future-proofed data archival and management



The diagram illustrates the integration of laboratory equipment, data management, and analysis software. At the top, three pieces of laboratory equipment are shown: a large white and black instrument, a smaller white instrument, and a rack of blue and white sample bottles. Below these, a large, semi-transparent gear is overlaid with the text **XML Conversion** and **Data Management**. In the center, a magnifying glass is positioned over a computer screen displaying the 'Exploring - Aliquot-05-07-2006 (1)' window. The screen shows a file explorer view with a 'New' button and a 'DM2' button. A white arrow points from the 'DM2' button to the 'XML Conversion' text. Below the magnifying glass, another computer screen displays the 'GRAVITY - [Linked Data Viewer - 1]' window, showing a chromatogram plot with a peak at 1.012 minutes. A white arrow points from the 'Seamless Data Access' text to this plot. The text **Seamless Data Access** is located at the bottom right of the diagram.

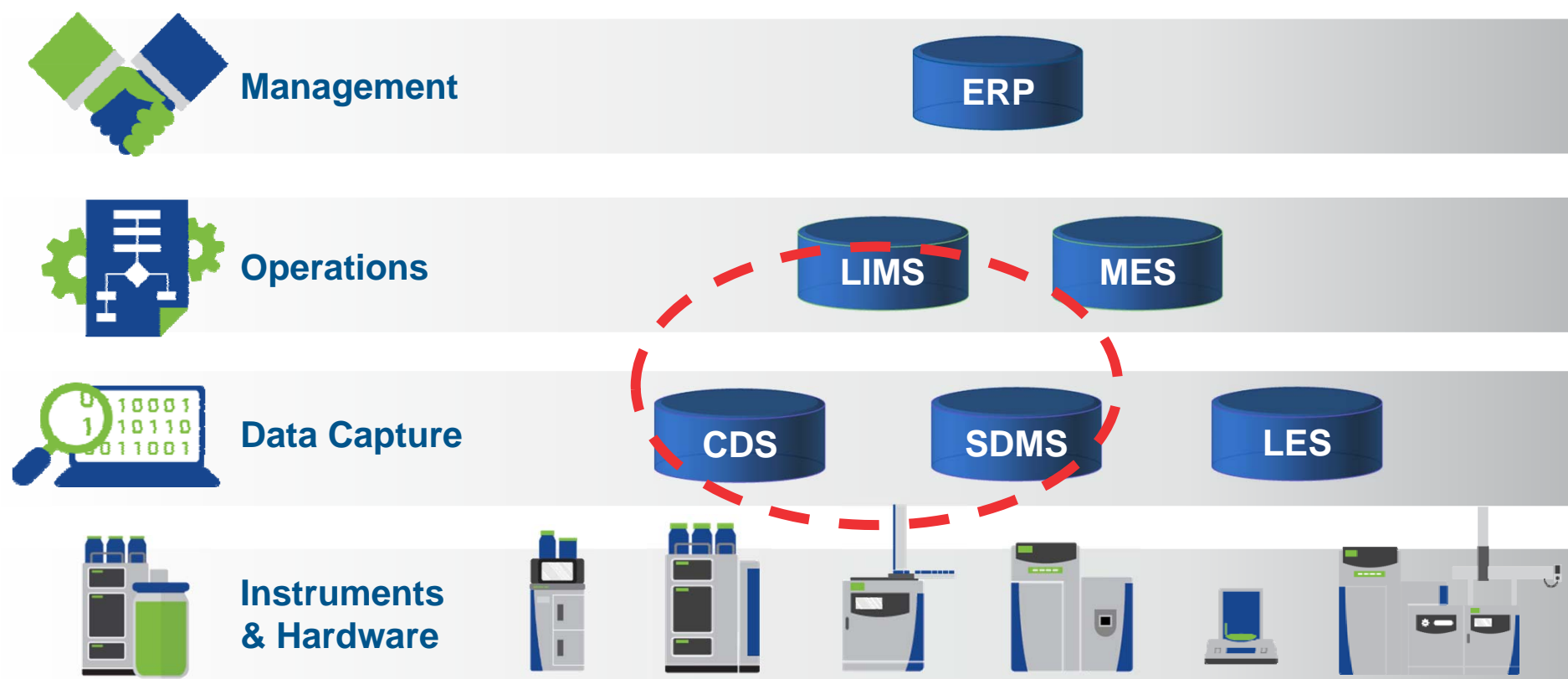
Thermo Fisher Integration Manager Software

Provides bi-directional interfaces between CDS, LIMS, instruments and Enterprise systems



More Than a CDS

What if you don't have all this infrastructure
but still need more than a CDS?



Thermo Scientific Chromeleon XTR: Laboratory Management System

Chromeleon Just Got Smarter!

- ✓ Management and tracking of all samples in the lab
- ✓ Secure, compliant control of all analytical data including SDMS
- ✓ Calibration and service records for all instruments
- ✓ Training record management for all users
- ✓ Built on superior compliance capabilities of Chromeleon 7.2 CDS



Scalable Portfolio of Enterprise Software

Chromeleon CDS



Chromatography & Mass Spectroscopy

Designed for 24/7 operations
Advanced automation for better quality results
Multi-vendor, multi-technique
Support MS for development & QA/QC workflows

NEW!

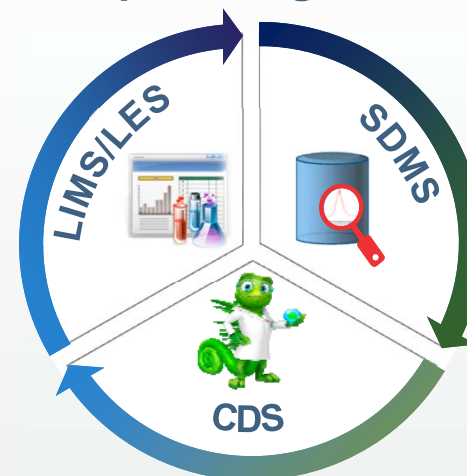
Chromeleon XTR



Chromeleon + Basic Lab Management + SDMS

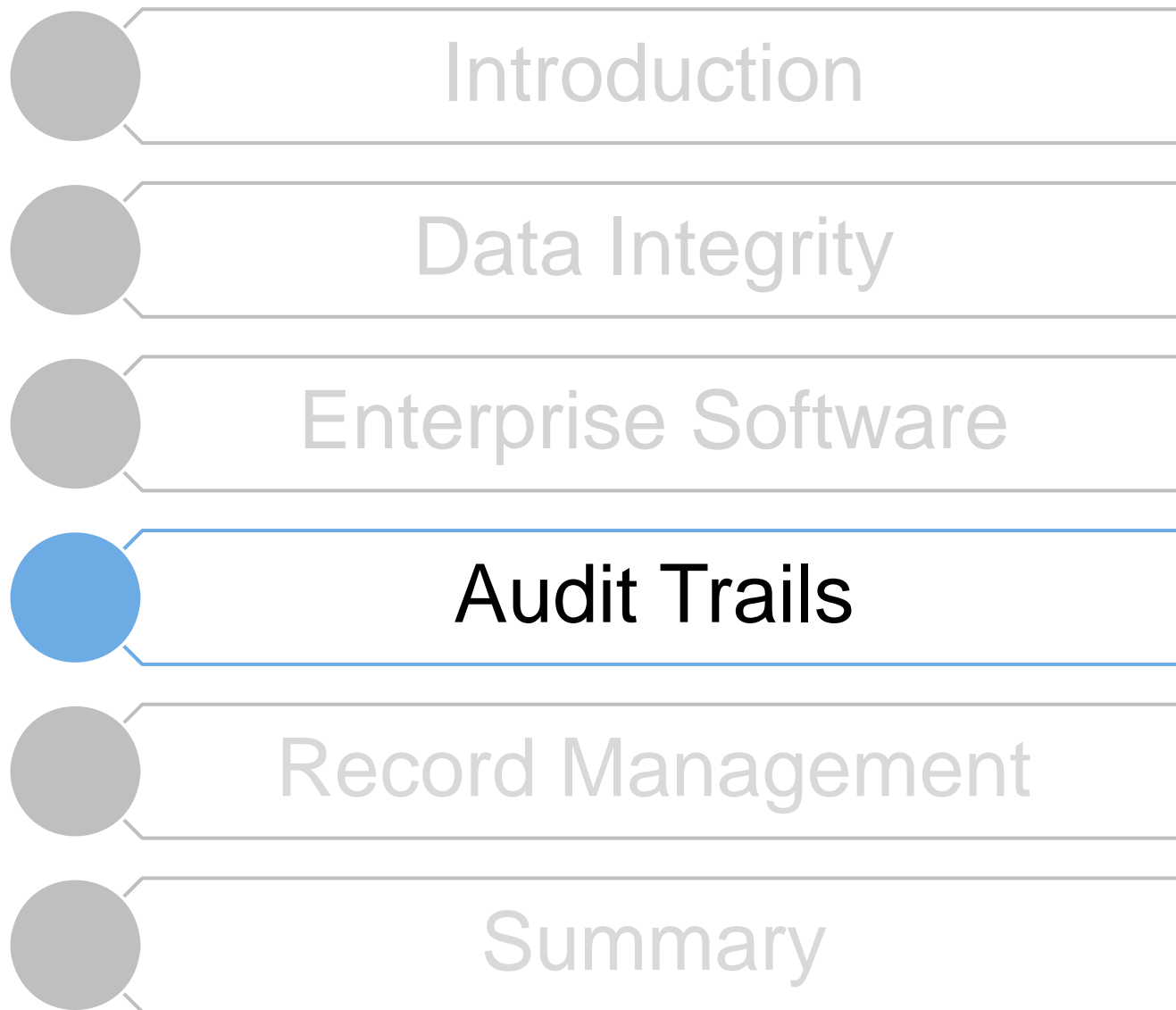
Basic sample management and tracking
Analyses can only be performed by authorized, trained individuals on calibrated instruments
Long-term data storage and archival of data regardless of instrument type

Chromeleon CDS & SampleManager LIMS



Complete Laboratory Management

Comprehensive sample, test & result management
Management of lab personnel & resources
Specification management and ERP integration
Laboratory Execution System
Configurable to meet your end to end business process



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.
 - 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.



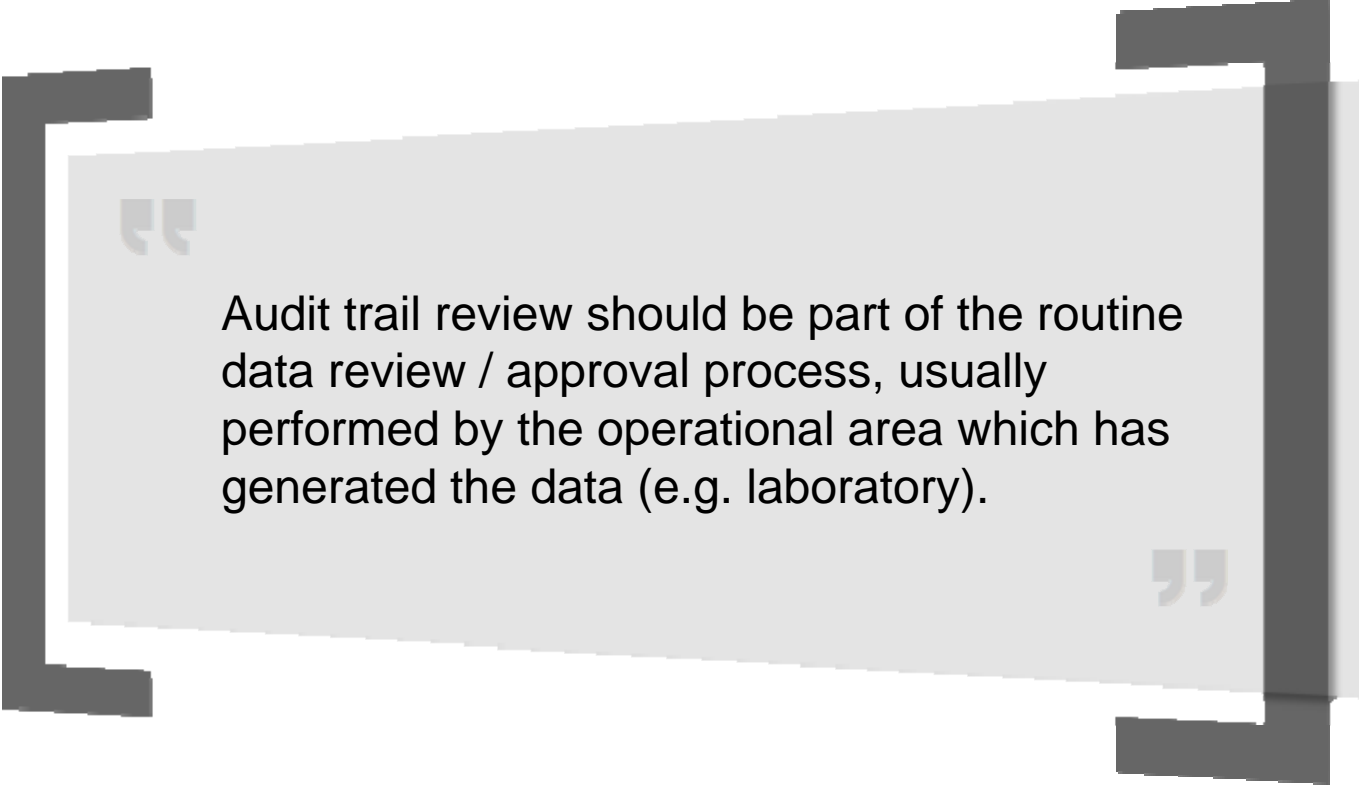
Chronology of the “who, what, when, and why” of a record

Audit Trails

- Audit Trails are critical requirement of electronic record regulations that:
 - Enable detection of non-desirable activity by users
 - Provide management with a tool that influences users' behavior (based on the degree of review of audit trails)
 - Ensure data integrity
- Regulators use audit trails to review the honesty and trustworthiness of data that is being presented to them
- Regulators are aware of available audit trails and expect to see that audit trails are:
 - Enabled
 - Configured correctly

Audit Trail Review: Data

- Revised Annex 11 introduced concept that audit trails should be reviewed



“
Audit trail review should be part of the routine data review / approval process, usually performed by the operational area which has generated the data (e.g. laboratory).
”

Audit Trail Review: Frequency

- WHO Guidance: audit trail review based upon a documented and justified risk assessment

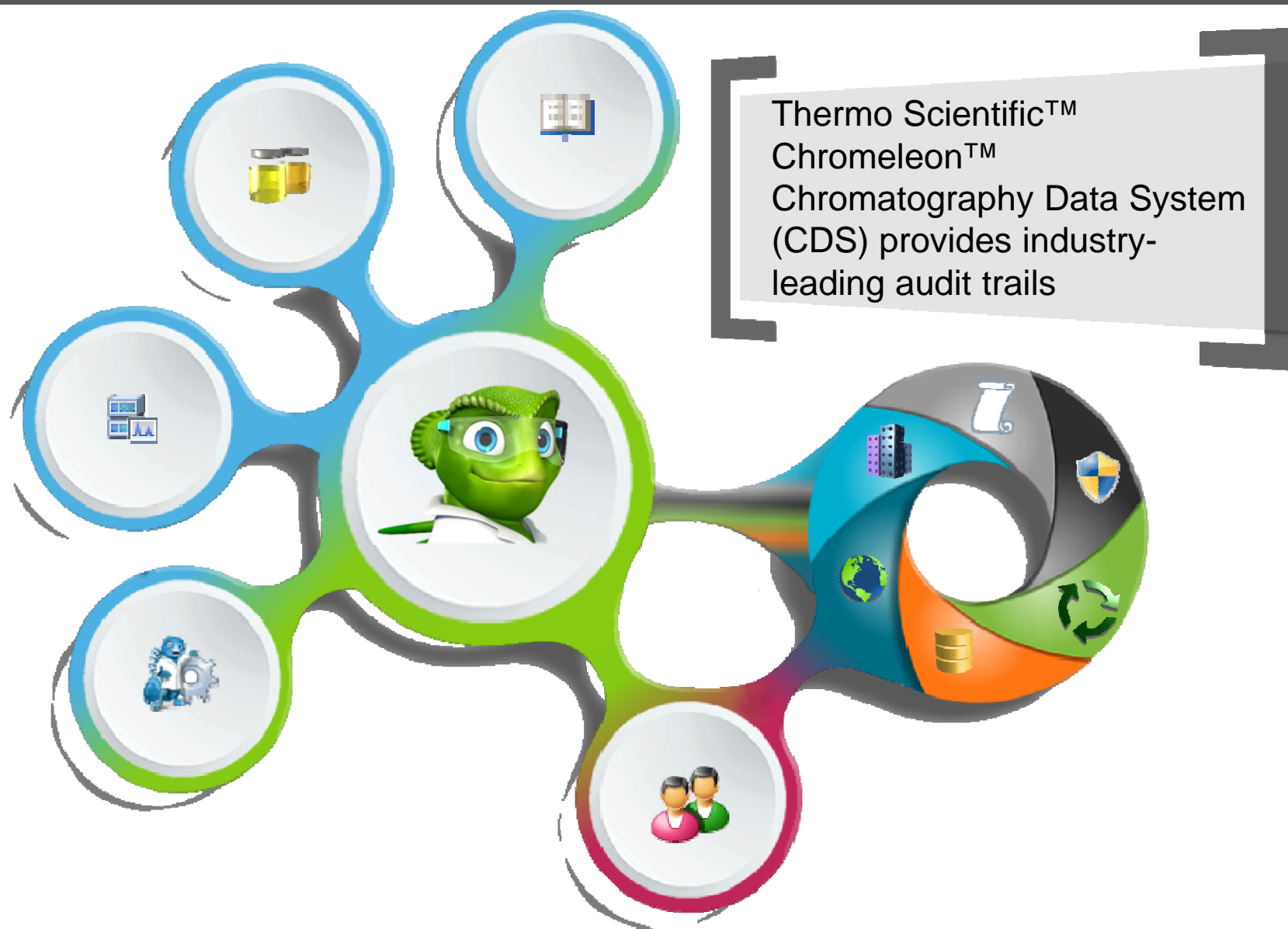
“

an organization may justify periodic review of audit trails that track system maintenance activities

Whereas audit trails that track changes to critical GxP data with direct impact on patient safety or product quality would be expected to be reviewed each and every time

”

Audit Trails in Chromeleon CDS



Data Audit Trail

Data Audit Trail

- Log of changes to Data Vault (DV)
- Separate data audit trail maintained per DV & per data object (folder, sequence, injection, etc.) in DV.

Data Audit Trail - WIN-DV\CM7SQLDV

Report Show Changes Restore Include Subfolders from 5/11/2017 to 5/14/2017 Filtering Grouping Find Next

#	Name	Type	Version	Date / Time	Operator	Operation	Comments
19	Vitamin_E	Instrument Method	1	5/14/2017 2:15:17 PM +01:00	charlie	Copied	copied instrument method
18	New Project	Folder	1	5/14/2017 2:03:46 PM +01:00	inewton	Moved	folder created in error
17	New Project	Folder	1	5/14/2017 2:02:25 PM +01:00	jmaxwell	Created	
16	Ibu Assay 14 May 2017	Sequence	1	5/14/2017 2:00:54 PM +01:00	jmaxwell	Moved	moved sequence to relevant location
15	Ibu Assay 14 May 2017	Sequence	1	5/14/2017 1:44:33 PM +01:00	jsmith	Save As	created new sequence via save as
14	\$RecycleBin\$	Folder	1	5/14/2017 12:55:37 PM +01:00	jsmith	Created	
13	Default MS Report	Report Template	1	5/14/2017 12:40:54 PM +01:00	charlie	Moved	moved Default MS Report sheet to relevant l
12	Default MS Report	Report Template	1	5/14/2017 12:38:58 PM +01:00	charlie	Created	
11	Dissolution Templates	eWorkflow	1	5/14/2017 12:33:35 PM +01:00	charlie	Created	imported Dissolution eWorkflow
10	Environmental Workflow Templates - Daily Anal	eWorkflow	1	5/14/2017 12:32:56 PM +01:00	charlie	Created	imported Environmental Analysis eWorkflow
9	GPC	Folder	1	5/12/2017 8:32:30 AM +01:00	charlie	Created	Imported from "C:\Users\administrator.CM7V
8	Spectra	Folder	1	5/12/2017 8:23:12 AM +01:00	charlie	Created	Imported from "Iwin-hpv\Software\Thermo\Sy
7	MSData	Folder	1	5/12/2017 8:13:25 AM +01:00	charlie	Created	
6	ICH	Folder	1	5/11/2017 5:14:54 PM +01:00	charlie	Created	
5	Site_B	Folder	1	5/11/2017 5:14:29 PM +01:00	charlie	Created	
4	Site_A	Folder	1	5/11/2017 5:03:10 PM +01:00	charlie	Created	
3	Data	Folder	1	5/11/2017 4:40:49 PM +01:00	charlie	Created	
2	CM7SQLDV	Data Vault	1	5/11/2017 4:12:54 PM +01:00	charlie	Changed	
1	CM7SQLDV	Data Vault	1	5/11/2017 2:12:30 PM +01:00	charlie	Created	

Data Audit Trail

Data Audit Trail

- Log of changes to Data Vault (DV)
- Separate data audit trail maintained per DV & per data object (folder, sequence, injection, etc.) in DV.

Changes of Instrument Method 'Vitamin_E' version 1 vs. version 5

Report Display All Properties

Version	Date/Time	Operator	Operation	Comment
1	5/11/2017 5:30:23 PM +01:00	charlie	Created	Imported from 'C:\User\edited instrument met
5	5/14/2017 2:19:38 PM +01:00	charlie	Changed	

Overview Script Smart Startup/Shutdown/Standby

Version 1

Time	Symbol	Value
Initial Time	Instrument Setup	
	Sampler.AcquireExclusiv...	On
	ColumnOven.TempCtrl	30.0 [°C]
	ColumnOven.Temperatur...	85.0 [°C]
	ColumnOven.Equilibra...	0.5 [min]
	ColumnOven.ReadyTem...	5.0 [°C]
	ColumnOven.Column_A...	No
	PumpModule.Pump.Pres...	15 [psi]
	PumpModule.Pump.Pres...	5802 [psi]
	PumpModule.Pump.Maxi...	1.500 [ml/min]
	PumpModule.Pump.Maxi...	3.000 [ml/min]
	PumpModule.Pump.% A...	""A"
	PumpModule.Pump.% B...	""B"
	Sampler.DrawSpeed	10.000 [µl/s]
	Sampler.DrawDelay	5000 [ms]
	Sampler.DispSpeed	20.000 [µl/s]
	Sampler.DispenseDelay	0 [ms]
	Sampler.WasteSpeed	32.000 [µl/s]
	Sampler.InjectWash	NoWash
	Sampler.PunctureOffset	0.0 [mm]

Version 5

Time	Symbol	Value
Log	System.Com...	
	Sampler.AcquireExclusiv...	On
	ColumnOven.TempCtrl	40.0 [°C]
	ColumnOven.Temperatur...	85.0 [°C]
	ColumnOven.Equilibra...	0.5 [min]
	ColumnOven.ReadyTem...	2.0 [°C]
	ColumnOven.Column_A...	No
	PumpModule.Pump.Pres...	15 [psi]
	PumpModule.Pump.Pres...	5802 [psi]
	PumpModule.Pump.Maxi...	3.000 [ml/min]
	PumpModule.Pump.Maxi...	3.000 [ml/min]
	PumpModule.Pump.% A...	""A"
	PumpModule.Pump.% B...	""B"
	Sampler.DrawSpeed	10.000 [µl/s]
	Sampler.DrawDelay	5000 [ms]
	Sampler.DispSpeed	20.000 [µl/s]
	Sampler.DispenseDelay	0 [ms]
	Sampler.WasteSpeed	32.000 [µl/s]
	Sampler.SampleHeight	3.000 [mm]
	Sampler.PunctureOffset	0.0 [mm]

Addition

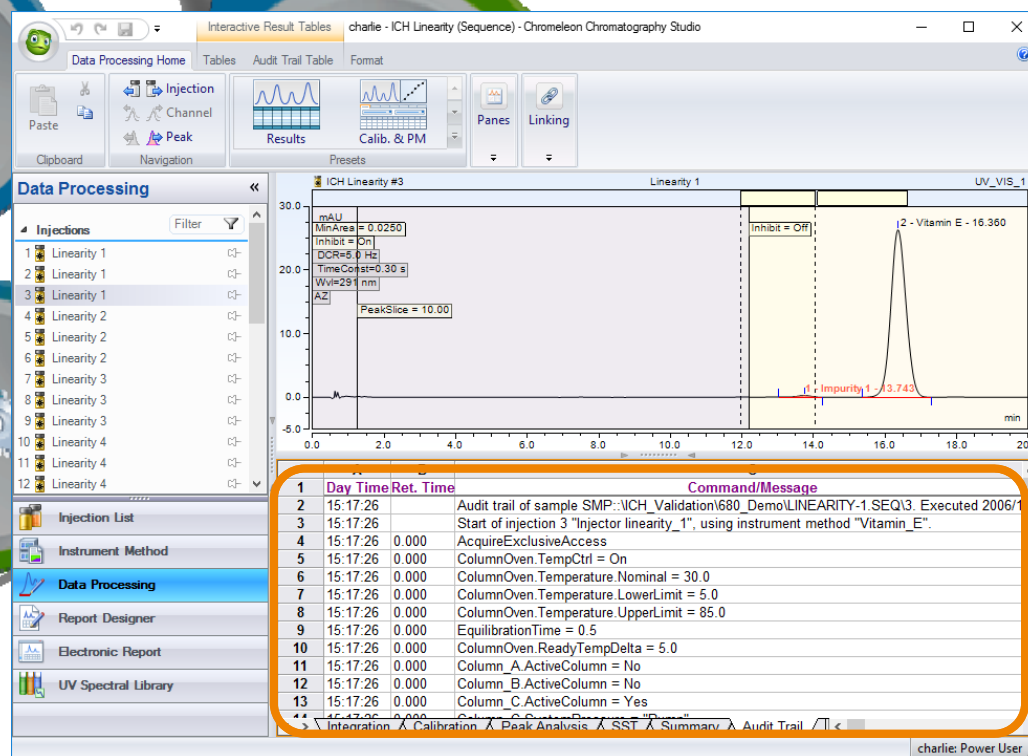
Change

Deletion

Injection Audit Trail

Injection Audit Trail

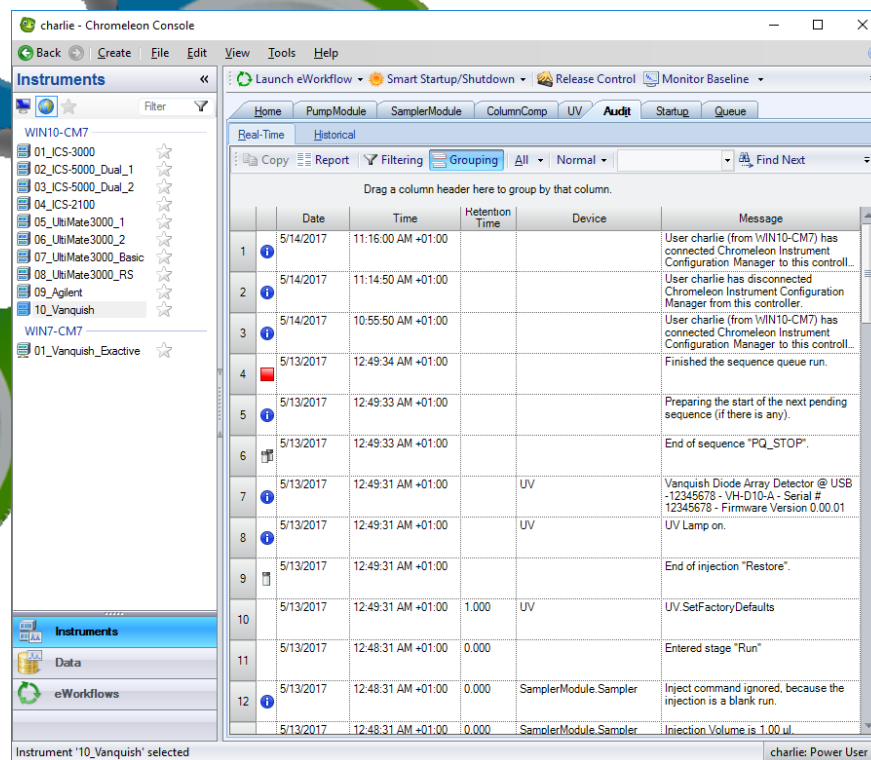
- Log of all information recorded in Instrument Audit Trail for specific injection



Injection Audit Trail

Instrument Audit Trail

- Daily event log per instrument
- Records all instrument operation events, e.g. system events, pre-run settings, commands & errors

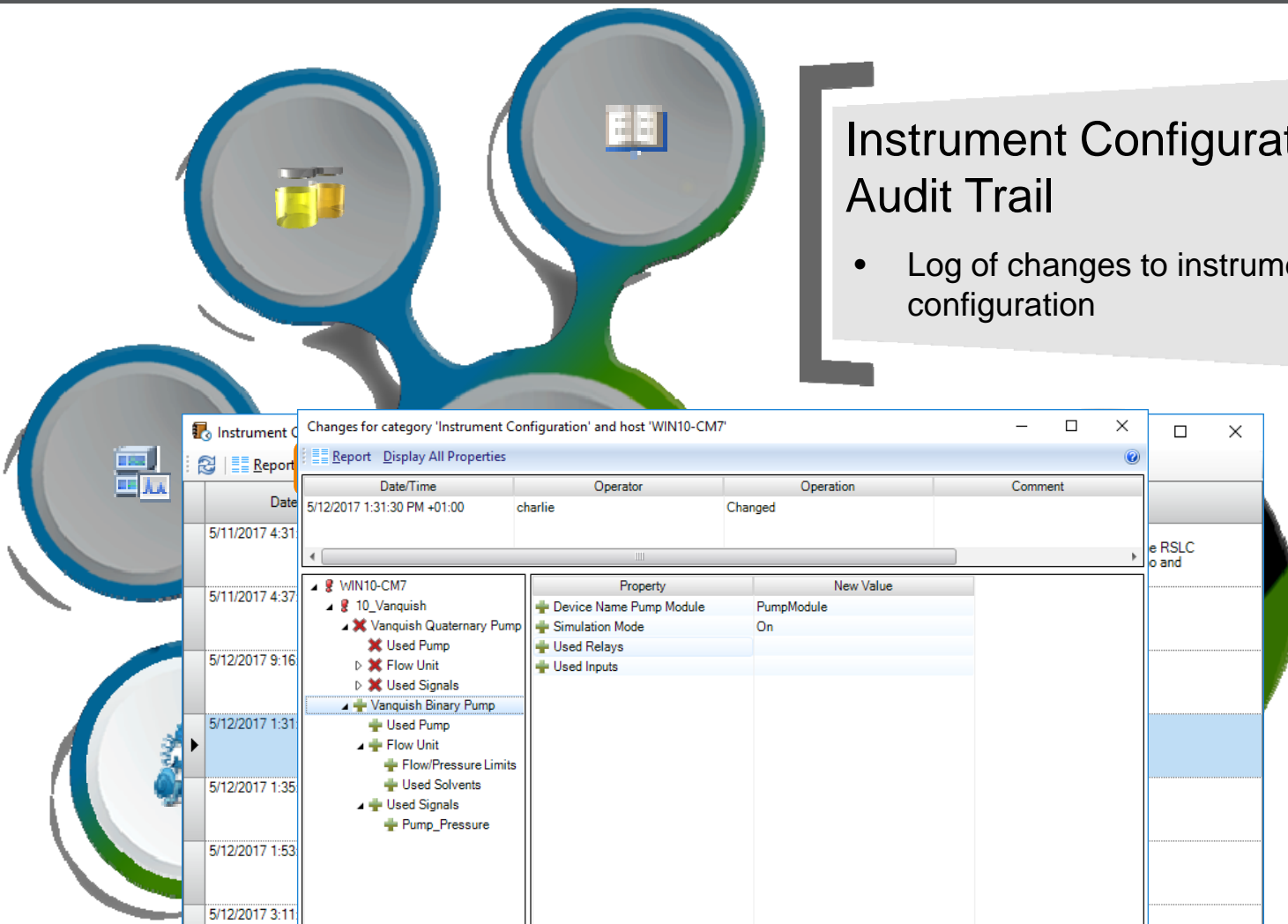


	Date	Time	Retention Time	Device	Message
1	5/14/2017	11:16:00 AM +01:00			User charlie (from WIN10-CM7) has connected Chromeleon Instrument Configuration Manager to this controll...
2	5/14/2017	11:14:50 AM +01:00			User charlie has disconnected Chromeleon Instrument Configuration Manager from this controller.
3	5/14/2017	10:55:50 AM +01:00			User charlie (from WIN10-CM7) has connected Chromeleon Instrument Configuration Manager to this controll...
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 - VH-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.

Injection Audit Trail

Instrument Configuration Audit Trail

- Log of changes to instrument configuration



Changes for category 'Instrument Configuration' and host 'WIN10-CM7'

Report Display All Properties

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

Property	New Value
Device Name Pump Module	PumpModule
Simulation Mode	On
Used Relays	
Used Inputs	

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

Injection Audit Trail

User Management Audit Trail

- Log of changes to user management

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 charlie

Injection Audit Trail

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

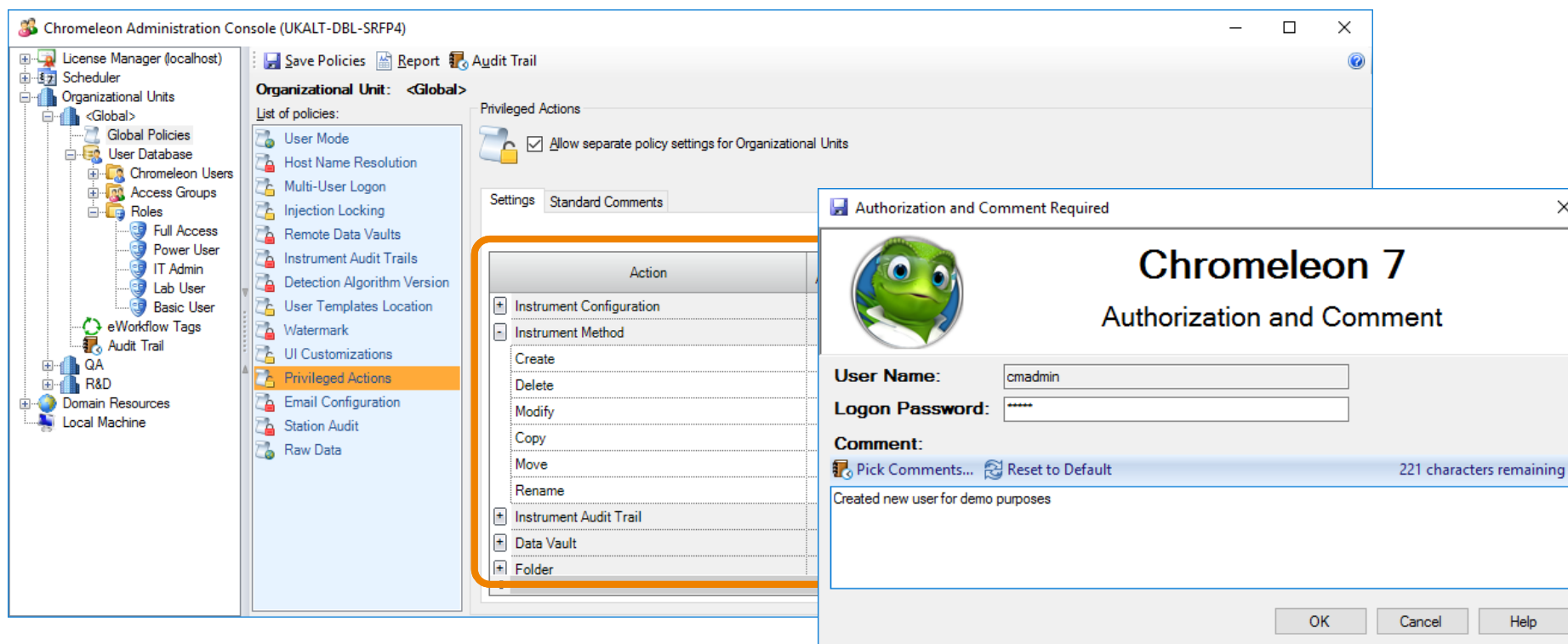
Audit Trail charlie

Injection Audit Trail



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



Audit Trails in SampleManager LIMS

- Similarly, SampleManager™ LIMS captures information about:
 - User Access (Logon/Logoff via the web or desktop clients including login failures)
 - Data changes (record insertion, record deletion, and field level modification)
 - Actions (who performed the action and when)

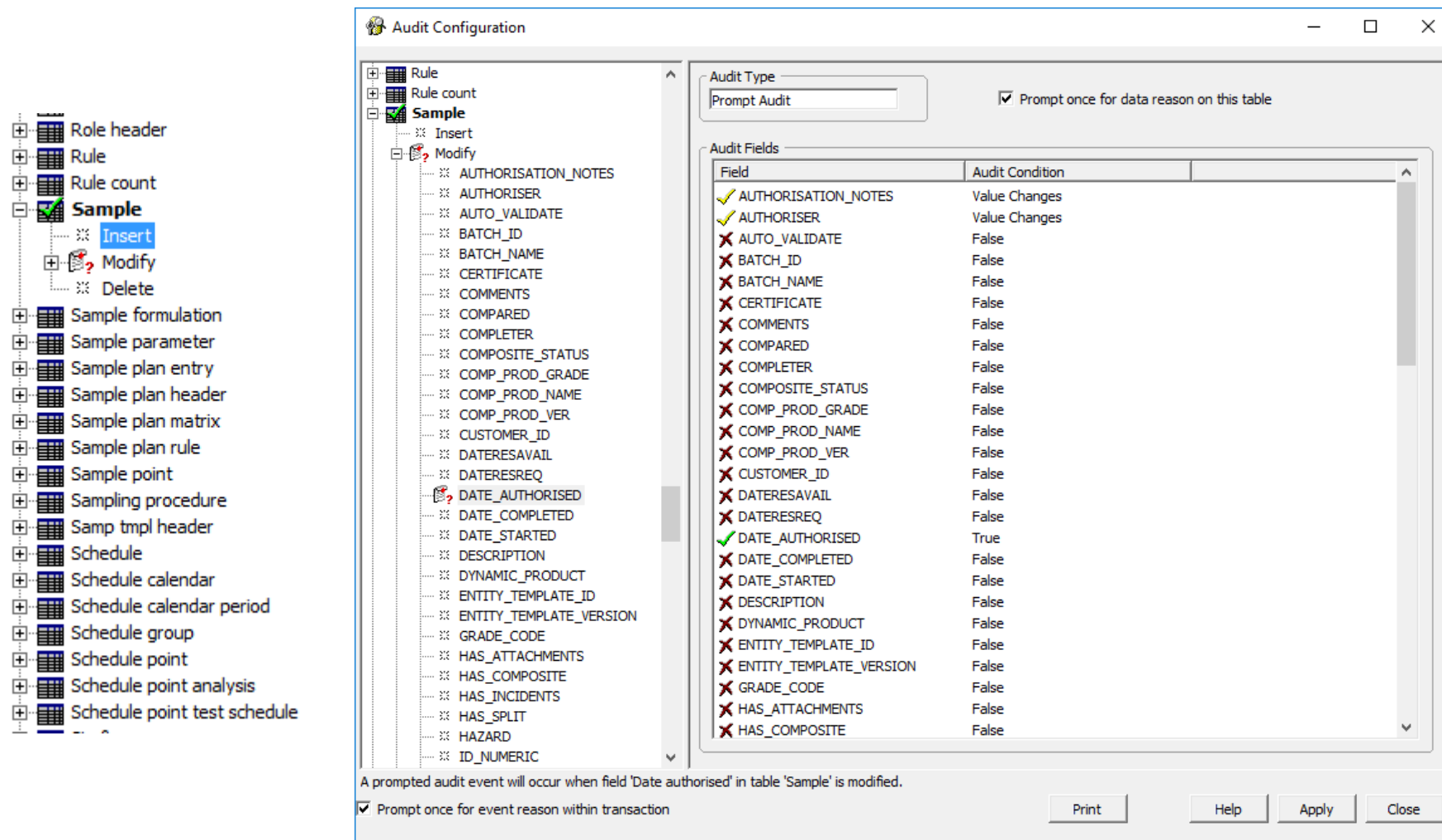
Example of the Access Log that captures all user session information

The screenshot shows the 'Access Log Viewer' application window. It contains a table with columns: Session, PID, Server Name, Server Date, Server Time, Client Name, Client OS User, Client Date, Client Time, and Action. The table lists various user sessions, including logins and failures. An 'Access Log Filters' dialog box is open over the table, allowing users to filter by Types (Fatal, Warning, Information) and Actions (Client login, Client login failure, Setup login, WEB login). The dialog also has fields for Server Dates (From and To) and buttons for OK, Help, and Cancel.

Session	PID	Server Name	Server Date	Server Time	Client Name	Client OS User	Client Date	Client Time	Action
33394	12112	UKALT-DEVDEMO1	25-JUL-2017	10:31:49.58	UKALT-2039HC2	katie.evans	25-JUL-2017	10:31:49.00	Client login
32848	8816	UKALT-DEVDEMO1	18-JUL-2017	10:22:11.36	UKALT-8R2NKC2	caroline.loveridge	18-JUL-2017	10:22:11.00	Client login
		DEVDEMO1	17-JUL-2017	17:54:01.38	UKALT-DEVDEMO1	User	17-JUL-2017	17:53:50.00	Client login
		DEVDEMO1	13-JUL-2017	13:54:44.00				08:54:45.00	Client login
		DEVDEMO1	4-JUL-2017	16:09:41.00				16:09:41.00	Client login
		DEVDEMO1	4-JUL-2017	15:11:10.00				15:11:10.00	Client login
		DEVDEMO1	28-JUN-2017	10:11:35.00				10:11:35.00	Client login
		DEVDEMO1	27-JUN-2017	16:34:21.00				11:34:21.00	Client login
		DEVDEMO1	23-JUN-2017	13:47:29.00				13:47:29.00	Client login
		DEVDEMO1	23-JUN-2017	13:44:54.00				13:44:54.00	Client login
		DEVDEMO1	22-JUN-2017	15:07:03.00				15:07:03.00	Client login
		DEVDEMO1	22-JUN-2017	14:40:04.00				14:40:04.00	Client login
		DEVDEMO1	22-JUN-2017	14:37:36.00				14:37:36.00	Client login
		DEVDEMO1	22-JUN-2017	14:33:19.00				14:33:19.00	Client login failure
		DEVDEMO1	22-JUN-2017	14:31:12.00				14:31:12.00	Client login
		DEVDEMO1	22-JUN-2017	14:31:03.00				14:31:03.00	Client login
		DEVDEMO1	21-JUN-2017	09:46:04.00				09:46:04.00	Client login
		DEVDEMO1	19-JUN-2017	14:39:10.00				14:39:10.00	WEB login
		DEVDEMO1	19-JUN-2017	14:23:00.00				14:23:00.00	WEB login
		DEVDEMO1	19-JUN-2017	14:22:08.00				14:22:08.00	WEB login
		DEVDEMO1	19-JUN-2017	14:21:14.00				14:21:14.00	WEB login
		DEVDEMO1	19-JUN-2017	14:19:56.00				14:19:56.00	WEB login
		DEVDEMO1	19-JUN-2017	14:19:56.00				14:19:56.00	WEB login

Data Audit Trails in SampleManager LIMS

- Audit trails offer the ability to log any data change within SampleManager LIMS



Data Audit Trails in SampleManager LIMS

- Captured audit records can be displayed system wide for the different entities or by particular users, or can be seen on the entity Property Sheet

The screenshot displays the SampleManager LIMS interface. On the left, the 'Audit Explorer' tree shows a hierarchy of entities: Operators (SM39QUSER, SYSTEM, USERA), Tables, and Instrument (01ICS_3000, 123INST, 47HINSA01, AB_01). The 'AB_01' entity is selected, showing its audit trail in the 'Transaction' pane. The 'Transaction' pane shows details for Transaction 7, System PID 2492, User ID SYSTEM, Name 'ProcedureNum 77, ActionType MODIFY, TaskName InstrumentTask', and Date '16-MAR-2017 13:55:17.82'. The 'Event' pane shows Table ID 'INSTRUMENT', Action 'MODIFY', Record key 'AB_01', and Reason. The 'Data' pane shows a table of field changes.

Field	Old Value	New Value	Reason
* IDENTITY	AB_01	AB_01	
* GROUP_ID			
* DESCRIPTION	TABERý Ro...	TABERý Ro...	
* MODIFIABLE	TRUE	TRUE	
* MODIFIED_ON	16-MAR-20...	16-MAR-20...	
* MODIFIED_BY	SYSTEM	SYSTEM	
* REMOVEFLAG	FALSE	FALSE	
* MANUFACTURER	TABER	TABER	
* INSTTYPE_ID			
* INSTRUMENT_T...	PHYS-TEST	PHYS-TEST	
* SERIAL_NO	k345jlk	k345jlk	
* INSTRUCTIONS			
* LOCATION_ID	LAB_01	LAB_01	
* SOP_REFERENCE	SOP_251	SOP_251	
* AVAILABLE	TRUE	TRUE	
* RETIRED	FALSE	FALSE	

The 'Properties - AB_01' dialog box is open, showing the 'Audits' tab. It displays a table of audit records:

User	Date	Transaction	Action	...
System Manager	16/03/2017 13:53	Load 'INSTRUMENT	...	INSERT
System Manager	16/03/2017 13:55	ProcedureNum 77, ActionTy...	MODIFY	
System Manager	13/06/2017 17:08	ProcedureNum 77, ActionTy...	MODIFY	

A yellow callout box points to the 'Recreate Data' button in the bottom left corner of the 'Audit Explorer' pane, with the text: 'Changes can be rolled back'.

Data Audit Trails in SampleManager LIMS

- Creation of Audit Trails during the execution of Result Entry

The screenshot displays the 'Result Entry - SM-11-OCT-2020-000099' window. On the left, a tree view shows the sample hierarchy. The main table lists analysis results. An audit trail window is open, showing the change from 12 to 14 for 'Instrumental colour'.

Analysis	Component Name	Type	Value	Units	Status
COL_001/1	Colour matching	T	Complies		E
COL_002/1	Instrumental colour	N			
COL_003/1	Instrumental colour	N	14		M
COL_004/1	D65 (artificial daylight)	T	15		M
	CIE Illuminant A tungsten filament lig	T	15		M
	TL84 (fluorescent light)	T			
GLOSS_001/1	Gloss 20 degrees	N	54		E
	Gloss 60 degrees	N	72		E
	Gloss 85 degrees	N	62		E

Level ID	Min	Date	Who	Previous Value	Audit Reason
		20-JUL-2017 21:55	SYSTEM	12	Audit Reason

Audit on Field VALUE within RESULT

Identity: 983Instrumental colour

Old Value: 12

New Value: 14

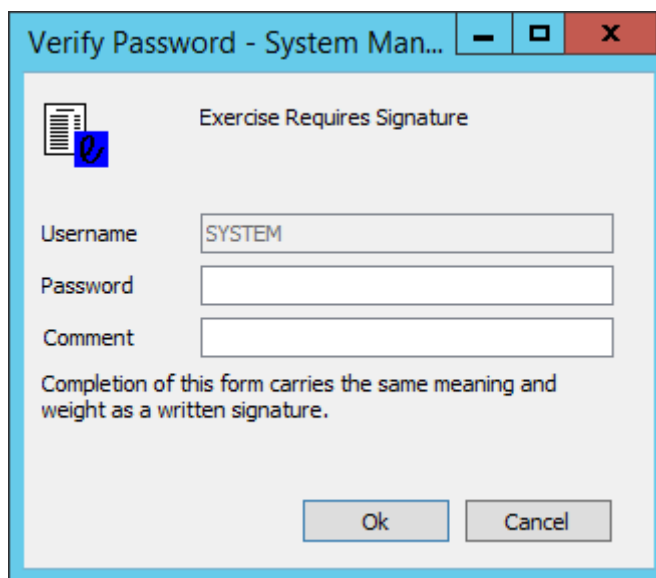
Reason: Audit Reason

Close

Audit records are visible in result entry

Action Audit Trails in SampleManager LIMS

- Privileged actions can be configured against any action to capture who performs that action and when
- A comment can be captured, which can be freeform or available as a drop-down picklist



Verify Password - System Man...

Exercise Requires Signature

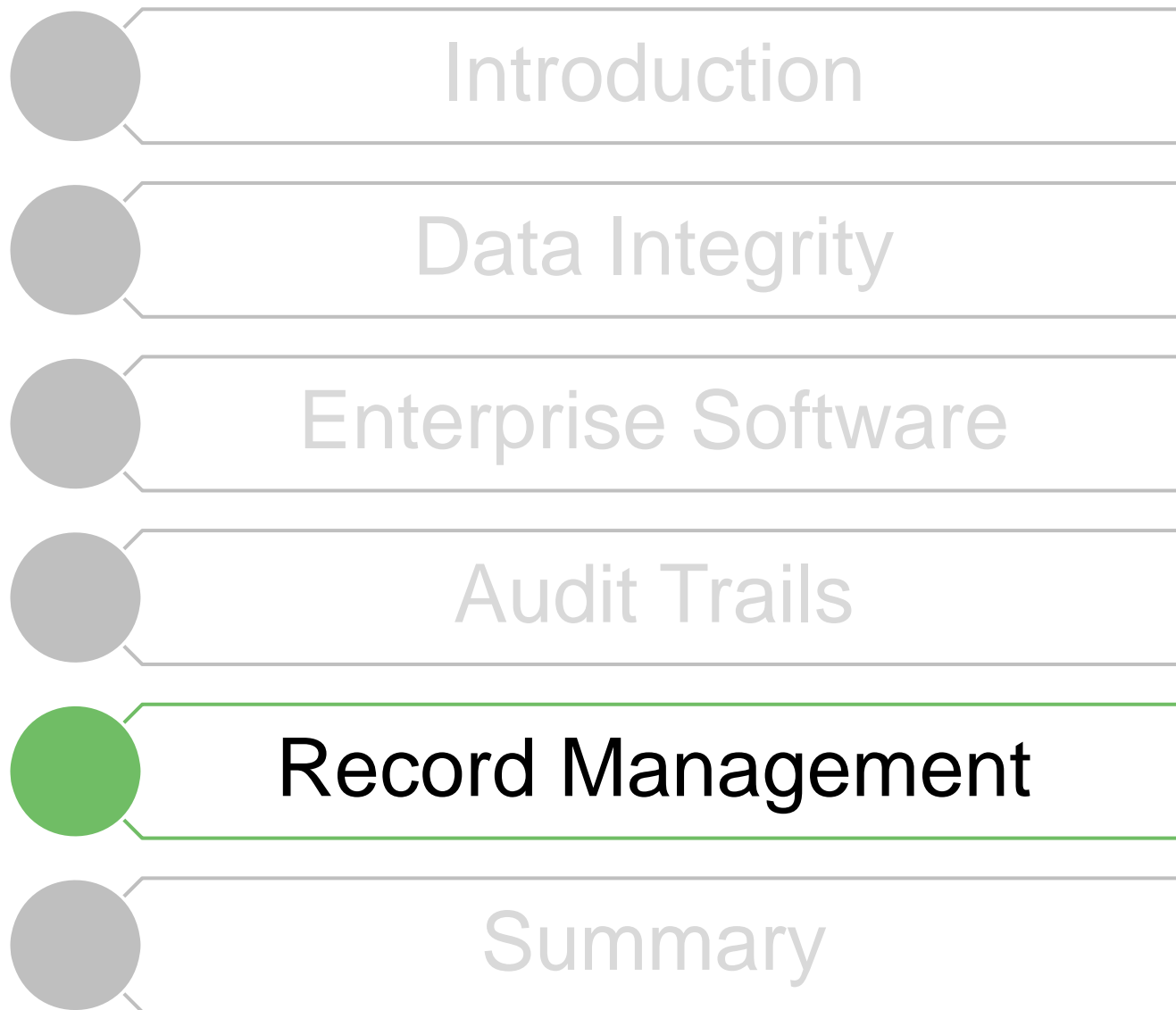
Username: SYSTEM

Password:

Comment:

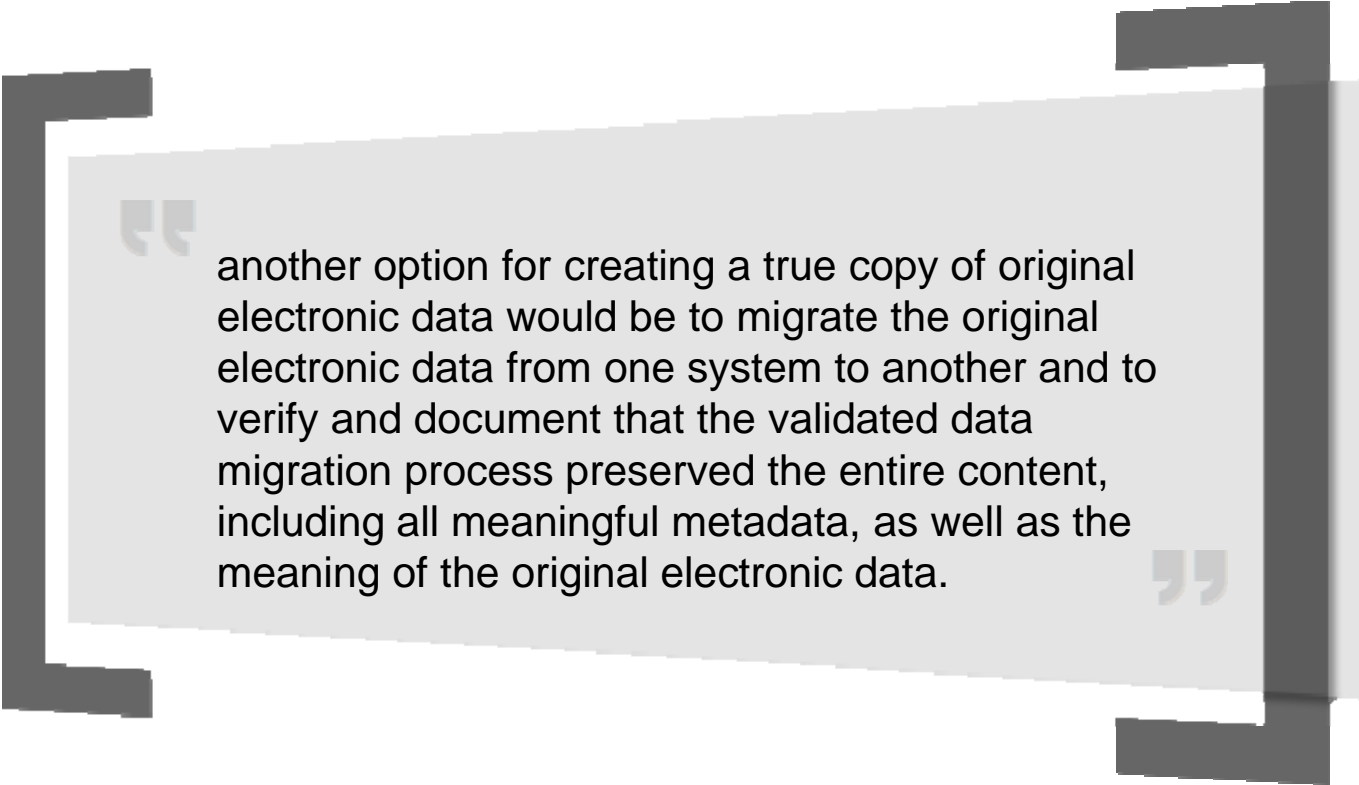
Completion of this form carries the same meaning and weight as a written signature.

Ok Cancel



Data and Record Management

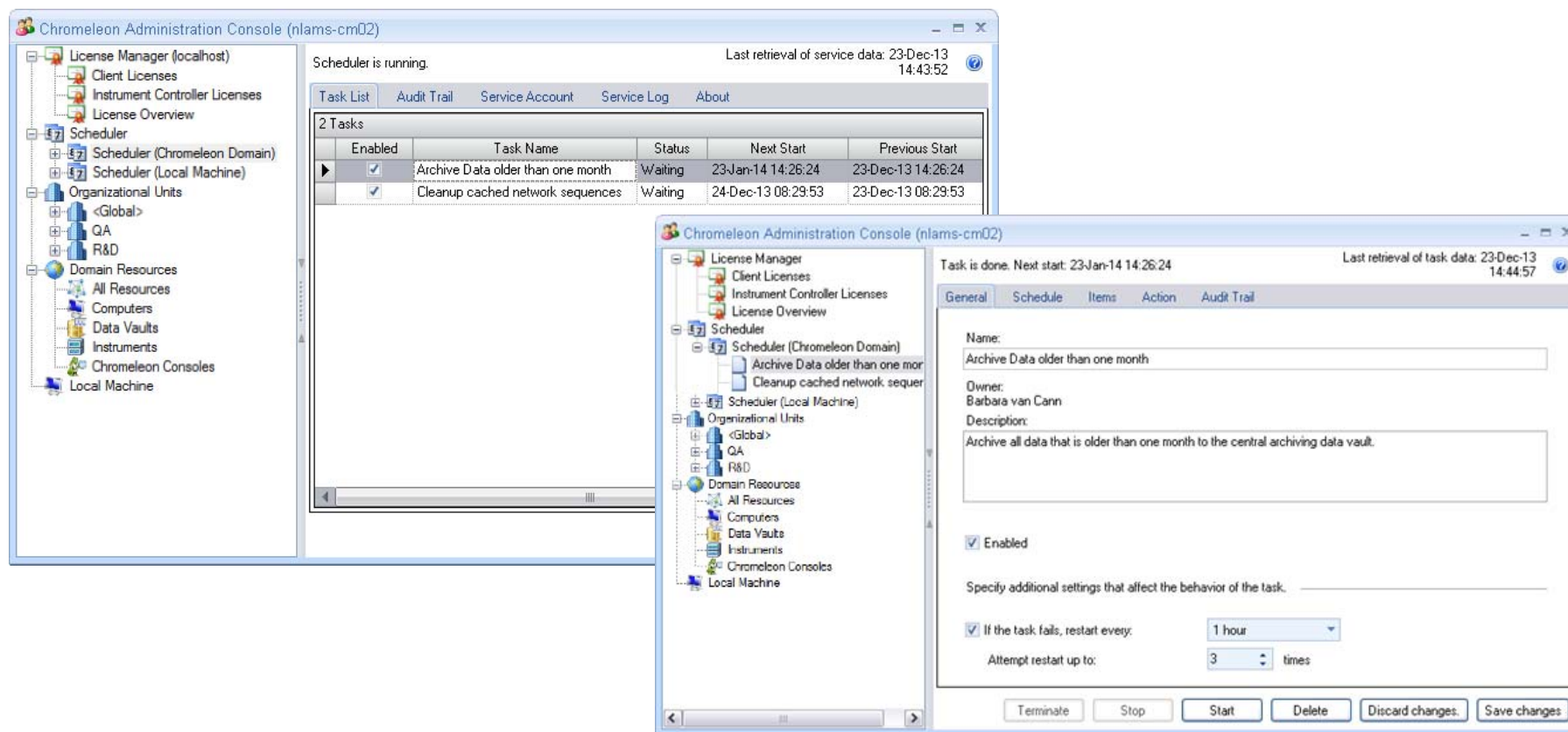
- WHO - Special risk management considerations for retention of original records and/or true copies



“another option for creating a true copy of original electronic data would be to migrate the original electronic data from one system to another and to verify and document that the validated data migration process preserved the entire content, including all meaningful metadata, as well as the meaning of the original electronic data.”

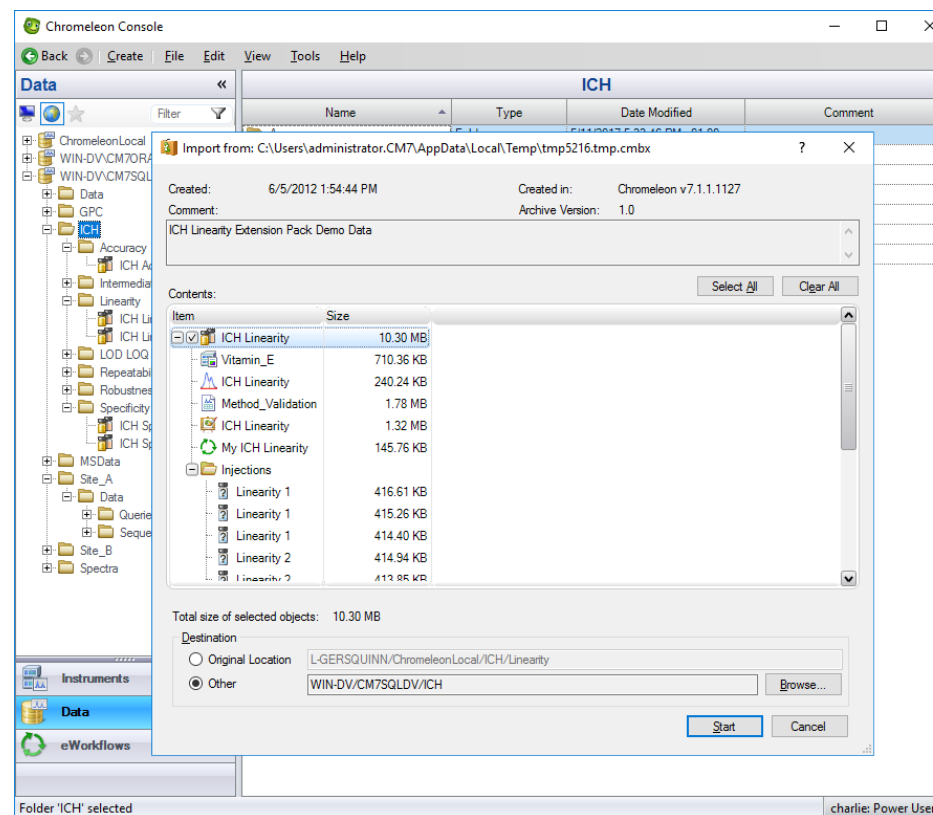
Administration Console - Scheduler

- Automatically copy/move data by combining powerful injection queries with the Scheduler
- Create true copies and simplify backup/archiving



Data Management – Import/Export

- Chromeleon CDS Data
 - cmbx files
 - cmb files
 - eWorkflows and ePanels
- Create true copies with metadata
- Quickly restored
- Bulk Imports
 - Chromeleon 7 CDS data file (*.cmbx)
 - Chromeleon 6 CDS data file (*.cmb)
 - AnDI file (*.cdf)
 - GAML file
 - Xcalibur Data
 - Atlas Workbook
 - ChemStation files



Data Management – Electronic Signatures

The screenshot displays the Chromeleon 7 interface. The main window is titled "jsmith - ICH Linearity (Sequence) - Chromeleon Chromatography Studio". The top menu bar includes "Home", "Update", "Review", "Remove", "Verify", "Print", "PDF Export", "Previous Injection", "Next Injection", "Previous Page", "Next Page", "Zoom", and "Zoom +". A yellow status bar at the top of the main window reads: "The sequence is signed. Modifications to the sequence are not possible."

The left sidebar contains a tree view with the following items: "Injections", "Injection List", "Instrument Method", "Data Processing", "Report Designer", "Electronic Report" (highlighted), and "UV Spectral Library".

The main window displays the "Electronic Report" for "Linearity Test 1". The report includes the following data:

Component Details	
Component Name	Impurity 1
Calibration Type	Lin. With Offset
Intercept	0.0229
Slope	74.1331
Min. Correlation Coefficient (Spec)	0.9995
Correlation Coefficient (actual)	0.9999
Correlation Coefficient (rounded)	Pass
Residual Sum of Squares	0.0010
Test Origin within CLT	Yes

The "Linearity Results" table is as follows:

No.	Name	RANGE_LEVEL	X Value	Y Value	Residual	Residual Squared
1	Linearity 1	10	0.0004	0.1005	-0.0118	0.0002
2	Linearity 1	10	0.0005	0.1006	-0.0117	0.0002
3	Linearity 1	10	0.0006	0.1007	-0.0116	0.0002
4	Linearity 2	80	0.0112	0.8112	-0.0008	0.0001
5	Linearity 2	80	0.0113	0.8113	-0.0007	0.0001
6	Linearity 2	80	0.0114	0.8114	-0.0006	0.0000
7	Linearity 3	70	0.0108	0.7108	-0.0004	0.0000
8	Linearity 3	70	0.0109	0.7109	-0.0003	0.0000
9	Linearity 3	70	0.0110	0.7110	-0.0002	0.0000
10	Linearity 4	100	0.0225	1.6225	-0.0004	0.0000
11	Linearity 4	100	0.0226	1.6226	-0.0003	0.0000
12	Linearity 4	100	0.0227	1.6227	-0.0002	0.0000
13	Linearity 5	150	0.0333	2.4333	-0.0004	0.0000
14	Linearity 5	150	0.0334	2.4334	-0.0003	0.0000

The "Submit Signature" dialog box is open, titled "Enter Chromeleon User Name And Signature Password". It features the Chromeleon 7 logo and the text "Submit Signature". The fields are:

- User Name: jsmith
- Signature Password: [masked]
- Comment: sequence complete and submitted for review and approval (200 characters remaining)

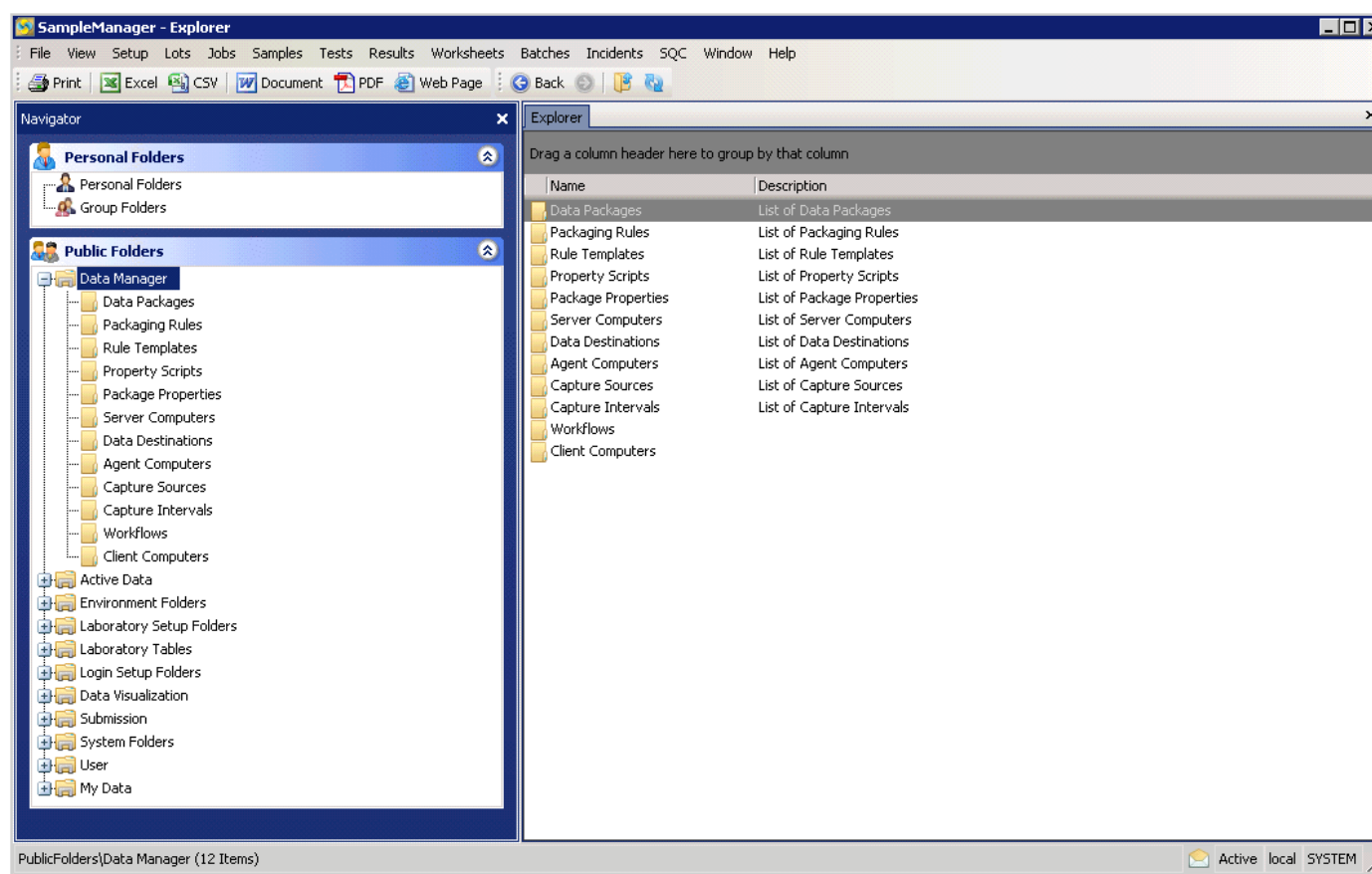
Buttons at the bottom include "OK", "Cancel", and "Help".

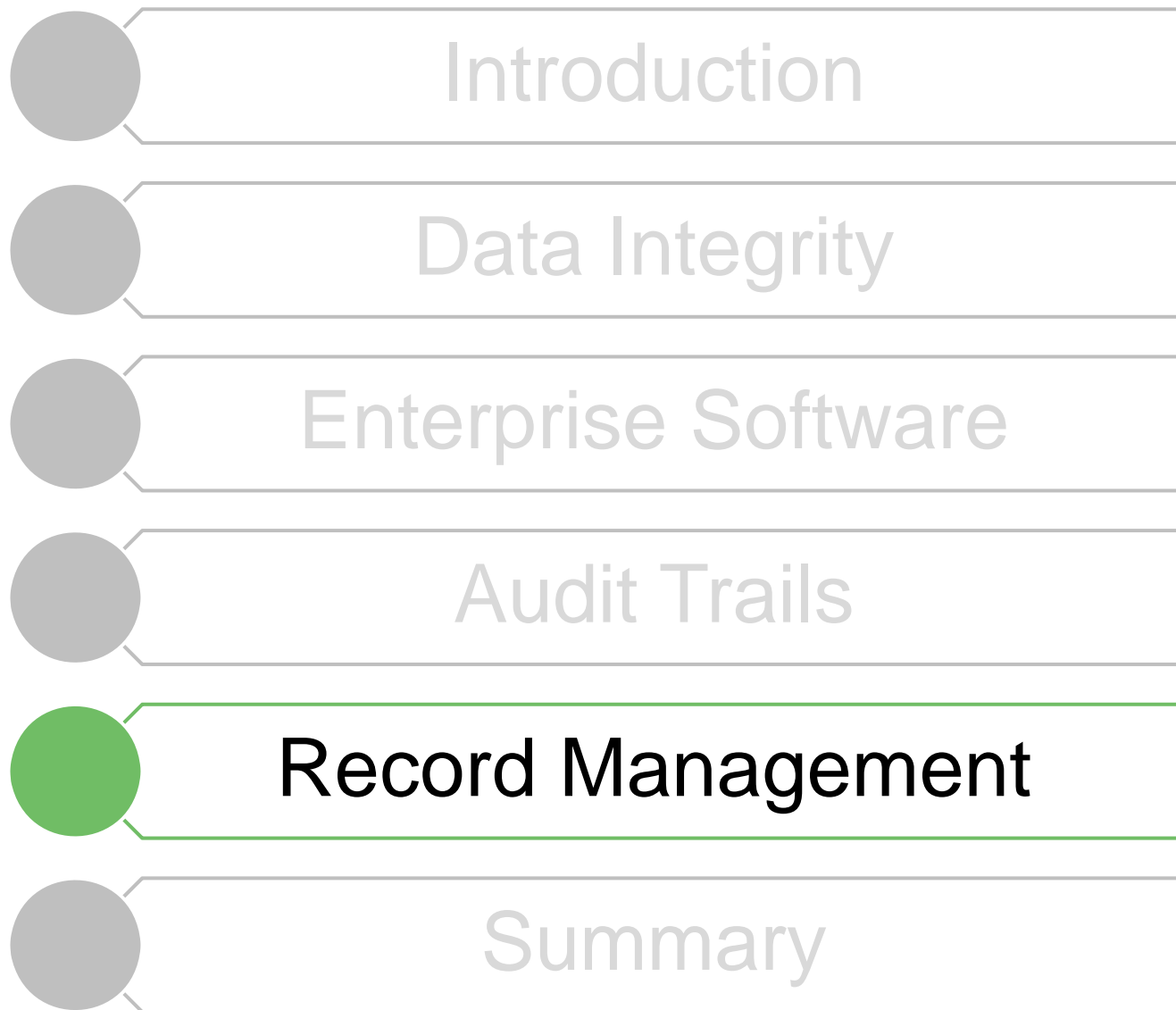
- Electronic Report
 - Snapshot in time of sequence
 - Any changes tracked
 - Can be sent for review
- Electronic Signatures
 - 3 Levels of signature Submit, Review, Approve
 - Applied to electronic report
 - Complete sequence protected by checksums
 - Controlled by privileges

Thermo Fisher Data Manager



More than SDMS!
Simply storing raw data is not enough – store it
against correct records for easy traceability





Summary

- Data integrity and compliance go hand-in-hand
 - Subject to elevated scrutiny by regulatory bodies
- Enterprise software with Chromeleon CDS and SampleManager LIMS meet 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

Connections...

For more information on Chromeleon software visit:

thermofisher.com/OneCDS

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



facebook.com/CharlieLovesChromatography

Thank you

Make Compliance A Competitive Advantage