



OpenLAB CDS and Data Integrity a practical approach

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Topics for today

Short overview of what is required

Solution provided in OpenLAB CDS 2

Short but comprehensive overview

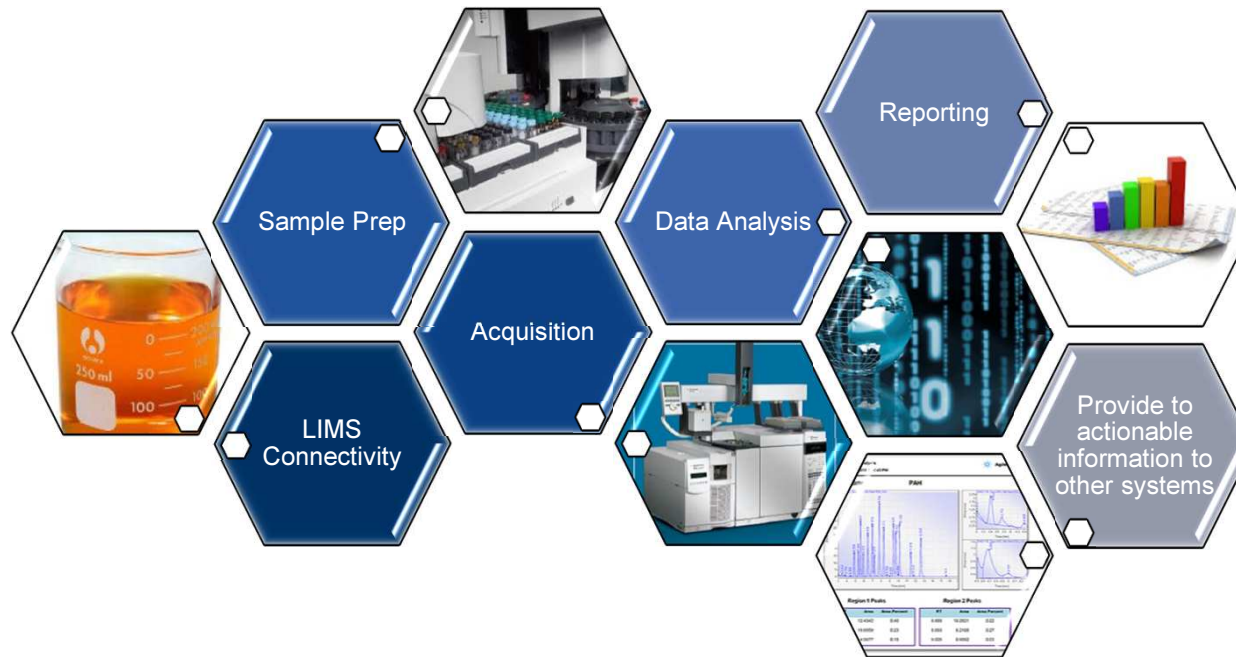
Conclusion

Q&A

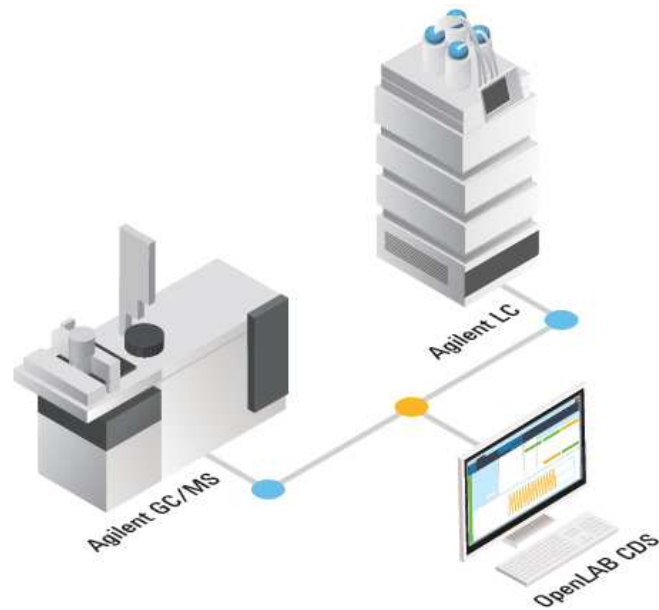


Next Evolution of OpenLAB CDS

“OpenLAB CDS 2.0 - One data system for chromatography and mass spectrometry – Agilent GC, LC, core MS along with third-party instruments.”



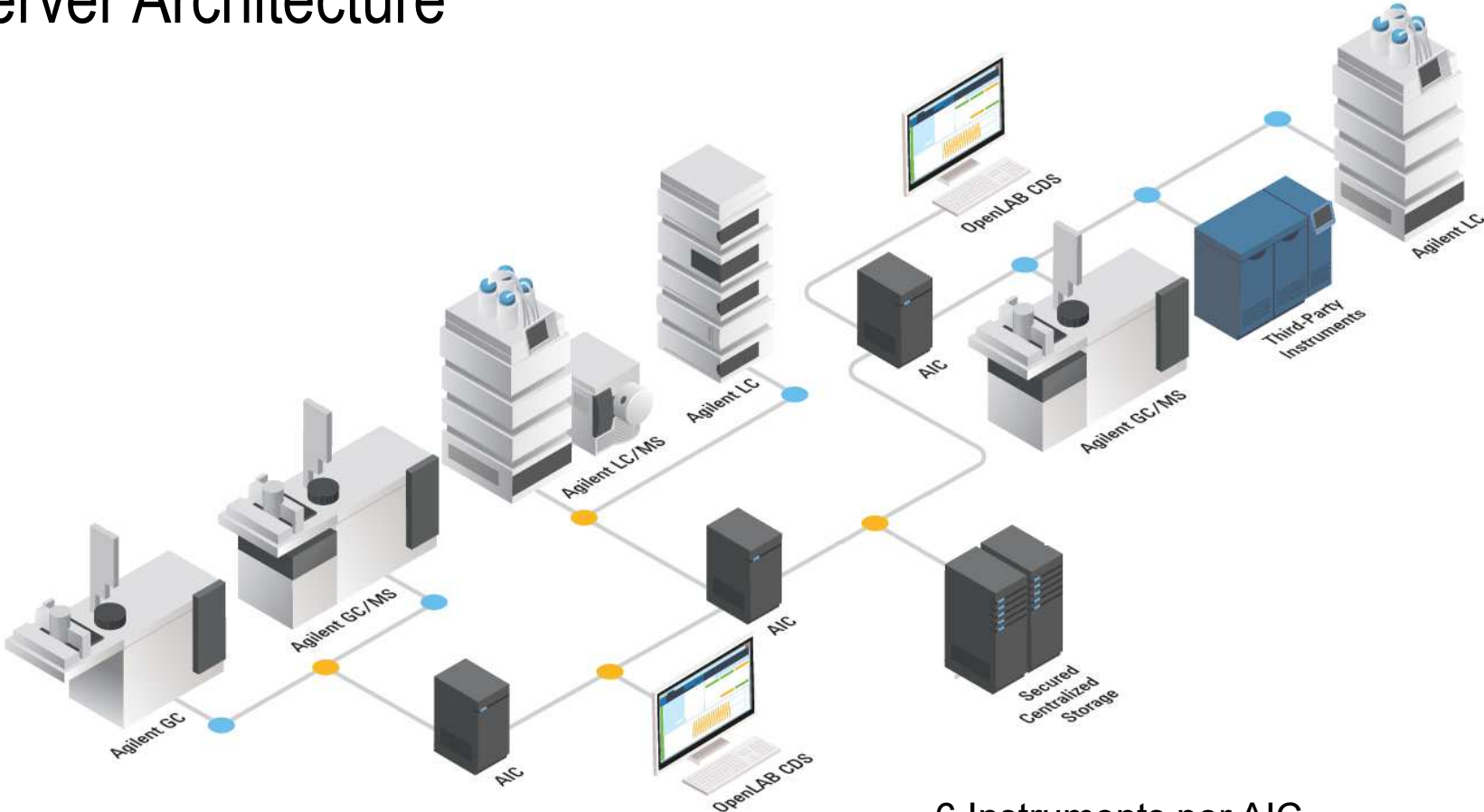
OpenLAB CDS 2.0 Workstation



M8410AA Werkstation en komt met 2 instrument licenties

4 * GC / LC or
1 * MS or
2 * 3D LC

Client/Server Architecture



6 Instruments per AIC
200+ instruments supported

Short overview

Integrity

Authenticity

Audit Trail and review

Electronic signatures

Log-on

Secured storage.

Solution provided in OpenLAB CDS 2

Integrity and authenticity

Secured and central storage

- File encryption
- Access control
- Built-in archiving
- Life cycle management
- Audit trail

We call it DataStore.



Solutions provided in OpenLAB CDS 2

Access control, *who can work with what*

Structure

- Projects
- Instruments
- Users
- Groups
- Roles

Define your structure and grant access rights and roles to users and/or groups

Note for companies:

When a lab person also is admin, take care that this person has 2 separate log-ons!!!



Solutions provided in OpenLAB CDS 2 Structure

Assigned users and groups

Name	Description
reviewer	first reviewer for results
operator1	Lab Technician
operator2	Lab technician
admin	System Administrator
Approver	2nd reviewer adn approver

Roles for reviewer

Name	Description
Data Store Approver	View, Read, Add, Modify, and Sign content

Solutions provided in OpenLAB CDS 2 Structure

Instruments

- Agilent Demo Lab
- Gas Labo
 - Tafel 1
 - LAQGC17
 - Tafel 2
 - Tafel 3
 - 1220A
 - 490
 - 7890B
 - virtual instrument

Projects

- Agilent D
- GCN
- GC1
- F_E
- Mor
- Vers
- demo
- DemoAu

Edit Privileges

Inherit privileges from parent
Privileges set for the parent will also be applied to this object.

Assigned users and groups

Add User or Group Remove User or Group

Name	Description
operator1	Lab Technician
operator2	Lab technician
admin	System Administrator

Roles for operator1

Add Role Remove Role

Name	Description
Instrument User	View and run instruments

OK Cancel

Solutions provided in OpenLAB CDS 2 Structure

The screenshot displays the OpenLAB CDS 2 Administration interface. On the left, the 'Instruments' section is expanded, showing a hierarchy: Instruments > Gas Labo > Tafel 1 > LAQGC17. The 'Administration' pane is open to the 'Roles' configuration page. The 'Roles' table lists various roles and their descriptions, with the 'Technician' role selected and its permissions expanded.

Name	Description
Everything	All privileges
System Administrator	Manage users and security settings
Instrument Administrator	Manage instruments and locations
Project Administrator	Manage projects and project groups
Instrument User	View and run instruments
Archivist	Archive and Dearchive content
Data Store Contributor	View, Read, Add, and Modify content
Data Store Reader	View and Read content
Data Store Approver	View, Read, Add, Modify, and Sign content
Technician	Laboratory technician
	View project or project group
	Edit content of project
	Create and modify sample prep
	Create and modify acquisition method
	Save result set method
	Edit sample information
	Create and modify sequence
	Edit users own running sequences
	Manual control (only when instrument idle)
	MS autotune
	Reprocess data
	Do manual compound identification
	Do manual integration
Chemist	Analytical chemist

Solutions provided in OpenLAB CDS 2 Audit Trail

Full audit trail of course

- Important: how quickly can I access my audit trail???
- One mouse click away

According to GMP and 21/11

- No obscuring of previous actions

Fit for Annex 11

- Review of audit trail

More in the demo

Audit Trail Sample 05_1220A_20151206_234200 - Sample 05_1220A_20151206_234200.dx (Number of entries: 15)

State	User name	Date (GMT+01:00)	Description	Host name	Reviewed	Reason	Category
	Freek Varossieau	12/14/2015 11:15 PM	Saved results.	WIN-3QABAHQ...	I signed off		Saving
	Freek Varossieau	12/14/2015 11:15 PM	Locked results	WIN-3QABAHQ...	I signed off		Lock
	Freek Varossieau	12/7/2015 12:44 AM	Saved results.	WIN-3QABAHQ...	I signed off		Saving
	Freek Varossieau	12/7/2015 12:44 AM	User 'Freek Varossieau' signed on level 3 (Lab Manager) with meaning 'Ap...	WIN-3QABAHQ...	I signed off		Signature
	Groucho Marx	12/7/2015 12:42 AM	Saved results.	WIN-3QABAHQ...	I signed off		Saving
	Groucho Marx	12/7/2015 12:41 AM	User 'Groucho Marx' signed on level 2 (Shift Supervisor) with meaning 'Rea...	WIN-3QABAHQ...	I signed off		Signature
	Clark Gable	12/7/2015 12:40 AM	Saved results.	WIN-3QABAHQ...	I signed off		Saving
	Clark Gable	12/7/2015 12:40 AM	User 'Clark Gable' signed on level 1 (Technician) with meaning 'Reviewed'	WIN-3QABAHQ...	I signed off		Signature
	admin	12/7/2015 12:20 AM	Saved results.	WIN-3QABAHQ...	I optimized integrat...		Saving
	admin	12/7/2015 12:19 AM	User 'admin' revoked signature with level 3 (Lab Manager) with meaning 'I...	WIN-3QABAHQ...	I optimized integrat...		Signature revoked
	admin	12/7/2015 12:18 AM	User 'admin' signed on level 3 (Lab Manager) with meaning 'Approved'	WIN-3QABAHQ...	I optimized integrat...		Signature
	Bob Hope	12/6/2015 11:43 PM	Injection processed with warnings using method /DemoAudited/Results/t...	WIN-3QABAHQ...			Processing
	Bob Hope	12/6/2015 11:43 PM	Acquisition completed for Injection: 5	WIN-3QABAHQ...			Sequence
	Bob Hope	12/6/2015 11:42 PM	Injection 5 - Injection source: Als	WIN-3QABAHQ...			Sequence
	Bob Hope	12/6/2015 11:42 PM	Acquisition started for injection 5 using method /DemoAudited/Results/te...	WIN-3QABAHQ...			Sequence

Buttons: Review, PDF Export..., Print, Close

Solutions provided in OpenLAB CDS 2

Archiving and management

Central encrypted storage for all files, including reports

Access control and independent audit trail

Built-in archiving and controlled deletion

Storage for reports included

Web based

Security!



Solutions provided in OpenLAB CDS 2

Archiving and management

Central encrypted storage for all files, including reports

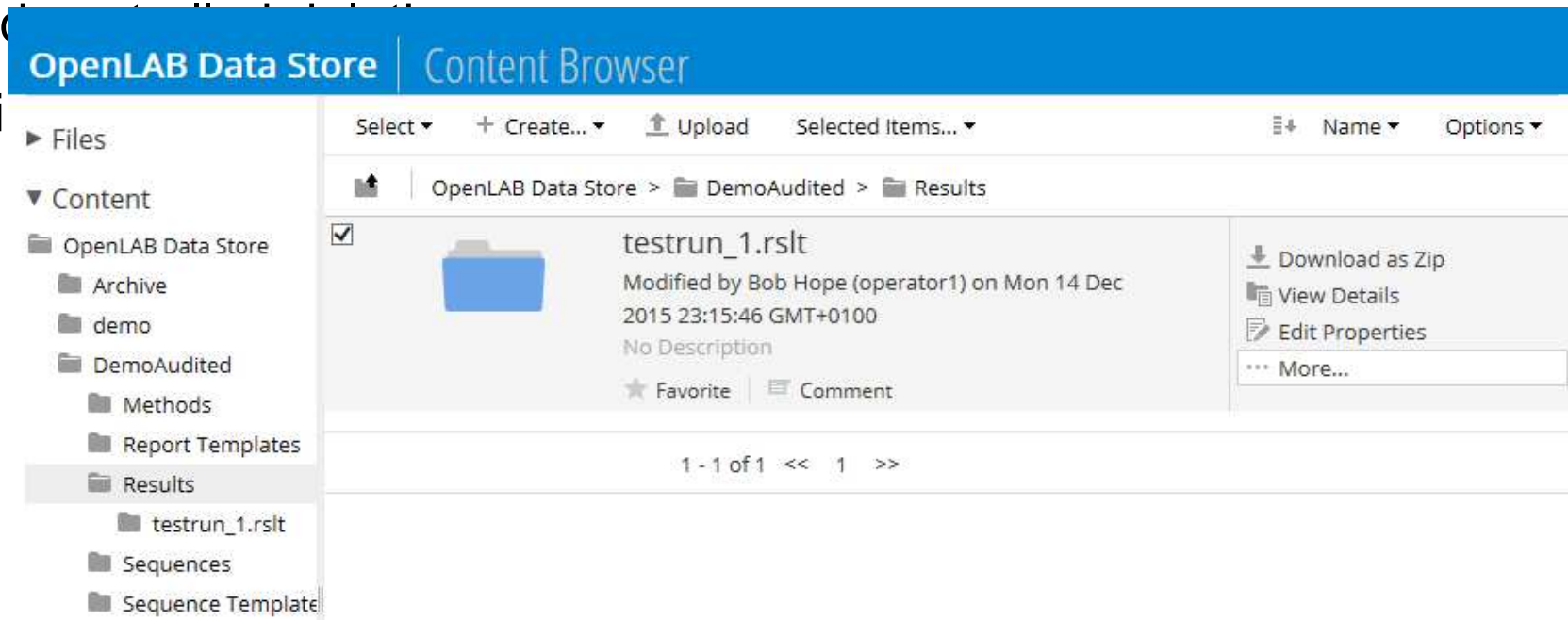
Access control and independent audit trail

Built-in archiving and retention management

Storage for reports in

Web based

Security!



Solutions provided by OpenLAB CDS 2

And now the real thing!



Agilent Technologies

OpenLAB CDS 2

Your Advantages

Compliance gaps closed

- Secured vault
- User access and control

Easy access to Audit Trail: satisfy your auditor

Built-in archiving and maintenance

Cheap to run

Fits in any IT organisation

Supported by a professional Consultancy team.

