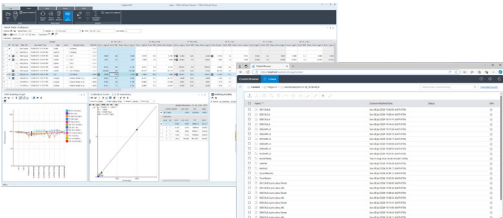




Data Integrity Options for GxP Facilities

For Agilent ICP-MS and ICP-QQQ spectrometers

Agilent
OpenLab



Agilent OpenLab ICP-MS Workstation software provides flexible yet simple method development and data analysis functionality. Combining OpenLab ICP-MS with the Agilent OpenLab ICP-MS Workstation Plus or Agilent OpenLab servers, assures data integrity with secure database storage for all electronic records.

Agilent ICP-MS solutions to help meet regulatory requirements

Agilent ICP-MS and ICP-QQQ instruments are used for pharmaceutical applications such as elemental impurities analysis and extractables and leachables risk assessments.

Agilent ICP-MS systems are compatible with compliance solutions ranging from single workstation to enterprise-level installations. Agilent OpenLab ICP-MS software performs instrument control and data analysis functions, while User Access Control (UAC) with Agilent OpenLab Shared Services (OLSS) provides flexible, multilevel user management and audit trails. Agilent OpenLab ICP-MS Workstation Plus is a single workstation compliance option and Agilent OpenLab Basic Server, ECM XT, or ECM are networked client-server solutions. Agilent compliance software solutions focus on the ALCOA+ principles of compliance, which list the critical factors that should be considered when designing any 21 CFR Part 11 solution.

Compliance functions and quality

Regulatory compliance and quality require more than just a bolt-on software solution. Quality must be designed into the products at conception and continually monitored throughout the product development and working life through to obsolescence. Agilent software products and ICP-MS instruments are developed under the Agilent ISO-9001 compliant Quality Management System (QMS) and Product Lifecycle Management (PLM). These processes ensure traceability throughout the product lifecycle.

Software controls to ensure that data is securely acquired and stored are essential for laboratories that must comply with FDA 21 CFR Part 11, EU Annex 11, and similar regulations in other countries.

These regulatory controls specify a framework to:

- Ensure that electronic records and signatures can be treated as “trustworthy, reliable, and equivalent to paper records”
- Require that electronic records are “complete and accurate copies” of corresponding paper records
- Set out requirements for data security, integrity, and traceability to ensure that records are available throughout the retention period for inspection by the regulatory and audit bodies

OpenLab ICP-MS software

OpenLab ICP-MS is a fully-featured instrument control and data analysis software solution that operates on the Microsoft Windows platform. OpenLab ICP-MS offers a robust set of sample measurement and data analysis tools accessed using an easy-to-use interface for both CFR compliant and non-CFR compliant environments. Key features include:

- Preset methods for many applications, including pharmaceutical elemental impurities testing, to get the instrument productive as quickly as possible
- Off-line data analysis allows data assessment and approval of already acquired batches while the instrument is busy measuring samples
- Automatic optimization and performance checks that provide batch-to-batch consistency regardless of operator experience
- Advanced maintenance monitoring ensures peak performance, allows easy maintenance scheduling, and avoids unnecessary maintenance tasks
- Options for advanced QC control, chromatography, single nanoparticle (sNP), single-cell, and isotope analysis ensure complete application coverage

OpenLab ICP-MS has all the features to get the very best from your ICP-MS investment.

Optimized applications package

An optimized applications package consists of standard solutions and SOP documents, allowing any laboratory setting up their pharma metals analysis to get quickly up to speed.

Access control

OpenLab ICP-MS user management is provided by the User Access Control (UAC) module with OLSS, which is easy to use yet secure and configurable with multi-level, password-protected user profiles. Permitted actions are defined for each user level in the control panel’s users, groups, and roles panes; the default settings can be modified to suit each laboratory’s needs. Each permitted action can be configured to require the entry of a valid username/password combination and reason. Control panel user management is independent of Windows users/groups and includes a built-in system activity log audit trail.

Agilent CrossLab Automated Compliance Engine (ACE)

Agilent ACE minimizes regulatory risk and assures ICP-MS data integrity by providing Qualification services for ICP-MS hardware and software. ACE ensures the Installation Qualification (IQ) and Operational Qualification (OQ) are managed efficiently with a single point of contact. Ongoing or periodic requalification services are also available. Agilent ACE fully manages ICP-MS compliance solutions, offering:

- Defined and scheduled tests according to an agreed Equipment Qualification Plan (EQP)
- Audited calculations independent of the instrument software
- Audit-ready and traceable Equipment Qualification Report (EQR) documentation

ACE is scalable from individual systems up to client-server based installations. Whichever option is selected, analytical instrument qualification (AIQ) using ACE is compliant with GAMP and USP 1058.

User	Group	Time(Local)	Action	Reason
icpmhadmin	ICPMHAdmin	2024-07-28 17:39:02 GMT-08:00	Execute the right to configure MassHunter.	
icpmhadmin	ICPMHAdmin	2024-07-28 17:33:52 GMT-08:00	Set SpecifiedTimeSettings = C:\Agilent\ICPMH\1\UserTune_8900-DEMO.b.1 on Hardware information; previous value = C:\Agilent\ICPMH\1\UserTune_8900-DEMO.b.1	
icpmhadmin	ICPMHAdmin	2024-07-28 17:33:51 GMT-08:00	Set Load Option = StandardTune on Hardware information; previous value = StandardTune	
icpmhadmin	ICPMHAdmin	2024-07-10 05:15:37 GMT-08:00	Closed Batch.	
icpmhadmin	ICPMHAdmin	2024-07-10 05:15:08 GMT-08:00	Closed Batch Folder.	
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:13 GMT-08:00	End method editing.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:12 GMT-08:00	Clear method from method setup session.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:04 GMT-08:00	Import current method into method setup session.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:04 GMT-08:00	Start method editing.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:57:02 GMT-08:00	Execute the right to enter method editor	
icpmhadmin	ICPMHAdmin	2024-07-10 04:56:44 GMT-08:00	User 'admin' signed on level 1 (Technician) with meaning 'I am the author'.	
icpmhadmin	ICPMHAdmin	2024-07-10 04:56:44 GMT-08:00	Version: 2024-07-10-1251-41784	
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:41 GMT-08:00	Result Succeeded	
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:41 GMT-08:00	Analysis Result Locked	
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:39 GMT-08:00	Saved Batch.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:39 GMT-08:00	Analyze batch.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:39 GMT-08:00	Sample import completed.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:39 GMT-08:00	Import samples from data files local\host\Project A\Test\2024-07-10_05-42-55\b\0025MPL.d	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:25 GMT-08:00	Analyze batch.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:21 GMT-08:00	Sample import completed.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:20 GMT-08:00	Import samples from data files local\host\Project A\Test\2024-07-10_05-42-55\b\001CAL5.d	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:01 GMT-08:00	Import method from batch C:\Users\icpmhadmin\AppData\Local\Temp\hba32565\Test\2024-07-10_05-42-55\b\DA\Method\batch.xml	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:01 GMT-08:00	Batch was opened.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:01 GMT-08:00	Opened Batch Result: local\host\Project A\Test\2024-07-10_05-42-55\b\QuantResults\Test\2024-07-10_05-42-55\batch.bir.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:51:00 GMT-08:00	Create new batch local\host\Project A\Test\2024-07-10_05-42-55\b	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:50:40 GMT-08:00	Exit Warning Up on Queue.	
icpmhadmin	ICPMHAdmin	2024-07-10 04:50:40 GMT-08:00	Added Batch Folder: local\host\Project A\Test\2024-07-10_05-42-55\b to queue.	
icpmhadmin	ICPMHAdmin	2024-07-10 04:49:56 GMT-08:00	Closed Batch.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:49:56 GMT-08:00	Added Batch Folder: local\host\Project A\Test\2024-07-10_05-42-55\b to queue.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:49:56 GMT-08:00	End method editing.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:49:56 GMT-08:00	Clear method from method setup session.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:48:02 GMT-08:00	Saved Batch Folder.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:58 GMT-08:00	Allow batch folder Save/Save as.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:50 GMT-08:00	Allow Batch Tasks to be added to Queue.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:40 GMT-08:00	Allow modification of Sample List.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:40 GMT-08:00	Changed Value at line 2 from "1" to "1".	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:35 GMT-08:00	Allow modification of Sample List.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:35 GMT-08:00	Changed Value at line 1 from "1" to "1".	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:35 GMT-08:00	Changed Sample Type at line 2 from "1" to "Sample".	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:35 GMT-08:00	Allow modification of Sample List.	Autogenerat
icpmhadmin	ICPMHAdmin	2024-07-10 04:47:35 GMT-08:00	Added sample at line 2.	Autogenerat

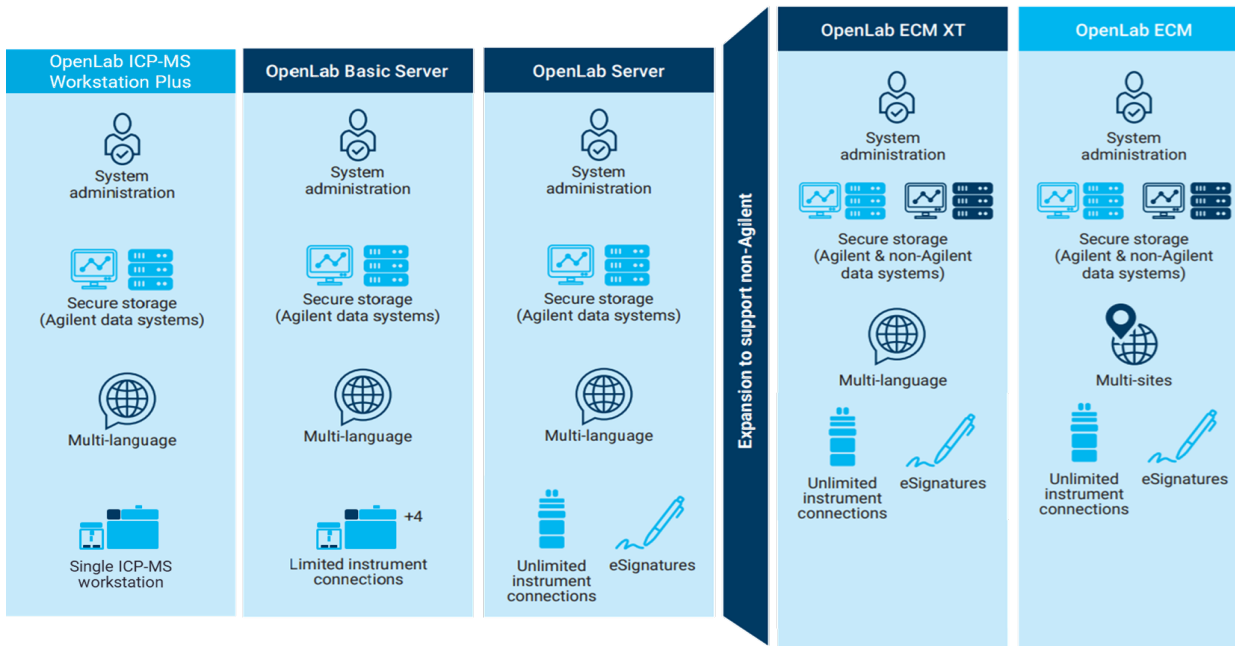
The audit trail captures all activities by all users and is searchable by keyword and date range.

Securing and managing ICP-MS data

Agilent OpenLab ICP-MS is compatible with two secure storage schemes:

- Data is stored and managed locally, on the instrument Workstation PC
- Data is stored and managed centrally in one of the OpenLab server options

The diagram below illustrates the available options:



Learn more:

www.agilent.com/chem/icpms

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This information is subject to change without notice.

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