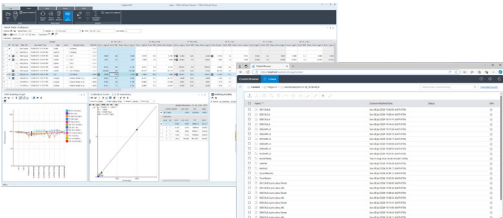




Data Integrity Options for GxP facilities

For Agilent ICP-MS and ICP-QQQ spectrometers

Agilent
OpenLab



Agilent ICP-MS MassHunter Workstation software provides flexible yet simple method development and data analysis functionality. Combining ICP-MS MassHunter with the Agilent ICP-MS MassHunter Workstation Plus or Agilent OpenLab software, 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 ICP-MS MassHunter Workstation 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. ICP-MS MassHunter 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 21CFR 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), 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

ICP-MS MassHunter

Agilent ICP-MS MassHunter is a fully-featured instrument control and data analysis software solution that operates on the Microsoft Windows platform. ICP-MS MassHunter 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

ICP-MS MassHunter 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

ICP-MS MassHunter 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 as needed to suit the laboratory's need. 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 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, and whichever option is selected, analytical instrument qualification (AIQ) using ACE is GAMP and USP 1058 compliant.

