Regulatory Compliance for ICP-MS

Generating, Storing and Protecting Electronic Records in Regulated Laboratories

Regulatory Compliance for Analytical Instruments

Compliance with Federal regulations is a key aspect of sample analysis in many industries, including pharmaceutical manufacturing.

The 4 areas of compliance related to analytical results are:

- System validation, including design qualification (DQ), manufacturing QC, lifecycle management, installation and operational qualification (IQ/OQ), and performance verification (PV or PQ) for analytical instruments and software
- Control of access to the workstation for instrument control and data processing (restricted user access with password protection)
- Electronic records control (secure storage, file versioning, audit trail, electronic signatures, and archive/retrieval)
- System operation, suitability testing, procedures, and physical access to the laboratory and records

The first of these must be demonstrated through the manufacturing quality records and equipment validation certification of the instrument manufacturer. The fourth requires appropriate controls on physical laboratory access, and that system suitability tests (SST) and standard operating procedures (SOP) are documented and followed.

The remaining 2 components are typically implemented through user access control software and an integrated system for managing the electronic records generated during the lab's activities.

ICP MS MassHunter User Access Control Software

Agilent's ICP-MS MassHunter software can be configured with a flexible, password-protected, multi-level user access control package to manage access to the workstation and individual functions within the software. Using the audit trail map (ATM) configuration utility, administrators and lab managers can define the access rights for each user level, and whether a user must validate their identity and provide a reason for performing certain actions.

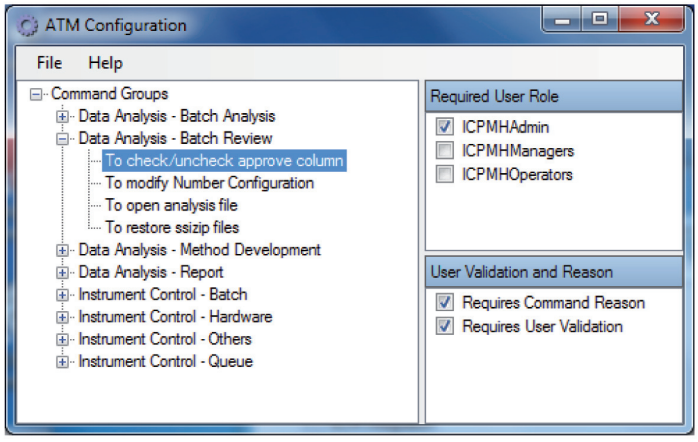

Figure 1. Audit Trail Map (ATM) configuration for ICP-MS MassHunter software

In conjunction with ICP-MS MassHunter User Access Control software, Agilent OpenLAB ECM (Enterprise Content Manager) provides a solution that satisfies all the requirements of 21 CFR Part 11.

Agilent OpenLAB ECM and 21 CFR Part 11

Part 11 in Title 21 of the US Code of Federal Regulations (commonly referred to as 21 CFR Part 11) governs food and drugs in the US, and includes the US Federal guidelines for storing and protecting electronic records and applying electronic signatures. The purpose of these regulations is to ensure the ***security, integrity and traceability*** of electronic records, which includes data, analytical reports and other records (such as daily performance checks) associated with the operation of an analytical instrument.

OpenLAB

CAPTURE • ANALYZE • SHARE

Used as a complete laboratory content management solution, OpenLAB provides the opportunity for laboratories to go "paperless", where all electronic records, including R&D reports and equipment maintenance schedules as well as analytical results can be collected, maintained, accessed and archived using a single user interface.

User Access Control provides traceability, while security and integrity are ensured by the server-based file management of OpenLAB ECM. Using a LCDF (location, cabinet, drawer, folder) structure, analytical results and pdf report files are securely stored in checksum protected files. A new file is generated whenever a new report is created.

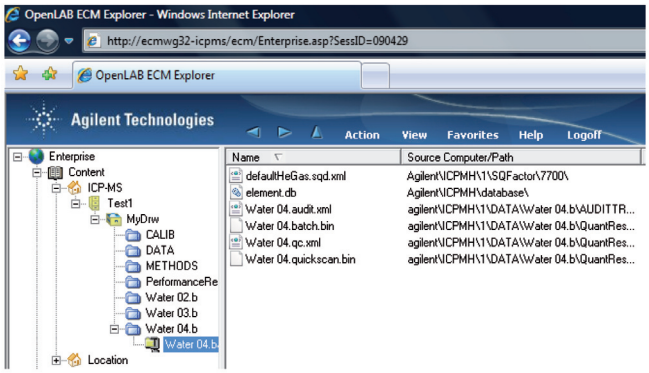

Figure 2. LCDF data structure in OpenLAB ECM's web-browser interface, showing secure, checksum protected ssizip file storage

Unrivalled Regulatory Compliance for ICP-MS

Agilent's flexible, multi-level ICP-MS User Access Control software integrates with Agilent OpenLAB ECM to provide unmatched security, integrity and traceability for ICP-MS data, essential for full compliance with regulatory requirements. Combined with manufacturing quality certification and full installation and operational qualification services (IQ and OQ) for ICP-MS hardware and software, Agilent provides the most complete range of compliance services for regulated laboratories.

For more information on the 7700 Series ICP-MS and OpenLAB ECM visit the Agilent Technologies website: **www.agilent.com/chem/icpms** and **www.agilent.com/chem/ecm4icpms**

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