



**Malvern
Panalytical**
a spectris company

OmniTrust

Built for data integrity. Trusted for compliance.



The OmniTrust advantage

Accelerating time to market while ensuring compliance with regulatory requirements is key to succeeding in today's pharmaceutical industry. From instrument qualification to compliance and auditing software, Malvern Panalytical will help you minimize the risks associated with data integrity in the regulated environment.

Are you

- Focused on protecting the integrity and traceability of your data?
- Concerned about the time it takes to ensure data compliance with regulatory guidance?
- Frustrated by configuring and validating instruments using different compliance tools?
- Finding it challenging to access data on a range of platforms for both routine and external audits?
- Constantly adapting analytical workflows to suit instrument capabilities rather than your own requirements?

For simple, secure and seamless data compliance, trust Malvern Panalytical and choose OmniTrust.



Take control of compliance. Stay audit ready.

Regulatory compliance shouldn't slow you down.

OmniTrust empowers you to validate and audit your Malvern Panalytical systems with confidence by cutting through complexity and freeing up your team to focus on what matters.



Why OmniTrust?

- Effortless Compliance: OmniTrust simplifies regulatory workflows with secure, audit-ready infrastructure.
- Smart Access Control: Flexible role-based permissions, multiple role compatibility, single sign-on, and e-authentication that fit both R&D and QC.
- Expert-Driven Confidence: Backed by decades of compliance experience, OmniTrust delivers peace of mind from deployment to long-term support. Built with industry experts, OmniTrust delivers a unified approach to data integrity across your instruments. It's more than software, it's a smarter way to work.

What's included

- Powerful software to simplify validation and ensure data integrity.
- Rapid deployment and expert support.
- Intuitive design for fast adoption and daily efficiency.

The result?

- OmniTrust helps you stay compliant, productive, and always one step ahead.

Compliance made simple: secure, audit-ready

OmniTrust reduces the burden of data integrity and compliance across your Malvern Panalytical portfolio so you can focus on productivity, not paperwork

- A consistent user interface and workflow across the OmniTrust family makes adoption simple.
- Installed and configured from as little as 60 minutes
- Flexible role configuration for different environments (R&D/QC), with single sign-on and e-authentication
- OmniAccess gives you a complete overview of access and permissions at a glance
- Electronic signatures
- Comprehensive documentation for compliance validation
- Convenient audit history review in one place through OmniTrail

Trusted Expertise: from deployment to long-term compliance

Our decades of experience in 21 CFR Part 11 regulations and regulatory test scripts guarantees peace of mind, efficiency, and confidence in regulatory compliance

- On-site setup for local and central management, ensuring seamless integration
- Let our experts configure access controls tailored to your environment - optional
- Fast implementation to get your system operational within days
- We accelerate network setup for centrally managed roles and permissions and audit review
- Access class-leading compliance support and advice from our trained experts

Centralized Management: for scalable data integrity

OmniTrust makes it easy to manage roles, permissions, and audit trails across your Malvern Panalytical instruments remote, traceable and reliably

- Configure once, deploy many times - save time by setting up roles and permissions once and deploying them across multiple instruments, from anywhere in a traceable and compliant manner
- Eliminate mistakes from repetitive, instrument-by-instrument setup
- Central and traceable data review for single or multiple instruments (currently applicable to XRD portfolio and Mastersizer)
- Combined system audit trail data review also from your desk

OmniTrust software

OmniAccess

- Authorization - who can access the system and what they can access.
- Authentication - the source of users (e.g. Windows domain, Active Directory including AD Groups, and EntraID).
- Synchronization - define how the System Audit Trail is synchronized and set up Central Management (optional license needed).
- Signing and Reason - define whether events require a user's signature and/or reasons for doing the event and if so, for what type of events this is necessary.

OmniTrail

- View and audit system and user activity in an OmniTrust environment.
- System audit trail for tracking system events and security controls.
- Record audit trail through software application interface for tracking individual measurement records.

Central Management (optional)

- Set up multiple instruments simultaneously.
- View system audit trails across multiple platforms.
- Reduces manual errors and simplifies internal and external audits.



OmniAccess: configure analytical systems to your workflow

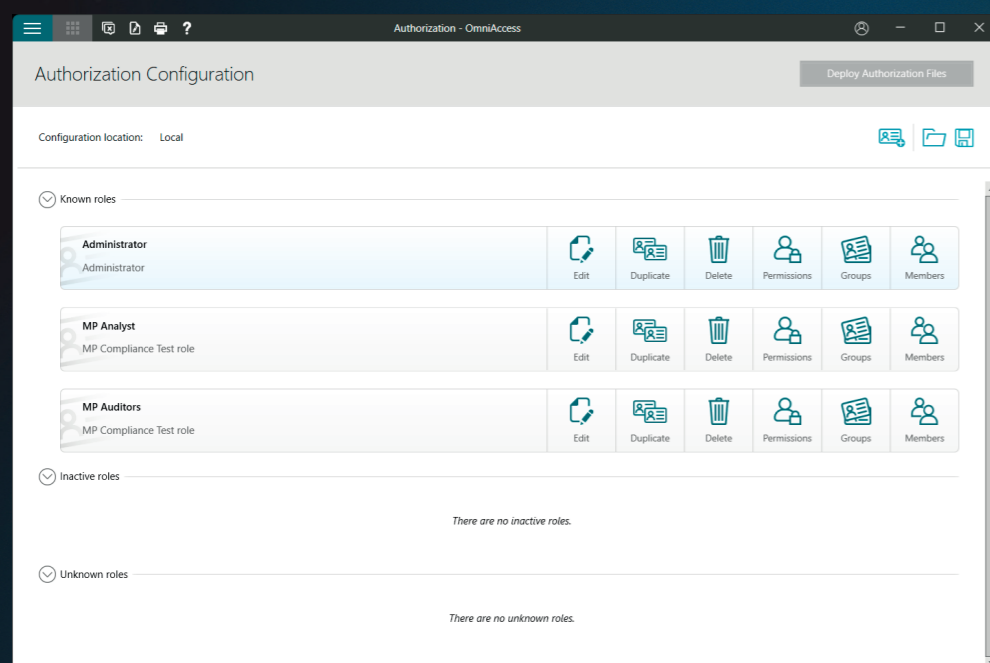
Malvern Panalytical's OmniAccess flexible system configuration and role management software enables you to control, access and audit your critical analytical capabilities in line with your specific workflow requirements.

OmniAccess is designed to be flexible and adapt to your analytical workflow with ease, saving analyst time and simplifying the audit process.

It enables you to:

- Configure the rules associated with auditing record events according to your workflow and validation requirements, eliminating unnecessary requests for signatures or audit entries
- Control access to specific instrument and analysis capabilities through role permissions, ensuring only those with the required training and authority can create, modify or audit electronic records
- Allow users who perform multiple functions within a laboratory to confirm their role in line with their current task requirements (**multiple role**)
- Standardize and automate routine electronic record creation processes
- Handy overview of users that have access to the instruments, their roles and permissions
- Transfer instrument access control and auditing configurations between systems, delivering significant time savings while reducing the risk of inconsistencies across different instruments and laboratories following similar analytical workflows

Example of authorization configuration of roles in OmniAccess



OmniTrail: approach regulatory audits with confidence

Malvern Panalytical's OmniTrail provides configurable audit trail review tools for simple and rapid audit of analytical measurement and analysis activities, ensuring compliance with data integrity requirements.

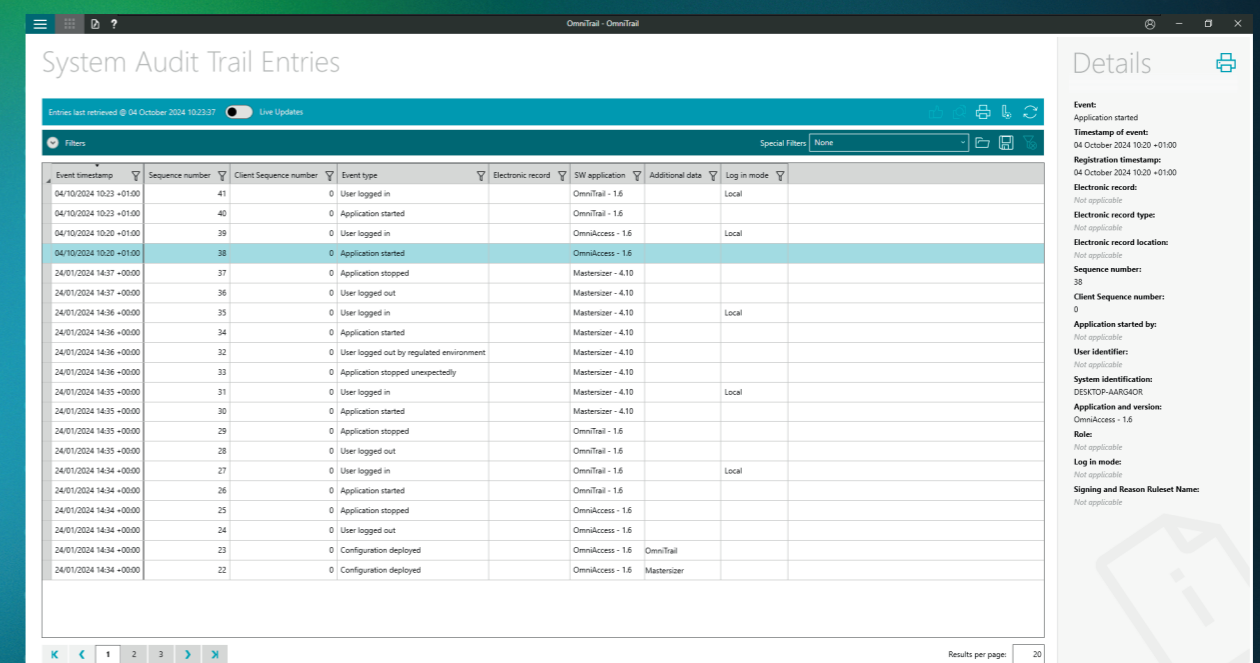
OmniTrail builds a seamless audit trail, recording all relevant system and record creation activities. Whether you are undertaking internal or external audit reviews, OmniTrail provides access to the data you need and gives you confidence that you are in control of your data, in line with ALCOA++ principles.

OmniTrail is Malvern Panalytical's dedicated application for audit trail records across your regulated environment. It provides powerful filtering and review tools to help you quickly locate and verify key system events. Manual audit trail entry strengthens reproducibility of SOPs and allows to capture additional information that is critical for ensuring the work is done in a compliant manner according to the regulations.

OmniTrail enables two types of audit trails:

- System Audit Trail (SAT) – Tracks system-level events across all OmniTrust applications, including user actions and system-generated events like shutdowns. SAT entries are accessible from the Omnitrail interface
- Record Audit Trail (RAT) – Logs detailed activity related to individual measurement records. RAT entries are stored with the records themselves and can be visualized within instrument control and analysis application interface. Each application presents its own view of the Record Audit Trail, tailored to the specific measurement context

Example audit trail review in OmniTrail



Central Management: configure once, deploy many times

Simplify your data integrity strategy with centralized audit trails and remote role/user management. Central management is designed to save you time, reduce manual errors and ensure traceability.

Lab efficiency

Maximize instrument availability for what matters most: data collection and analysis

- Increase instrument availability for running measurements rather than audit tasks
- Customer feedback 'Every hour in the lab requires another hour to do the (related audit) admin normally. Central Management reduces the admin.'
- Audit trail reviews can be performed from a separate workstation, minimizing interruptions to lab workflows

Admin efficiency

Simplify configuration management and remove repeated actions of configuring same settings multiple times

- Avoid starting configurations from scratch by keeping role, permissions and workstation configurations maintained centrally
- Configuration updates are deployed without interrupting users
- Admins can manage OmniAccess updates directly from their own workstations in a traceable manner

QA efficiency

Enable faster, more effective audit reviews without disrupting operations

- Routine QA audits can be conducted from the QA department in a traceable manner, without interfering individual instruments
- Combined system audit trails from all instruments and analytical workstations streamline the review process
- No need for physical access to each system, ensuring audits are efficient and non-intrusive

| | Aeris | Empyrean | Zetasizer | NanoSight Pro |
|--|-------|----------|-----------|---------------|
| Central management of authorization (roles and permissions) | ✓ | ✓ | ✓ | ✓ |
| Combined system audit trail of all the centrally managed workstations | ✓ | ✓ | ✓ | ✓ |
| Central review of combined system audit | ✓ | ✓ | ✓ | ✓ |
| Ability to remotely access measurement/analysis data on multiple workstations* | ✓ | ✓ | ✗ | ✗ |

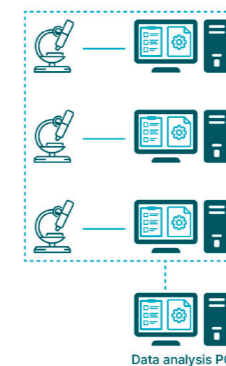
Deployment designed around you

Developed with flexibility in mind, OmniTrust offers three deployment methods to support a wide range of operational environments and compliance needs. Whether you are working on a single workstation or across a network of users, each option is designed to ensure secure data handling, simplified configuration, and full traceability. By adapting to your infrastructure, our deployment models help streamline validation processes and reduce complexity, giving you confidence in your setup from day one.

Local Management

A straightforward setup for single-instrument environments

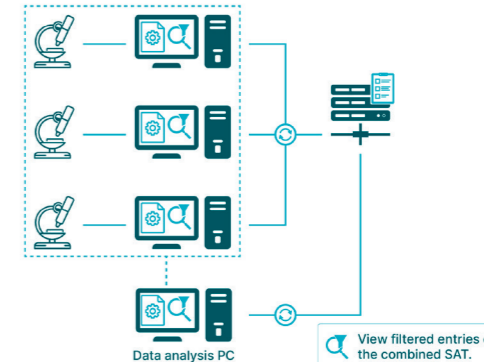
- One computer is directly connected to one instrument
- Audit trail (SAT) and configuration files are stored locally on the same computer
- All events are recorded by the SAT on this computer
- SAT is accessible only from this computer, and only by users with the appropriate role permissions



Local Management with Synchronized SAT

Local control with centralized audit trail storage

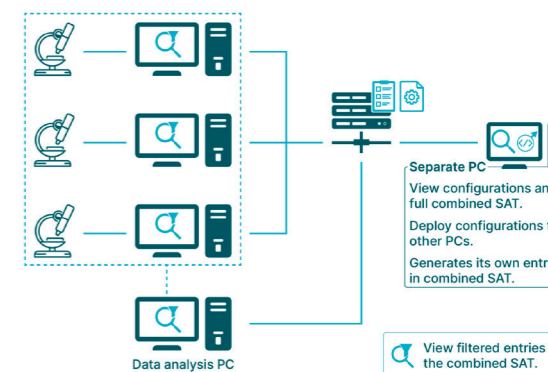
- Each instrument computer is connected to a central server
- Audit trail (SAT) is stored on the server, while configuration files remain local to each instrument computer
- SATs are synchronized to the server but remain viewable only from the local computer connected to the instrument



Central Management

Ideal for multi-instrument environments requiring centralized oversight

- All instrument and analytical computers are connected to a central server
- Both audit trail (SAT) and configuration files are stored centrally
- Combined SATs are accessible from any computer connected to the server, enabling centralized review and management
- Configuration settings can be deployed from the server to all connected instrument computers



Data integrity compliance

OmniTrust enables seamless alignment with key regulations such as 21 CFR Part 11, EU Annex 11, MHRA GxP Data Integrity Guidance, and ERES Guidelines, while embedding the ALCOA++ principles at the core of your data management strategy.

Attributable

All actions logged within the audit trail are assigned to the respective user, with secure electronic signatures and role-based access controls as defined withing OmniAccess.

Legible

Audit trails can be reviewed within the software, using search tools which enable you to easily confirm correct system use and detect possible data integrity concerns. Audit trails can also be printed or exported in support of audit activities.

Contemporaneous

Events are captured in real time with time-stamped audit trails, ensuring accurate chronological documentation.

Original

The OmniTrail audit trail, supported by the metadata stored with each electronic record, ensures that you can identify an original record and accurately track how it has been modified within the system.

Accurate

Modification of electronic records is fully audited via OmniTrail within a workflow that ensures the original record is never lost, maintaining the accuracy of the reported analytical data and its supporting audit metadata.

Complete

All data including modifications and deletions is recorded and retained, ensuring full traceability.

Consistent

System logic enforces proper sequencing and timestamping, supporting reliable and repeatable workflows.

Enduring

Data is securely stored in validated systems designed for long-term retention and audit readiness.

Available

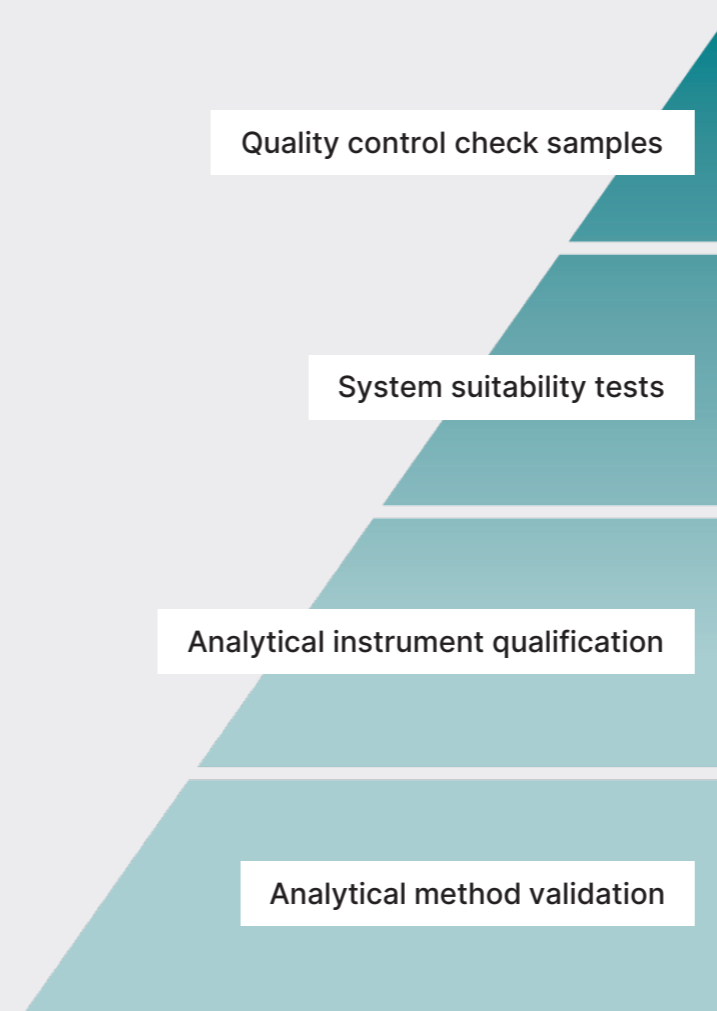
Authorized users can access records and audit trails from designated workstations as defined by OmniAccess, supporting efficient reviews.

Traceable

OmniTrust maintains detailed logs of who did what, when, and why ensuring full transparency across your operations.

Support & services

Developed to complement the OmniTrust software solution, our support and services simplify compliance with 21 CFR Part 11 and USP <1058>, reducing the complexity of validation in regulated environments. By combining expert-led services with intuitive tools, we help you streamline implementation and maintain confidence in your compliance posture.



The Data Quality Pyramid, based on USP <1058> guidance

Our OmniTrust offering includes:

- E-learning modules covering 21 CFR Part 11 fundamentals and practical guidance on using OmniTrust software, ideal for onboarding and continuous learning.
- Validation documentation, including comprehensive user guides and regulated environment guides, to support your internal validation efforts and simplify regulatory submissions.

Our extended Malvern Analytical offering includes:

- IQ and OQ services to verify installation and operational readiness as per USP <1058> 4Qs, providing documented assurance that your system performs as intended.
- Standards for performance qualification (PQ)
- Onsite configuration support, where our specialists tailor roles and permissions to your organizational needs, ensuring alignment with regulatory expectations.
- Regulated environment testing, designed to simulate real-world conditions and support your validation process, helping you prepare for audits with confidence.

Together, these services ensure a smooth path to compliance, reduce administrative overhead, and give you peace of mind that your system is compliance-ready.

**a powerful
combination**



SciAps

About Malvern Panalytical

Malvern Panalytical, Micromeritics and SciAps; a powerful and highly complementary combination of market leading technologies.

We are the toolmakers for the world's most innovative companies, academic institutions, and government laboratories. Customers see the difference when they use our instruments and feel the difference when they deal with our people.

Malvern Panalytical instruments analyze the chemical, physical and structural nature of materials, from proteins to polymers and semiconductors to minerals. Our leading technologies measure particle size, shape, concentration and zeta potential, biomolecular interactions and stability, elemental concentrations and crystallographic structure.

As a powerful combination our customers have access to technology leadership and an unwavering commitment to

customer support with a 1:1 ratio of sales to applications engineers, our customers' analysis is our priority – global expertise with local support tailored to their needs and access to an extended product portfolio.

With Micromeritics, customers can also measure surface area, porosity, density, adsorption and particle activity. With SciAps, our Center of Excellence for handheld instruments, customers can also access portable X-ray fluorescence (XRF), laser-based (LIBS), and near-infrared (NIR) analyzers to measure any element in any environment.

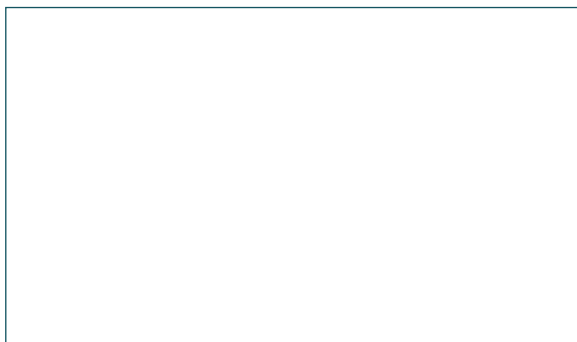
We have a global footprint with R&D and manufacturing sites in North America, Europe, and Asia. We are more than 2,500 employees in a customer-focused organization with sales and service offices in 20 countries, all committed to delivering expert and responsive customer support.

Service & Support

Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment, and ensure that as your analytical requirements grow, we're there to support you.

Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response, and maximum instrument uptime.

- Proactive local and remote support
- Full and flexible range of service agreements
- Compliance and validation support
- Onsite or classroom-based training courses
- e-Learning training courses and web seminars
- Digital services, including MyStore and My Customer Support Portal
- Sample analysis, method development, and applications consultancy



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