WHY CHOOSE
MALVERN PANALYTICAL?

We are global leaders in materials characterization, creating superior, customer-focused solutions and services which supply tangible economic impact through chemical, physical and structural analysis.

Our aim is to help you develop better quality products and get them to market faster. Our solutions support excellence in research, and help maximize productivity and process efficiency.

Malvern Panalytical is part of Spectris, the productivity-enhancing instrumentation and controls company.
www.spectris.com

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 with us, and ensure that as your laboratory and analytical needs grow, we are 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.

· Local and remote support
· Full and flexible range of support agreements
· Compliance and validation support
· Onsite or classroom-based training courses
· e-Learning training courses and web seminars
· Sample and application consultancy

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OMNI**TRUST**

Connect results to the people, processes and analytical instruments that produce them

THE OMNI**TRUST** 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 throughout your laboratory,
trust Malvern Panalytical and choose OmniTrust

OPTIMIZE YOUR PRODUCTIVITY AND EFFICIENCY WITHOUT COMPROMISING ON **COMPLIANCE**

Ensuring compliance with regulatory requirements is time-consuming and can put a strain on productivity. OmniTrust provides the software and system verification tools required to streamline how you validate and audit the operation of your Malvern Panalytical systems, optimizing the efficiency and compliance of your people and processes.

Designed in collaboration with leading industry experts, OmniTrust provides a common approach to validation and data integrity across a range of Malvern Panalytical instruments*. OmniTrust software tools provide a simple, user-friendly interface, speeding and simplifying the process of carrying out critical data integrity audits.

OmniTrust ensures record accuracy and enforces data integrity best practice by ensuring users can only perform the auditable actions that your workflow requires. System controls help users avoid errors and prevent the falsification of data, reducing errors and ensuring compliance with all relevant regulatory guidance. Furthermore, OmniTrust helps you identify potential data integrity problems quickly by placing the data you need at your fingertips, saving time and eliminating stress.

# 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:

- Standardize and automate routine electronic record creation processes

- 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

- Configure the rules associated with auditing record events according to your workflow and validation requirements, eliminating unnecessary requests for signatures or audit entries

- 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

OmniAccess records a full deployment history, so the addition of new users and any changes in roles over time can be audited. It also has solutions for the import of users, which can be tailored according to the size of your network.
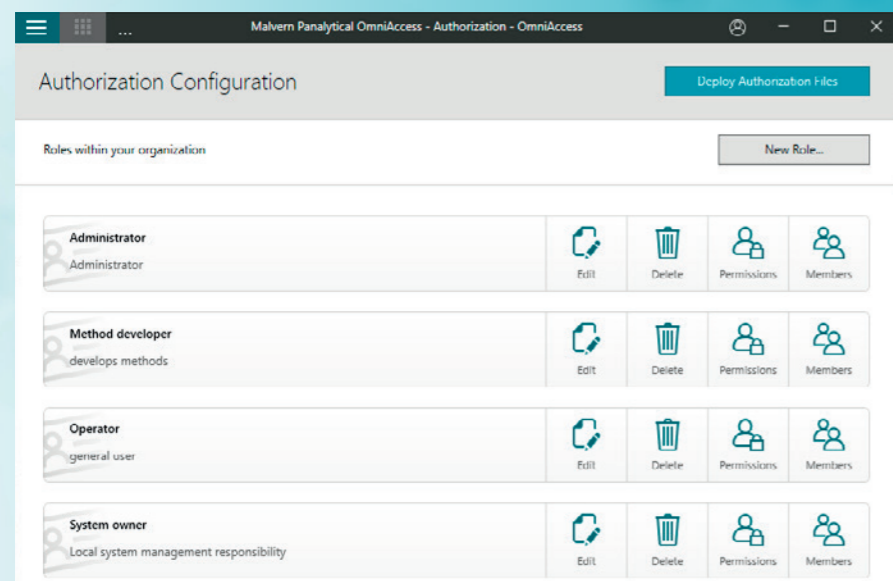
# OMNITRAIL: APPROACH **REGULATORY** AUDITS WITH **CONFIDENCE**

Malvern Panalytical's OmniTrail Audit trail review tools provide a configurable approach 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 activity. Whether you are undertaking internal, external or customer audit reviews, OmniTrail provides access to the data you need and gives you confidence that you are in control of your data, inline with ALCOA principles.

Within OmniTrail, all system actions are:

- Attributable: All actions logged within the audit trail are assigned to the respective user, as defined and configured within the OmniAccess tool

- 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: Every electronic record and audit entry is stored at the point of its creation, supported by the detailed metadata. This information confirms what

the record relates to, how it was created, and details any modifications made

- 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

Example of authorization configuration of roles in OmniAccess

Example audit trail review in OmniTrail
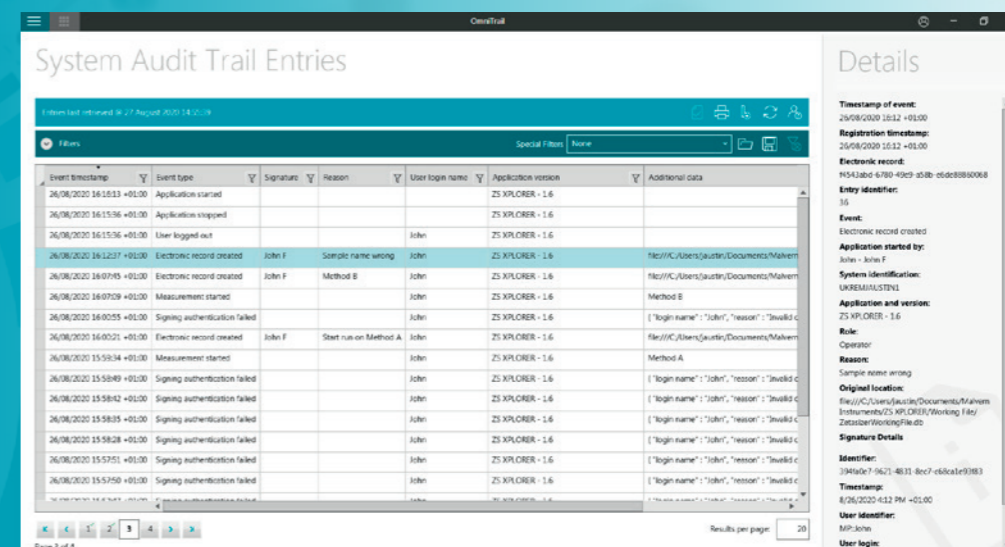
ACHIEVING ANALYTICAL INSTRUMENT QUALIFICATION

OmniTrust provides the fundamental building blocks you need to develop a validation framework for using Malvern Panalytical's analytical systems. The workflow-relevant access control and auditing capabilities offered by OmniAccess and OmniTrail

fit alongside our qualification, verification, training and support provision. This ensures that you consistently obtain the right data to ensure product quality, in line with regulatory guidance for Analytical Instrument Qualification.
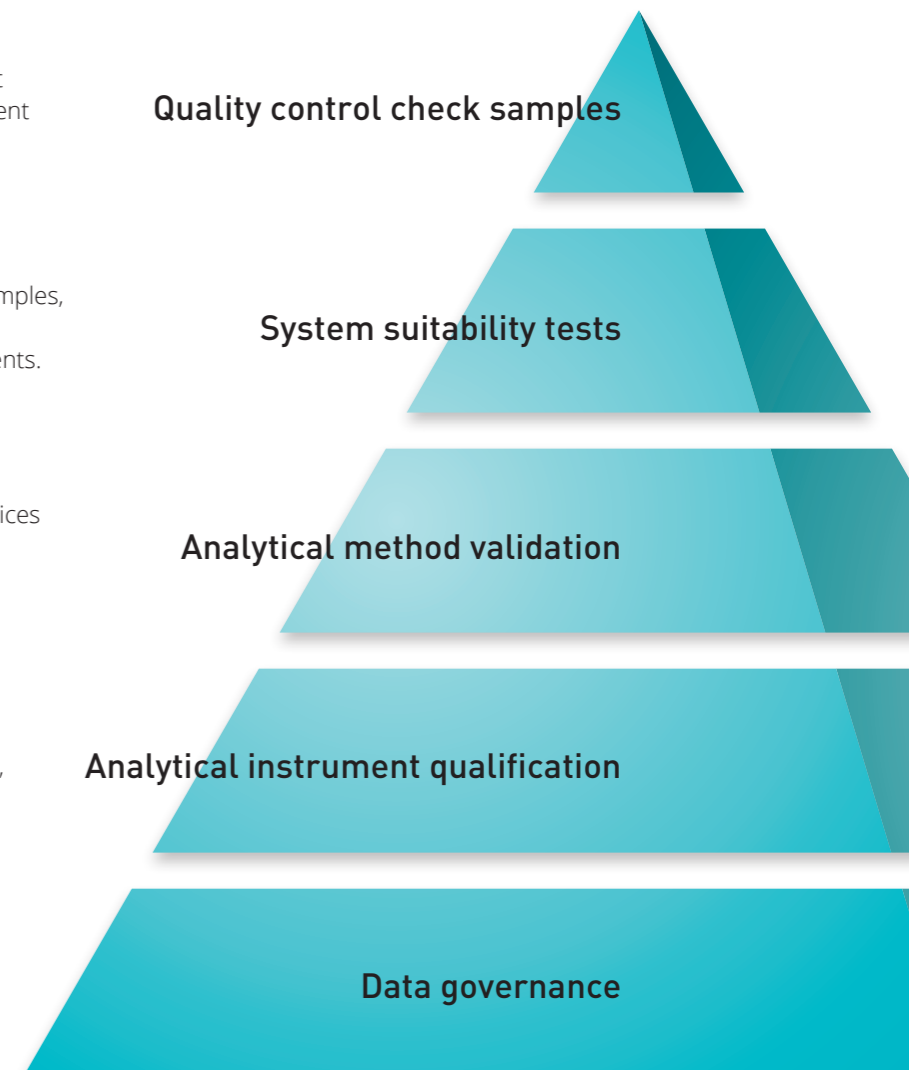
Our certified reference and calibration materials, supported by defined measurement procedures and specifications, ensure consistent performance from your analytical systems.

Access to our system Design Qualification documentation, supported by relevant test samples, ensures you select and configure our systems optimally for your specific analytical requirements.

Our bespoke training and support packages, alongside validated method development services via our Amplify Analytics program, ensure you select relevant methods to support product development and manufacturing control.

Our Operational Qualification and function test procedures support validation of your measurement and data compliance workflows, in line with regulatory requirements.

OmniAccess and OmniTrail provide the foundation for data quality, connecting each and every result to the people, processes and systems that deliver them.

Quality control check samples

System suitability tests

Analytical method validation

Analytical instrument qualification

Data governance

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