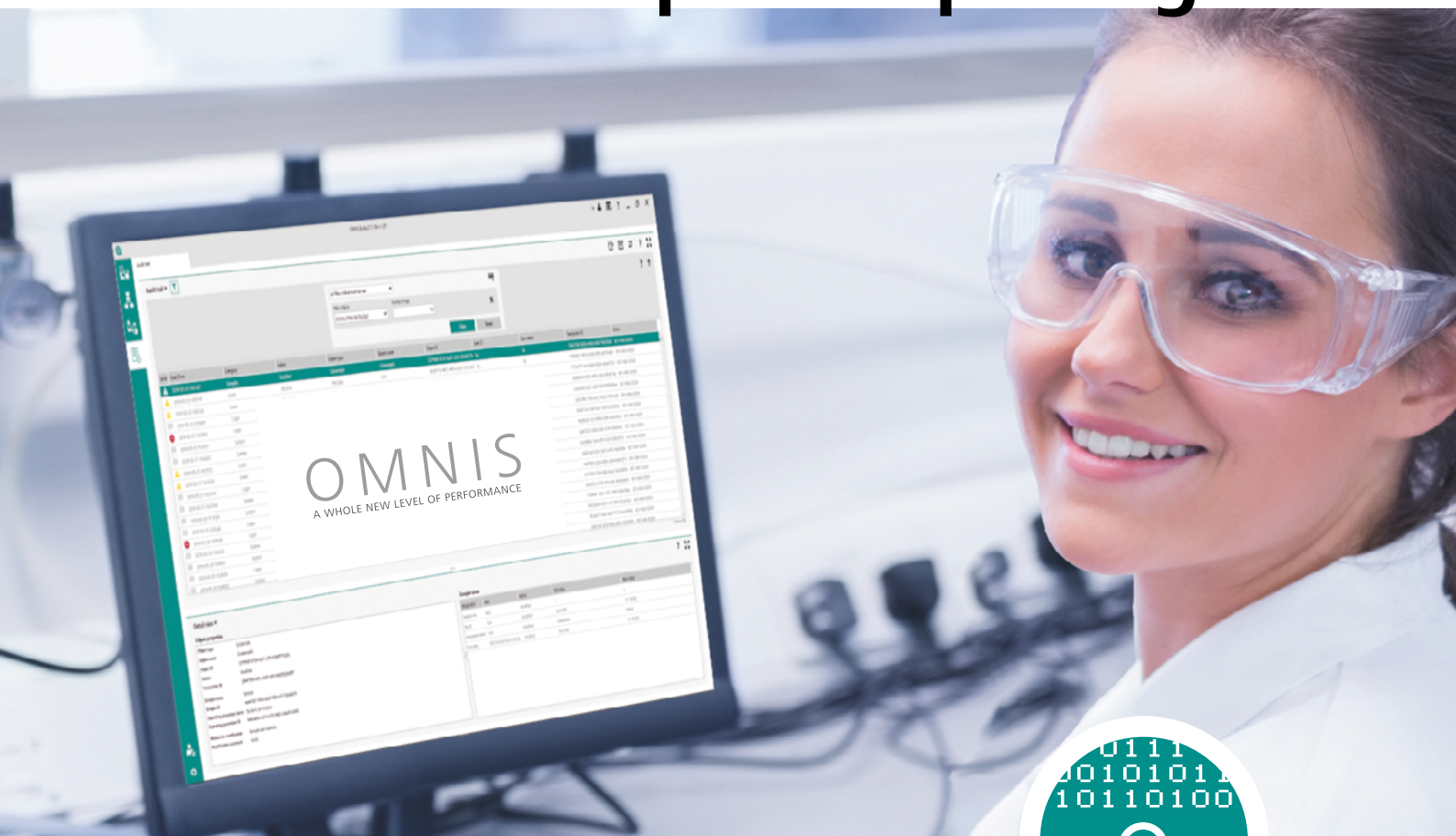


# Peace-of-mind with OMNIS Compliance package



## Compliance with the Data Integrity Guidelines made easy

Data integrity requires data to be complete, consistent, and accurate throughout their complete lifecycle, thus providing full transparency and traceability. Industry guidelines about data integrity, used by the FDA, WHO, PIC/S and GAMP, are described within the acronym **ALCOA** and **ALCOA+**, respectively. Our **OMNIS** software gives you peace of mind, as it ensures all data to have the following qualities stipulated by **ALCOA** and **ALCOA+**.

**OMNIS** compliance license (6.0600.4010) provides all necessary features for achieving data integrity and compliance to FDA 21 CFR part 11 and EudraLex, Vol.4, Annex 11.



# OMNIS

A WHOLE NEW LEVEL OF PERFORMANCE

## ALCOA

- **Attributable – who performed which action and when?**

**OMNIS** stores in the database and in the audit trail the name of the person performing the task, together with the date and time of each action. (Data creation, data modification, login/logout attempts, data retrieval, ...)

- **Legible – does data remain readable throughout the complete lifecycle?**

Whenever data are generated, **OMNIS** makes it possible to:

- save the data in the OMNIS database. Subsequent versions of OMNIS are able to read data created in earlier versions.
- export the data to the network or an external memory as a full set of dedicated PDF reports or in the OMNIS file format. In this case, the user is responsible for archiving the data in a permanently readable format.

- **Contemporaneous – are records created at the time of the activity?**

The **OMNIS** audit trail records all data generating activities from all users by creating a data record with the name of the user and the client, the action, date, and time.

- **Original – is this the first recorded observation or a verified, true copy?**

**OMNIS** identifies the original data based on the version number of the original record. It is possible to trace back to the original version and extract original parameter settings of the processes at the time of the data creation.

- **Accurate – is data stored correctly and are modifications clearly documented?**

**OMNIS** provides the necessary metadata for all data in order to identify the context (e.g., name of the method, the hardware, or the sensors and solutions), the meaningfulness of the data (e.g., indication of a result in connection with the used unit), date and time. Modifications are noted and documented in the audit trail.

In the **OMNIS** database the data is linked to the calibration, processes and complete instrumentation used during a determination.

## ALCOA+

The ALCOA guidelines were recently updated to also cover aspects such as completeness, consistency, endurance, and availability of data.

- **Complete – are all relevant data stored?**

**OMNIS** provides in its database all information required to create data records, including metadata and changes.

The audit trail provides information about all the activities required to obtain the data.

- **Consistent – can the operation workflow be reconstructed?**

A formalized process systematically repeats and retraces the data retrieval processes managed by **OMNIS** in always the same way. The original process of a determination is always available to restore and export for further use.

- **Enduring – does stored data remain readable over the complete lifecycle?**

Whenever data are generated, **OMNIS** makes it possible to:

- save the data in the **OMNIS** database.
- export the data to the network or an external memory as a full set of dedicated PDF reports or in the **OMNIS** file format. The user is responsible for archiving external data for the duration of the required retention period.

- **Available – is data accessible / readable / printable?**

The data records are available throughout the entire retention period for checks, reviews, and audits in the **OMNIS** database and are also available in other standard formats depending on the user's management after a data export (e.g., PDF). The audit trail can be exported as CSV for further review or archiving.



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