OMNIS Compliance package

Compliance with the Data Integrity Guidelines made easy

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OMNIS
A WHOLE NEW LEVEL OF PERFORMANCE

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+.

Compliance/Regulation license for OMNIS Stand-Alone (6.0600.4010) or Compliance/Regulation license for OMNIS Client/Server (6.06004.011) provides all necessary features for achieving data integrity and compliance with FDA 21 CFR part 11 and EudraLex, Vol.4, Annex 11. If the license is activated in OMNIS Client/Server, the compliance functionalities are available to all OMNIS Clients.

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 WORK-FLOW BE RECONSTRUCTED?
A formalized process systematically repeats and retraces the data retrieval processes managed by OMNIS is 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.

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.

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 the 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.

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