

Peace of mind with *MiraCal P*



Compliance with the Data Integrity Guidelines made easy

Data integrity requires data to be complete, consistent, and accurate throughout a complete lifecycle, providing full transparency and traceability. Industry guidelines about data integrity, used by the FDA, WHO, PIC/S and GAMP, are described within the acronyms **ALCOA** and **ALCOA+**. **MiraCal P** analytical software from Metrohm Raman gives you peace of mind, as it ensures all data processing adheres to standards stipulated by **ALCOA** and **ALCOA+**.

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

User management in **MiraCal P**, with automatic archiving and accessible audits, enables straightforward tracking of what actions were performed, when, and by whom (e.g. time and date, user, data acquisition and configuration changes).

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

Whenever data are generated, **MiraCal P** makes it possible to export the data to a local database or external memory in PDF, CSV, or XML format. The user is responsible for archiving the data in a permanently readable format.

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

The **MiraCal P** audit trail records all activities from all users by creating a data record with the names of the user and client, the action, date, time, and difference to UTC.

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

MiraCal P clearly displays both raw data results and processed results, identifying original and subsequent data based on version number. Each measurement has a unique digital signature and the encrypted database prevents manipulation of data.

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

MiraCal P provides necessary metadata for all data in order to identify the context (e.g., name of the method, instrument hardware, or acquisition parameters), the meaningfulness of the data (e.g., Pass/Fail results with statistical support), date and time. Configuration changes are validated by the required approval of the system administrator.





ALCOA+

ALCOA guidelines were recently updated to include features such as completeness, consistency, and availability of data.

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

All data is automatically stored in **MiraCal P's** database, including information required to create the record, including metadata and changes. The audit trail provides information about all activities required to obtain the data.

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

In **MiraCal P** all configuration changes and measurements follow a consistent and easily searched sequence of events that is logged with color coded time and date stamps.

- **Enduring – does stored data remain available for the duration of the required retention period?**

Whenever data are generated, **MiraCal P** makes it possible to save data in the database in many formats. Subsequent versions of MiraCal P are able to read data created in earlier versions.

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

MiraCal P records and audit trails are always available and can be easily reviewed using integrated monitoring features. Records and audit trails can be easily checked, exported, and printed at will.

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