WHITE PAPER

How to comply with OECD Guidelines about GxP

Since the OECD Guidelines on Principles of Good Laboratory Practice and Compliance Monitoring, ENV/CBC/MONO(2021)26, were released; companies conducting tests related to non-clinical studies have raised questions about how best to manage data and comply with the new guidelines.

Even if the generated data are not intended for the development of products in contact with humans (directly or indirectly); this does not mean that less rigour should be applied in managing the data.

Moreover, more and more data are being produced daily; either manually or with computerised systems. This requires us to adapt the way to optimise accessibility, what can be derived from the data, and how the data are stored, in both the short and long term.

We can broadly summarise by saying that the guidelines refer to the application of concepts already known for GMP environments; however, it is more than that. Firstly, these OECD guidelines provide some clarifications and definitions relating to the world of data.

This guidance provides basic definitions of data, metadata, and derived data: but also, more precise notions including:

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Static Format

"A static record format, e.g., a paper or electronic record, is one that is fixed and does not allow any interaction between the user and the record content", e.g., a paper; or without any link to other records.

Dynamic Format

"Records in a dynamic state are primarily electronic records that allow an interactive relationship between the user and the record content. Examples of a dynamic format include chromatographic data stored as an electronic record that enables the user to clearly view the integration at a baseline level; or to have direct access via electronic links to the analysis sequence, the table of results, the audit trails and methods of acquisition and integration. Electronically-signed records are also dynamic records, as these contain a link associated with signature authentication."

Data Migration

A static record format, e.g., a paper or electronic record, is one that is fixed and no interaction between the user and the record content is possible", e.g., a paper or e-data, or any link to other records.

Archivist

The archivist is the individual responsible for the management, operations, and procedures for archiving in accordance with the Principles of GLP; and includes archiving data, both physically and electronically.

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In addition to the OECD guidelines, it is essential to consider the requirements of the EU GMP Annex 11 for computerised systems. Annex 11 emphasises system validation, data integrity, audit trails, security controls, and periodical system reviews. Organisations should ensure that the computerised systems not only capture and manage data in compliance with ALCOA+ principles; but also adhere to the expectations of Annex 11 for system life cycle management, supplier assessment, backup and recovery processes, and controlled changes.

Taking all these definitions into consideration, companies should have people dedicated to electronic data management and especially for data archiving (long-term retention). It is not just a matter of asking all employees to store data on a common network drive; rather, specific management is required. This also shows us that data can exist in different formats, and that these can evolve over time, throughout their life cycle.

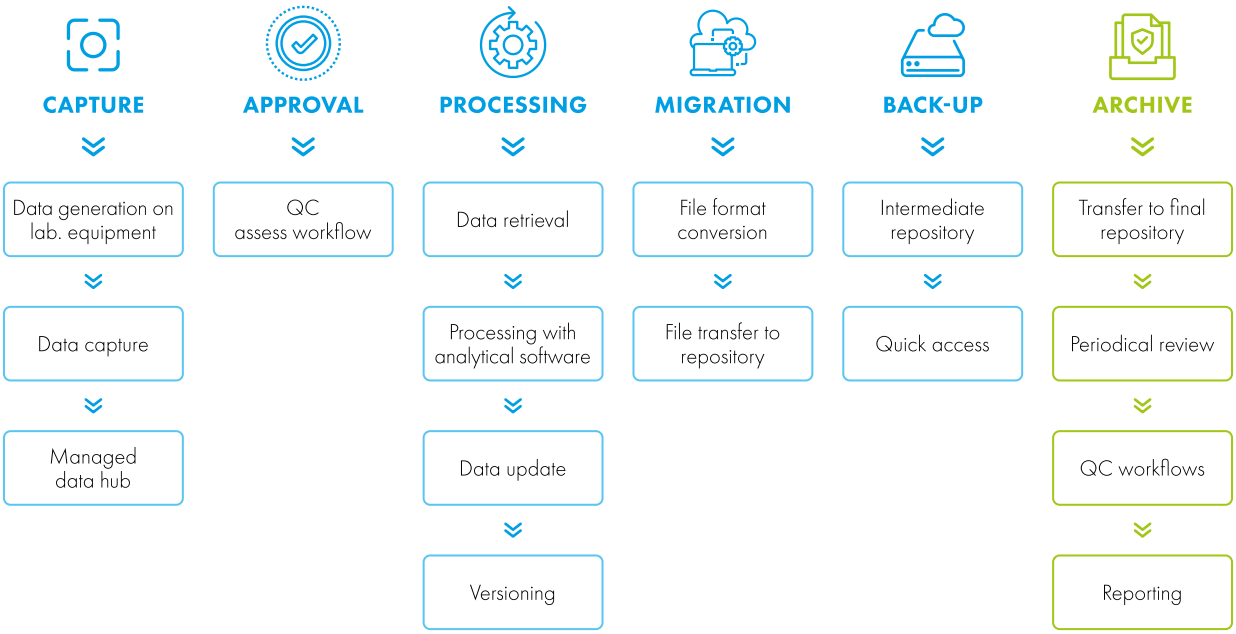
After all these clarifications, the principles promulgated by this guidance are primarily the same as those applied to GMP activities: thus ensuring the integrity of data throughout a life cycle. To achieve this, all types of data has to comply with the ALCOA+ principles (all data must be attributable, legible, contemporaneous, original, accurate, complete, enduring and available) and computerised systems must have audit trails so that all changes to data can be associated with the person who made the changes, and the date the changes were made, including the reason for the changes.

Throughout the retention period of the data, these guidelines must be adhered to. Data without associated metadata may not be interpreted correctly. Metadata enables the identification, description and linking of different sets of data; thus permitting the data to be contextualised and to be used in combination with other data.

In particular, metadata allows data to be analysed with new technologies such as artificial intelligence, deep learning or any other data mining method.

In terms of capturing, tracking, and retention time, electronic data is the most complex of cases. Optimal management of your data will therefore involve capture as soon as the data are generated by the laboratory equipment, associating metadata, transference to a storage medium, verifying the integrity of the data, managing the archiving; all whilst ensuring tracking of any type of change, and the availability of the data.

The complete data life cycle can be represented as follows:



The only way to ensure optimal data management through a complex workflow is to use a dedicated platform that will oversee and control each step of the process while simultaneously reducing operator intervention. That is why biomedion GmbH, with 25 years' experience in data management for regulated environments, has developed the brand-new Watcher 4.0 platform.

Watcher 4.0 allows you to manage your data, according to the Capture – Manage – Review model.

Watcher 4.0 will capture your data immediately when released from the lab. equipment (it can also be connected to a file share). Watcher 4.0 then takes possession of your data to store in the configured location.

Concurrently, your internal verification processes are applied and controlled. The platform will manage your archiving processes and data transferance between different types of repositories; thus optimising the total cost of ownership of your data.

Watcher 4.0 has been designed with full consideration of Annex 11 requirements. The modular architecture ensures that system validation is straightforward, with configurable user access management, and automated periodical review functionalities.

These features ensure that Watcher 4.0 is an ideal solution for laboratories aiming to meet both OECD and Annex 11 compliance while also streamlining GxP data management.

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Why biomedion?

Watcher 4.0
is the solution for end-to-end data integrity, uncompromising inspection readiness, and complete information lifecycle management. Professionals in the life sciences industry can trust Watcher 4.0 to help meet regulatory requirements and process compliance while ensuring archived data remains accessible for audits and inspections. Get the help you need to ensure your data is secure and compliant.

Raw-Data Transfer and Archiving
Raw data is an essential component of any research conducted by scientists. It is composed of raw information collected by various detection techniques, including, but not limited to, microscopy, chromatography, and spectroscopy.

Watcher 4.0

"Digitally watch raw data from the point of creation and ensure data integrity until archiving according to GxP conformity, and beyond"