How to comply on OECD Guidelines about GxP

WHITE PAPER

Since the release of the OECD guidelines on Principles of Good Laboratory Practice and Compliance Monitoring ENV/CBC/MONO(2021)26, companies conducting tests related to non-clinical studies have had a number of questions about how best to manage their data in order to comply with the new guidelines.

Just because the data we generate are not intended for the development of products directly or indirectly in contact with humans does not mean that we should be less rigorous in managing them.

Moreover, we are producing more and more data every day, either manually or using computerised systems, which requires us to adapt the way we manage data in order to optimise their accessibility, what we can get out of them, and how they are stored in the short and long term.

We could roughly sum up by saying this guidance refers only to the application of concepts already known for GMP environments, but it is more than that.
First of all, this OECD guidelines provides 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 such as:

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Watcher 4.0

Static Format

"A static record format, such as a paper or electronic record, is one that is fixed and allows no interaction between the user and the record content", such as paper or e-data without any link to other records.

Dynamic Format

"Records in a dynamic state are mostly electronic records that allow for an interactive relationship between the user and the record content. Examples of a dynamic format include chromatography data maintained as electronic records to allow the user to zoom on the baseline, to view the integration more clearly, or to have direct access via electronic links to the sequence of analysis, the table of results, the audit trails and the methods of acquisition and integration. Records electronically signed are also dynamic records as they contain a link with the authentication of the signature."

Data Migration

A static record format, such as a paper or electronic record, is one that is fixed and allows no interaction between the user and the record content", such as paper or e-data without 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, including archiving of data, physically and electronically.

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Considering all these definitions, it means that companies should have people dedicated to electronic data management and especially to their archiving (long-term retention). It is not just a matter of asking all employees to store their data on a common network drive. This requires specific management.
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 mainly the same as those applied for GMP activities: ensuring the integrity of data throughout their life cycle, whether paper or electronic data. To achieve this, all types of data must comply with the ALCOA+ principle (all data must be attributable, legible, contemporaneous, original, accurate, complete, enduring and available) that computerised systems must have audit trails to be able to associate all changes to data with the person having made those changes and the date they were made, including the reason for the changes. And this, throughout the retention period of the data. Data without their associated metadata may not be interpreted correctly. Metadata allow the identification, description and linking of different data. They allow the data to be contextualised and to be used in combination with other data. In particular, metadata allow data to be analysed with new technologies, such as artificial intelligence, deep learning or any other data mining method.

Consider the case of electronic data, which is the most complex case (in terms of capture, tracking and retention time). Optimal management of your data will therefore involve capturing them as soon as they are generated by the laboratory equipment, associating metadata, transferring them to a storage medium, verifying the integrity of the data, managing the archiving, while ensuring the tracking of any type of change and the availability of the data.
The complete data life cycle can be represented as follows:

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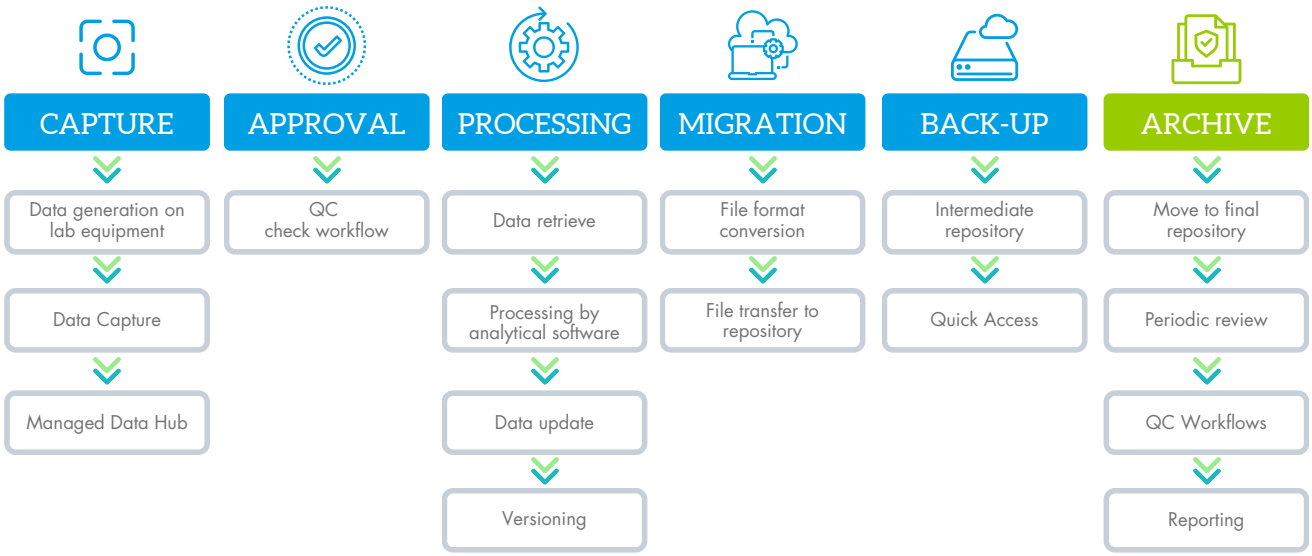

The only way to ensure optimal data management through such a complex workflow is to use a dedicated platform that will handle and control each step of the process, while reducing operator intervention.
That is why biomedion GmbH, with 20 years' experience in data management for regulated environments, has developed its brand new Watcher 4.0 platform.

Watcher 4.0 is a platform composed of different modules, specifically dedicated to raw data management. This application allows you to manage your data, according to the Capture – Manage – Review model.

WATCH+ will capture your data as soon as they are released by the lab equipment (it can also be connected to a file share). Watcher 4.0 then takes over your data to store them in the configured location, while applying and controlling your internal verification processes. The platform will manage your archiving processes and data movements between different types of repositories, to optimize the total cost of ownership of your data.

And if you are dealing with images, we can integrate our specific multi-format image viewer, IMAGE+, to allow review and consultation of these specific file formats.

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