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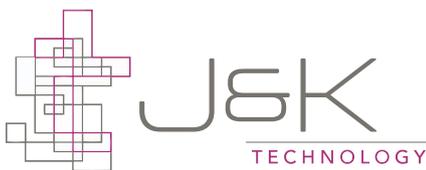
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## CVaI - The digital process and asset validation solution in COMOS

Increased data integrity and consistent data management with the object-orientation of COMOS

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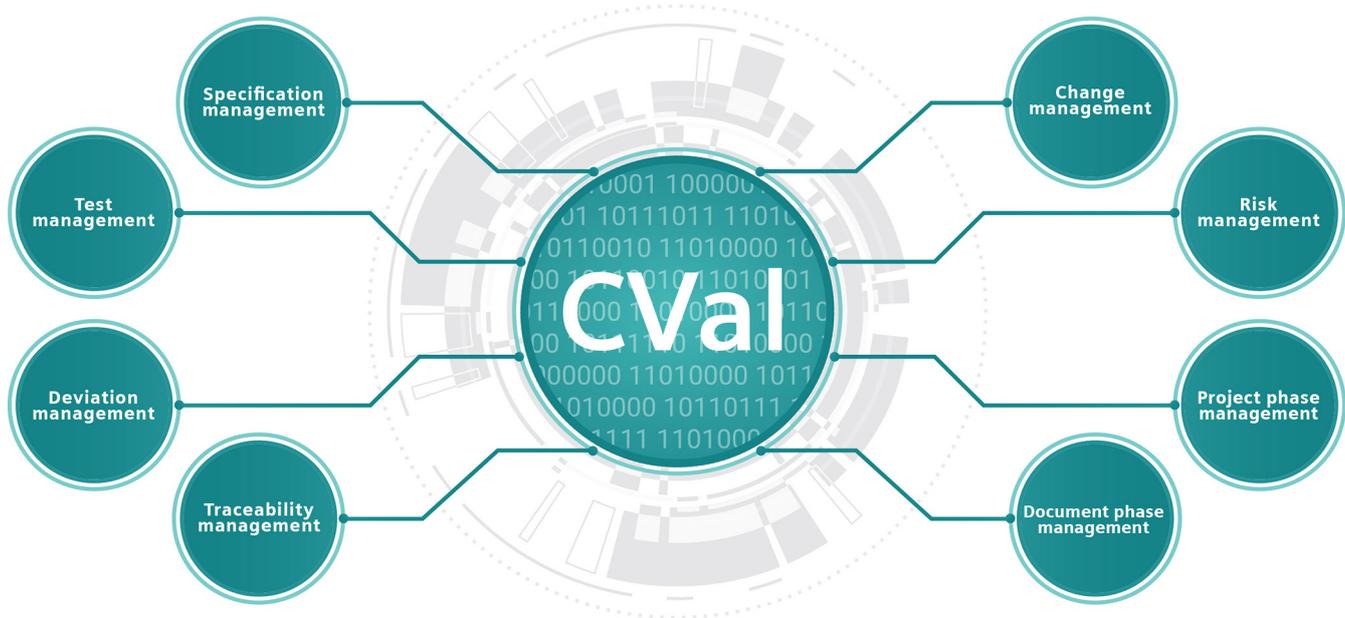
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New regulatory requirements are among the major challenges companies are facing in the pharmaceutical environment. In particular in the GMP guideline (Good Manufacturing Practice) - Annex 15: "Qualification and Validation" the guidelines for quality assurance were already adapted in 2015.

The result is an increase in complexity in lifecycle management and its processes. Complex processes require extensive qualification and validation efforts to meet the requirements. Established, paper-based procedures can only meet these challenges to a limited extent. Core aspects such as data integrity or traceability are examples that cannot be guaranteed in these processes and thus over the entire lifecycle of a plant. It is precisely these challenges that the interaction of COMOS and CVaI meets.

CVaI was developed by J&K Technology, a company of the J&K Group. It creates a digital and object-based lifecycle management that ensures data integrity and traceability. This allows all qualification and validation relevant activities to be carried out in a central application. This step of digitalization makes it possible to link data intelligently and eliminate redundancies.

Errors caused by manual data transfer or the adaptation of interfaces can thus be eliminated and all the trades involved in a process (e.g. engineering, operations and compliance) benefit together. The result is increased data integrity, more efficient processes and continuous traceability.



### COMOS platform

COMOS platform is an object-oriented and database-neutral software for cross-departmental plant engineering and plant management.

The software solution enables shortened processing times and an efficient workflow through decisive basic functionalities. COMOS platform is designed for international applications and can be used multilingually for global cooperation. In this way, all work areas and users involved in a plant project at different locations can access the same plant data. This reduces time-consuming and data-intensive exchange processes and accelerates the work processes. This means that up-to-date and consistent data can be made available to the respective users at any time, worldwide, regardless of the specific time zone.

### COMOS DDMS

COMOS Data and Document Management System offers a range of tools to enable a compliant documentation of plants and processes.

The data and documents generated by using COMOS platform and CVal are managed electronically and are available in a tamper-proof manner.

Documents are reviewed and approved on the basis of workflows and the use of electronic signature procedures.

This can greatly reduce the processing time for the release of documents.

Markup functionalities are also available for document correction, so that all red corrections can be recorded centrally and uniformly.

### CVal

The digital twin, which is available in COMOS, serves as the basis for CVal. The data of the various CVal modules can be generated object-based and directly based on the respective equipment or in already existing libraries. CVal supports the following validation-relevant functionalities in COMOS:

- Specification management
- Test management
- Deviation management
- Traceability management
- Risk management
- Change management
- Project phase Management
- Document phase management