

## Validation goes digital - Siemens and J&K Technology announce partnership

- **Siemens and J&K Technology support digital validation process**
- **New CVal software solution for digital process and plant validation in COMOS for the pharmaceutical industry**
- **Efficient data handling across all disciplines - using a central database and object orientation**

Siemens and J&K Technology, part of the J&K Group, announce the development of the new CVal software solution for COMOS. J&K Technology, a specialist in cGXP Compliance Services, has developed the CVal solution. CVal is a digital process and plant validation software for use in the pharmaceutical industry, based on the Siemens COMOS Plant Engineering software solution. This involves a wide range of different modules based on the COMOS platform and the COMOS Data Document Management System (DDMS). As a result, this digital application consistently creates greater data integrity, quality, coherence, and topicality.

Companies in the pharmaceutical industry have to ensure that their activities comply with regulatory requirements such as the Good Manufacturing Practice (GMP) – Annex 15: Qualification and Validation, constantly. Quality assurance guidelines had already been adapted in this field in 2015. The Siemens COMOS software has been successfully used for engineering and life cycle processes in regulated industries for decades.

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The new CVal software extension links data from the documentation system to the COMOS engineering system. This creates a digital and object-based life cycle management which ensures both, data integrity and traceability. CVal can be easily extended by other COMOS software solution modules, to produce efficient life cycle management processes within an application.

The COMOS software solution provides efficient data handling across a range of disciplines due to its central database and object-oriented approach. This and offers the possibility to build a so-called “digital twin”. CVal is based on the digital twin of the plant available in COMOS. The data for the various CVal modules can be generated directly on the relevant equipment or in existing libraries based on each object. CVal extends COMOS by the following modules: Specification management, traceability management, risk management, change management, test management, document phase management, deviation management, and project management.

The COMOS object orientation allows data to be linked within itself and with other plant equipment to provide the correct information where it is actually required. Errors, such as those produced by manual data entry or matching interfaces, can thus be prevented to the benefit of all the disciplines involved in a plant, such as engineering, operations, and compliance.

“With CVal, we have added a significant component to our product portfolio based on our Siemens COMOS plant engineering software solution. This allows us to help our customers in the pharmaceutical industry produce digital, auditable plant documentation,” says Philipp Fisler, Siemens Industry Software GmbH

“The interaction of COMOS and CVal enables completely new possibilities for the regulated industry. For the first time, all the involved trades during the construction of a new plant or the change of existing plants can work together in an integral

software solution. Therefore they can benefit from each other,” says Rainer Krueger of J&K Technology.



CVal is a digital process and plant validation software for use in the pharmaceutical industry, based on the Siemens COMOS Plant Engineering software solution

This press release is available at: <https://sie.ag/31bMQqp>

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Joint Press release  
**Siemens and J&K Technology**

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**Siemens Digital Industries** (DI) is a leading innovator in automation and digitalization. In close cooperation with its partners and customers, DI is the driving force for the digital transformation in the process and manufacturing industries. With its Digital Enterprise portfolio, Siemens provides companies of all sizes with all the necessary products, along with consistent solutions and services for the integration and digitalization of the entire value added chain. Optimized for the specific requirements of individual industries, this unique portfolio enables customers to enhance their productivity and flexibility. DI continuously extends its portfolio to include innovations and enable the integration of future-oriented technologies. Siemens Digital Industries, with its headquarters in Nuremberg, has a workforce of around 76,000 employees worldwide.

**Siemens AG** (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 170 years. The company is active around the globe, focusing on the areas of intelligent infrastructure for buildings and distributed energy systems, and automation and digitalization in the process and manufacturing industries. Through the separately managed companies Siemens Energy, the global energy business of Siemens, and Siemens Mobility, a leading supplier of smart mobility solutions for rail and road transport, Siemens is shaping the energy systems of today and tomorrow as well as the world market for passenger and freight services. Due to its majority stakes in the publicly listed companies Siemens Healthineers AG and Siemens Gamesa Renewable Energy (as part of Siemens Energy), Siemens is also a worldleading supplier of medical technology and digital healthcare services as well as environmentally friendly solutions for onshore and offshore wind power generation. In fiscal 2019, which ended on September 30, 2019, Siemens generated revenue of €86.8 billion and net income of €5.6 billion. At the end of September 2019, the company had around 385,000 employees worldwide. Further information is available on the Internet [www.siemens.com](http://www.siemens.com).

**J&K Technology** is part of the **J&K Group** and, together with **J&K Consulting**, forms the basis for balanced and goal-oriented consulting in the regulated industry. J&K Technology specializes in digital lifecycle management of systems and processes. With CVal, J&K Technology provides a software solution that bundles the GMP know-how of the J&K Group from the past 25 years and combines innovative processes in the area of compliance with established processes from the areas of engineering and operations. Further information is available on the Internet at [www.j-k-technology.de](http://www.j-k-technology.de).

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