

SIEMENS



Meeting future challenges for pharmaceutical plants today

COMOS Software Solutions



Pharmaceutical and
Life Science industries

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Efficient engineering and management of pharmaceutical plants

In the pharmaceutical industry, a product's time-to-market has to be extremely short, the production highly efficient, and the product quality impeccable.

In the engineering and operation of a plant, it is crucial to comply with the stipulations of national and international regulatory authorities, such as the Food and Drug Administration (FDA) or the European Medicines Agency (EMA). Recommendations of independent institutions like the International Society for Pharmaceutical Engineering (ISPE) support the operators of pharmaceutical plants in important processes. If a plant's qualification and the validation of the product quality are integrated into the plant's early planning stage as well as in its later operation, all parties involved will have access to all relevant information and compliance with all stipulations will be ensured. This shortens a product's time-to-market and allows the plant owner to more effectively take advantage of the patent protection term.

With COMOS, Siemens delivers a comprehensive software solution for the optimal integration of engineering and operation. Using a global, single data platform, the up-to-date engineering information is always available over the entire lifecycle of the plant. This information, as well as the individual steps taken in planning and operation, are documented in a complete and structured way. The loss of information due to duplicate data input or data transfer is minimized. This information quality ensures consistent documentation and highly efficient plant operation from the planning stage onward.

With the consistent data platform of COMOS, workflow becomes more efficient, ensuring higher productivity and quality. This comprehensive approach is based on a function-oriented overall view of all trades and specialist disciplines employed in a plant. The open system architecture of COMOS allows the seamless integration of various systems.

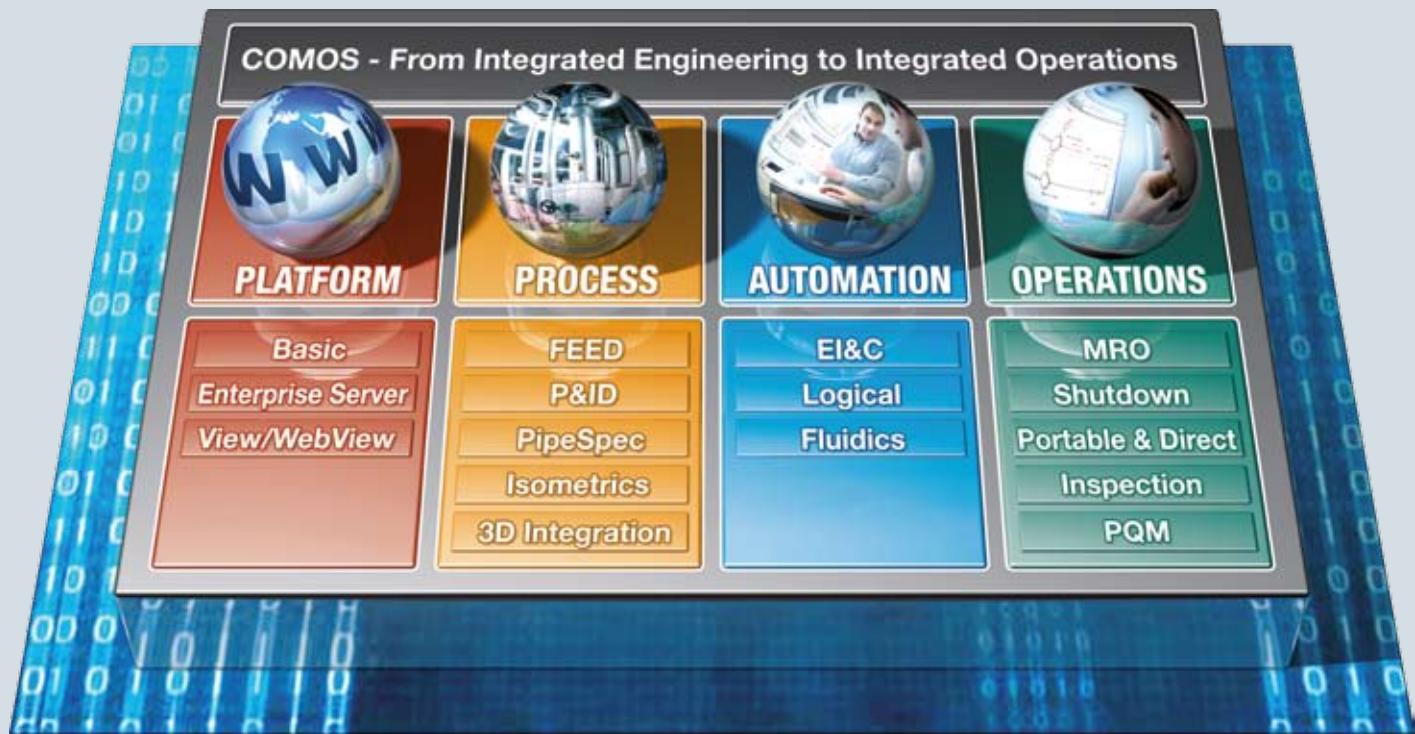


Maximum efficiency with integrated plant management

Development and production of pharmaceutical products requires the consistent planning and documentation of all processes over the entire plant lifecycle. There is high pressure to reduce costs because patent protection terms are short, and the cost for product development is increasing. The highly efficient use of time during the patent protection term is supported by COMOS with integration of plant implementation and operation. The development information from the clinical testing phases is also integrated with scale-up activities.

Ongoing market consolidation results in larger companies. This leads to increasingly complex production facilities. In order to run facilities in a profitable way and in accordance with Good Manufacturing Practice (GMP), the integration of plant engineering, operation, and maintenance becomes ever more important to drug manufacturers.

These factors have to be included in every development process from the very beginning in order to produce drugs efficiently. COMOS enables standardization globally as well as at the plant level. This increases the reusability of information that has already been generated. New plants can be constructed based on existing data and information. This means that new locations can be established flexibly and cost-efficiently all over the world.



Comprehensive software solutions for complex demands

The broad range of the COMOS solutions integrates planning and management over a plant's entire life-cycle.

The comprehensive range of COMOS solutions ensures the consistent acquisition and processing of all information from the first design and engineering phase. This results in maximum efficiency for planning and management of a plant.

The modular software solutions of COMOS can be implemented together or individually. This makes possible a comprehensive application as well as a step-by-step implementation. The result is an integrated system that does not only facilitate working in interdisciplinary global surroundings, but ensures the transparency that is required for compliance with all regulations.

Optimal transparency and interoperability in the planning and operation stages are vital for efficient information management. The foundation for this is COMOS Platform. Information from all applications and segments is stored centrally and in object-oriented form in the COMOS database.

COMOS Process comprises applications for process engineering. At an early stage of plant design, layout data can be used to create process flow diagrams that can then be used to form the more precisely defined piping and instrumentation diagrams. COMOS Process supports quality-controlled pipe engineering and pipe spec management conforming to international industry standards. Translation of process data on the geometric level, in the form of isometrics and 3D images, is easy to derive from the existing information.

COMOS Automation supports the electrical engineering of machines and plants all the way to full automation. All processes relevant to electrical, instrumentation, and control engineering are covered by customized solutions. Logical connections between objects as well as automated processes are shown graphically in diagrams, for instance, hydraulic and pneumatic flow charts are generated on the basis of preexisting data.

The benefits of COMOS for the pharmaceutical industry

- *Integrated compliance management across all stages of engineering and operation*
- *Consistent flow of information with a common database*
- *Logical connections and automated processes facilitate efficient process and electrical engineering*
- *Easier document management by using the Responsibility Matrix for assignment of responsibilities*
- *Automated generation of templates based on Document Execution Plan*
- *Efficient plant supervision with automatically generated maintenance schedules*



The solution for an efficient plant supervision strategy is COMOS Operations. All information from the engineering stage can be used in the operation stage as well. Solutions for maintenance during uptime and as well as during shut-down are available. Measures taken in the field or on the shop floor can be reported trouble-free.

The software solution for the pharmaceutical industry

One part of COMOS Operations is COMOS PQM (Project Quality Management). It has been extended to fit the special demands of the pharmaceutical industry. The result is a solution that meets the distinctive requirements of this field of business. The required documentation structure is generated on the basis of standardized templates as early as in the design and engineering stage. The timely delivery of documents to the responsible party is facilitated by the assignment of responsibilities based on a Responsibility Matrix. These processes are in accordance with the GMP and therefore compliant with the stipulations of the regulatory authorities.

COMOS PQM for the pharmaceutical industry enables the qualification of the entire plant during all stages of engineering and operation. The consistency of blueprint and plant as well as material and supplier specifications can all easily be checked with COMOS. The test results of the operational qualification can be documented, archived, and retrieved easily as well. The software creates all documents required and makes the latest version available at all times. This means that all steps toward approval can be taken properly and efficiently.

In order to validate the products of a plant, all assets influencing the quality of the finished product have to be identified. COMOS accesses the information from the development and test stages. Risk assessment within the system enables fast corrective and preventative intervention in the process.

Changes in the actual state of the plant are integrated into the database and synchronized with the digital plant. This avoids discrepancies between them. It can be checked easily if a new validation or qualification becomes necessary through changes in the plant and the necessary steps can be initiated.

COMOS makes it possible to easily transfer documents generated during earlier projects to a new one. This shortens the time-to-market and optimizes utilization of the patent protection term, which makes COMOS an integral part of any change management processes.



Meeting future challenges for pharmaceutical plants

Integration and standardization for increased competitiveness

The extension of COMOS PQM for the pharmaceutical industry provides integration of all process-relevant systems, thus enabling direct project monitoring. Additionally, the software solution is a foundation for standardization and bundling of competencies. COMOS PQM also supports continuous innovation across the lifecycle of the plant. This increases the efficiency of the entire production processes, enabling faster time-to-market and minimizing risks and costs, thereby improving the overall competitive position. Consistent process validation based on international standards can be ensured at all times. This is applicable to greenfield as well as brownfield projects. The modular structure of COMOS is well suited for projects of all sizes.

Access to the latest plant status is available with COMOS, enabling the seamless interaction between the plant operator and the engineering, procurement, and construction (EPC) supplier. This seamless interaction ensures that all demands and requirements can be addressed and tracked from the earliest project stages. COMOS can provide consistent and up-to-date information to applicable oversight agencies.

Consistent information management is the key to optimal planning and efficient management of pharmaceutical plants. COMOS supports all processes required for this and facilitates planning and documentation through its unique consistent database and its modular structure.

Glossary

Data consistency

Data is entered only once and is then available to all stakeholders at any time and everywhere. Stringent inheritance and linkage mechanisms provide all stakeholders involved in a project with access to up-to-date and consistent data from any location and at all times.

Interoperability

Interoperability is the ability of mutually independent systems and technologies to smoothly collaborate by complying with common standards. Information can be efficiently provided without the need for specific inter-system arrangements. This facilitates quick and reliable world-wide decision-making around the clock.

Object orientation in COMOS

Object orientation is the holistic description of an existing component and its true-to-life graphical representation. The graphical and alphanumerical manifestations within the database constitute a single entity – the object.

Transparency

Holistic, function-oriented mapping of plant and equipment makes for end-to-end communication across all levels, offering all stakeholders consistent data, without any losses, on a unified data platform. As a result, the complete documentation can be traced at any time.



Ask us about COMOS solutions for the pharmaceutical industry. Let us plan your plants of the future together.

If you would like further information today, simply visit our website:

[siemens.com/comos](https://www.siemens.com/comos)

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