SIEMENS
Ingenuity for life

Integrated FDA compliance for the pharmaceutical industry

Empower your data value with COMOS – Compliant data and document management

siemens.com/data-document-management

Manufacturer instructions and protocols, validation and qualification documents, standard operating procedures (SOP), lab documentation, etc. – the pharmaceutical industry is one of the most regulated industries and the requirements for compliant documentation are correspondingly extensive. Profit from our decades of experience in the pharmaceutical sector and convince yourself of COMOS as an integrated electronical data and document management system (EDMS) that meets the strict regulatory requirements of the pharmaceuticals industry (e.g. FDA, 21 CFR Part 11) and creates a real added value.

COMOS is much more than a valued system management system, it is a customizable and comprehensive software solution concept. COMOS permits strictly object-oriented work on an integrated data platform. This forms the basis for a consistent flow of information and solid documentation: there is a central and always up to date data administration which all participants can access anywhere and anytime based on their role. This lets us realize integrated system management projects for our customers over the entire lifecycle of industrial systems.

Central data platform

Our data and document management for the pharmaceutical industry meets FDA, 21 CFR Part 11 requirements as well as the regulations of other national and international regulatory agencies. At the same time, COMOS makes the entire documentation and associated revision significantly more efficient. Our software solution offers the technical basis and necessary performance for this task. All information is stored and managed in a central database. For all required documents, there are standardized templates with corresponding header data – adjusted to your company and your working methods.

The intuitive web interface of COMOS permits all stakeholders to view, process, or release their specific data.

Validated digital work flows

FDA regulations, in particular 21 CFR Part 11, concern all information that is generated, altered, stored, transmitted, or accessed electronically. In order to ensure gapless traceability of all steps, all users must be authenticated and correspondingly authorized. COMOS PQM (Project Quality Management) provides corresponding tools for the compliant handling of information. They range from the responsibility matrix that comfortably allocates responsibilities to the implemented eSign technology for electronic signatures all the way to integrated GMP standards such as Audit Trail and Change Management.

Rule-supporting web access

Mobile devices change our work life – and COMOS supports this new flexibility. We provide you with secure web-based access via COMOS Mobile Solutions for uploading, verifying, or releasing documents. Like the entire COMOS environment, the web application also meets the requirement of FDA, 21 CFR Part 11 and supports technologies like eSign, encryption, and user-based access restrictions. The intuitive web interface permits all stakeholders to view, process, or release their specific data – anywhere, anytime, per smartphone or tablet.

Tailor-made fits best

Even if you are not yet using COMOS for the planning and lifecycle management of your pharmaceutical plant, you can still enjoy the benefits of integrated data management and an object-oriented methodology for your compliant documentation. The easy import of foreign data formats is not just limited to documents: COMOS offers FDA compliant document and data management. Convince yourself of the benefits of this consistent data continuity and profit from more efficient approval workflows and reduced validation work.

Key features

- Integrated, electronical data and document management for integrated data consistency
- Validated system, conforming with FDA, 21 CFR Part 11 requirements (GMP / GAMP 5)
- Support of pharma-specific approval workflows incl. task management and eSign
- Integrated change management
- Secure, FDA compliant access via intuitive web interface on mobile devices
- Standardized interfaces to other software systems for easy data exchange
- Expandable to a complete life cycle engineering and plant management system
- World-wide service and support by Siemens

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Security information
In order to protect plants, systems, machines and networks against cyber threats, it is necessary to implement – and continuously maintain – a holistic, state-of-the-art industrial security concept. Siemens' products and solutions only form one element of such a concept. For more information about industrial security, please visit http://siemens.com/industrialsecurity.