engamp®
document control

Digital document control for
the life sciences industry

Content

In this white paper we introduce **engamp® | document control** a software solution that supports regulated industries in the precise management and control of documents.

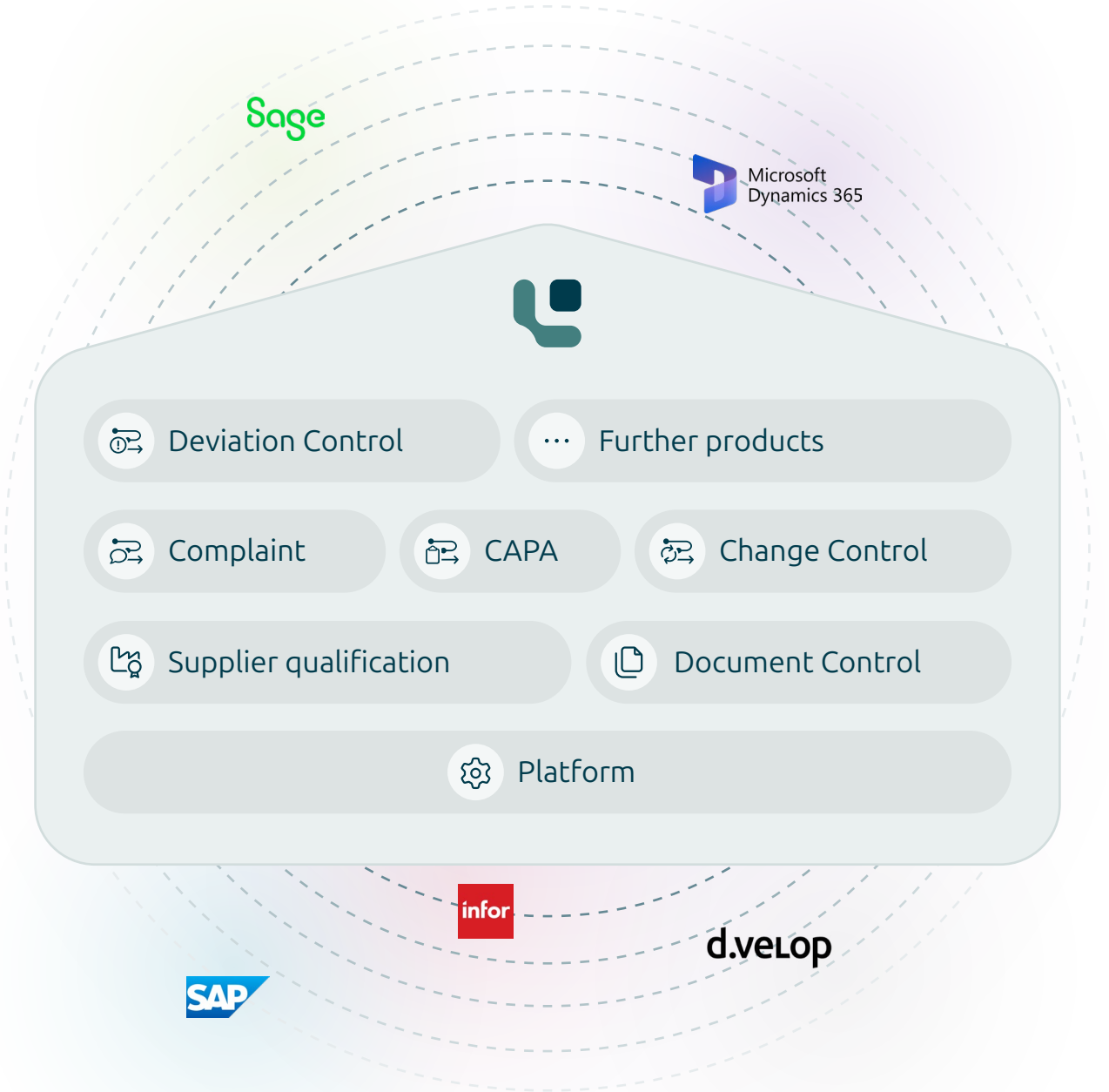
Introduction

Trust is good, documented traceability is better. With **engamp®** you not only save time, but also avoid compliance risks that can be costly.

In regulated industries such as the pharmaceutical or medical technology sector and laboratories, the precise management and control of quality-relevant documents is essential. At the same time, there are high demands on efficiency, transparency and traceability in the documentation.

Today, modern technologies make it possible to design document control processes that are not only digital, but also intelligent, integrated and user-friendly – while complying with all regulatory requirements.

This white paper introduces the solution **engamp® | document control** a module specially developed for the life sciences industry that digitizes the entire document lifecycle and automatically combines approval processes, versioning, training status and audit trails.



Basic principle

Your flexible solution

The basic principle of our software is a modular concept – all software solutions can be implemented as modular components and can be expanded like a building block model to form a complete GxP-compliant eQMS suite.

Only those who guarantee data integrity and audit-compliant documentation can create transparency and trust in the Document Control process.

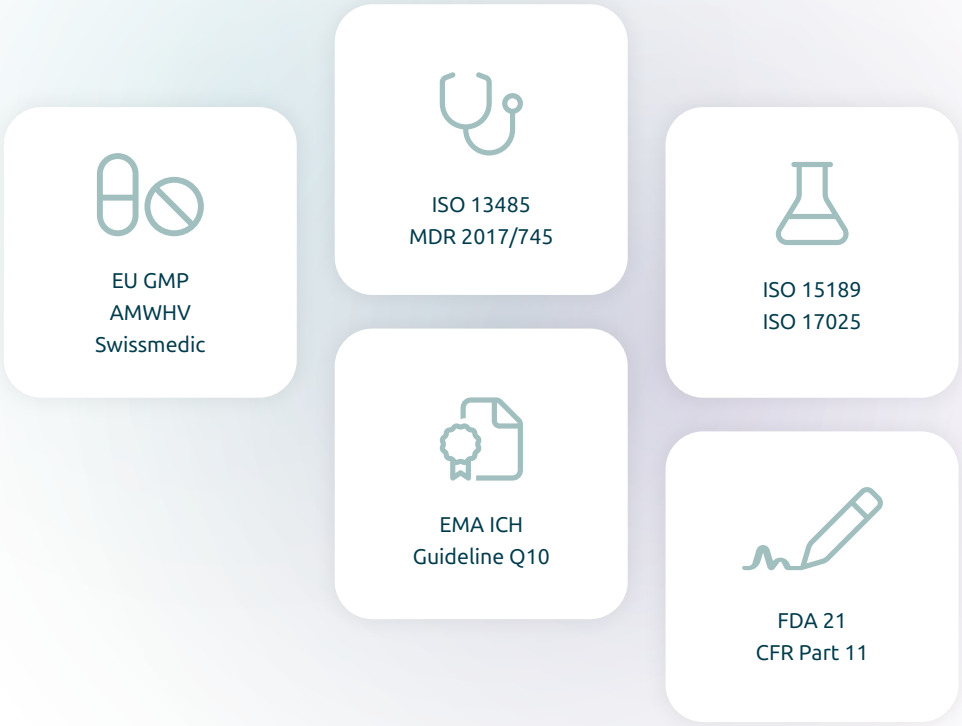
Objective

Requirements for modern Document Control

The requirements for a modern Document Control system in a regulated environment are high. The solution must ensure that all regulatory requirements - including those from EU GMP (Annex 11), 21 CFR Part 11 and ISO 13485:2016, etc. – are consistently met. All activities within the document lifecycle route must be documented consistently, including a complete, traceable audit trail.

A future-proof Document Control system must also maintain data integrity and enable audit-compliant management. It should provide standardized but customizable processes to ensure consistency and avoid compliance violations. A clear allocation of roles with defined responsibilities and a transparent distribution of tasks are also crucial – both for regulatory traceability and for internal efficiency.

engamp® | document control meets these requirements by providing a structured, compliant and digital representation of the entire document process – from creation and editing to verification, approval and release, right through to periodic review and archiving.



Regulatory requirements

Our digitalization solutions were developed specifically against the background of the applicable regulations, guidelines and standards in the regulated environment. Our many years of experience in the development of software for digital quality management ensures consistent compliance with standards.

Especially our solution **engamp® | document control** takes into account the requirements of the following regulations (excerpt):

- EU-GMP Guideline, Annex 11
- FDA 21 CFR Part 11
- ISO 13485:2016, Chapter 4
- ISO 9001:2015, Chapter 7.5
- ISO 15189 and 17025

5 essential aspects

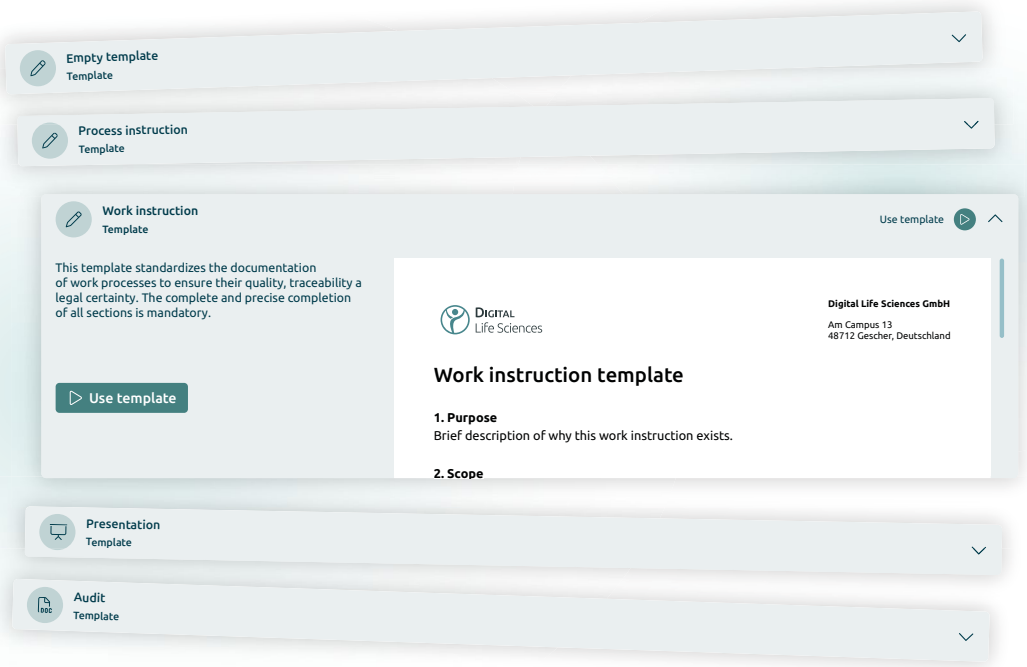
Create, find and manage documents

engamp® | document control enables centralized, structured and intelligent storage of all documents. This ensures that all authorized users have access to the information relevant to them at all times and from any location. The search for documents is significantly accelerated, making work processes more efficient and transparent.

Documents can be found, displayed and edited with just a few clicks. Thanks to the integrated versioning, it is always possible to see which document version is currently valid. Files and documents can be conveniently imported using drag-and-drop. This accelerates document creation and reduces media disruptions in day-to-day work. Use the integrated editor to create and edit documents directly in **engamp®** – of course we also support all common Office formats.

Other features in this context

- Combinable search via attributes and properties
- Creating and editing documents directly in engamp®
- Integrated, audit-compliant archiving
- Upload files and documents via drag-and-drop
- Connect your documents and create links between the documents



Uniform creation via templates

With the integrated template management of **engamp® | document control** you can ensure that all documents are created in a uniform, complete and formally correct manner. Centrally managed templates, which take your company-specific layout and format specifications into account, sustainably improve the consistency of your documentation – an important building block for reliable and professional quality management.

Templates can be updated centrally at any time, allowing changes to take effect quickly throughout the entire system. This means that all employees always have access to the latest version – automatically, without manual detours.

Other features in this context

- Centralized management and easy updating of templates
- Standardized format and layout specifications for all documents
- Minimization of formatting errors and structural inconsistencies

Edit, review, approve and release documents

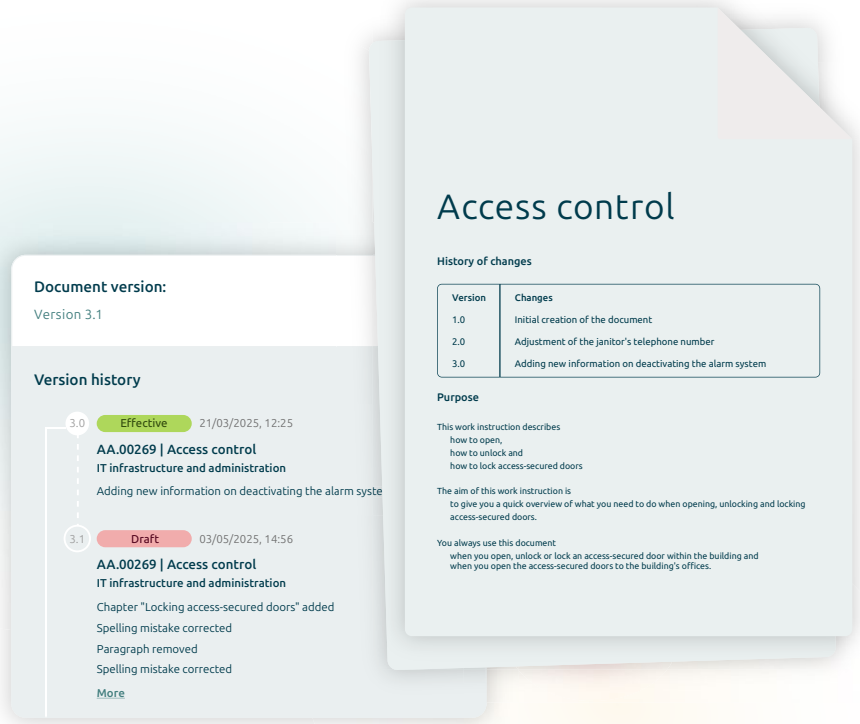
With **engamp® | document control** you control the entire lifecycle of your documents digitally, flexibly and fully compliant. From creation, verification, approval and release to training, setting effective and periodic review: All steps are mapped in the system in a traceable manner and confirmed in a legally secure manner with an electronic signature.

engamp® | document control also supports new process steps such as editing - for joint creation of documents - as well as pre-checking, which enables additional quality assurance prior to the checking process.

Particular attention is paid to the high level of adaptability: Document circulation can be configured in a clear administration interface and can be tailored precisely to your organizational processes. You can determine which roles and how many people are involved in the process yourself - or use tried-and-tested standard processes with predefined steps, groups and/or people.

Other features in this context

- Fully digital document lifecycle route - from creation to setting effective
- Flexible adjustment of the document circulation via an administration interface
- Integration of additional steps such as processing and pre-checking
- GxP-compliant, electronic signature for all actions



Track changes securely

engamp® | document control offers integrated versioning for all documents – regardless of whether they are controlled or uncontrolled documents.

The current version of a document is clearly visible to users at all times – ensures security when dealing with quality-relevant content. Previous versions remain traceable and can be called up or compared quickly if required. This allows you to retain control over the document history at all times and avoid unintentional editing on an outdated basis.

The integrated version comparison allows you to display differences between any versions directly in the system – especially for checking, approval or release tasks. This allows changes to be tracked in a targeted and time-saving manner without having to compare them manually.

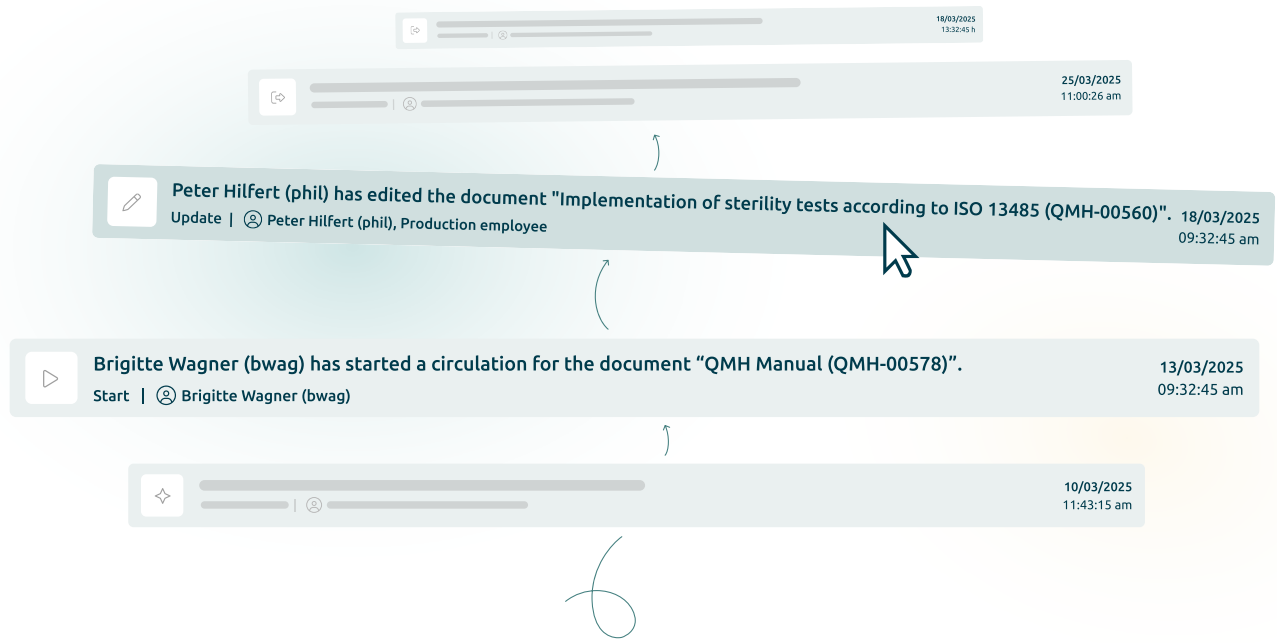
Other features in this context

- Automatic versioning with every change
- Comprehensive documentation of who made which changes and when
- Easy tracing and restoration of previous versions
- Numerical representation of editing and publication versions

Work in a fully auditable manner

engamp® | document control offers a fully integrated electronic audit trail function, with which all document-related activities are logged completely and unalterably. Whether processing, verification, approval, release, archiving or periodic review – every action is automatically recorded and stored.

This function fulfills the requirements of international regulations such as FDA 21 CFR Part 11, EU GMP, ISO 13485:2016 and many more, and helps companies to be audit-ready at all times. The comprehensive traceability of all changes ensures data integrity – and strengthens confidence in the documentation.



Other features in this context

- Complete and automatic logging of all document-related actions
- Support for regulatory requirements (including FDA 21 CFR Part 11, EU GMP, ISO 13485:2016)
- Visibility of changes throughout the entire document lifecycle route
- Protection of data integrity through unchangeable entries

Advantages

Summarized for you

engamp® | document control is a module specially developed for the life sciences industry that digitizes the entire document lifecycle route and automatically combines approval processes, versioning, training status and audit trails.

Benefit from:

- Efficiency and transparency throughout the entire document cycle
- Centrally available and up-to-date information
- Time and cost savings thanks to clear processes and intuitive operation

Request a non-binding demo now

Klaus Burmeester
klaus.burmeester@digital-ls.de

+49 2542 20201-65
+49 176 19202030
www.digital-ls.de

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