engamp®
change control

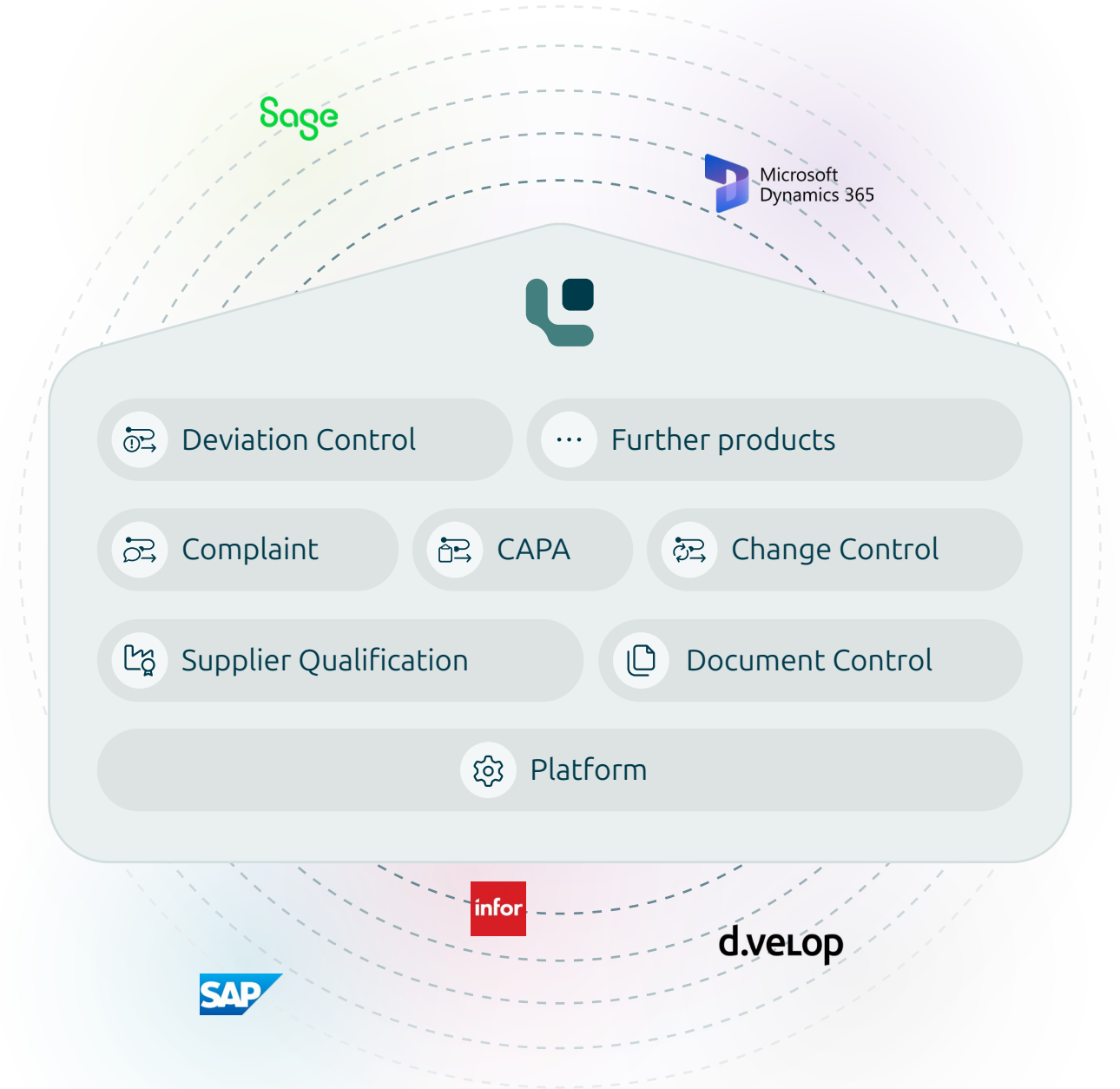
Digital Change Control
process for the life sciences
industry

Content

In this white paper we introduce **engamp® | change control**, a software solution that supports companies in the structured, compliant and efficient implementation of Change Control processes.

Introduction

In regulated industries such as the life sciences sector, every quality-related change is subject to strict regulatory requirements. The Change Control process ensures that all planned and unplanned changes are evaluated, approved, implemented and tracked - always in accordance with the applicable regulations. At the same time, it is intended to network the departments concerned, minimize risks and increase transparency. This white paper presents the solution **engamp® | change control** solution, which was developed specifically for these requirements.



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 change process.

Objective

Requirements for a sustainable Change Control process

The solution must ensure that all regulatory requirements are consistently met. All activities within the scope of the change process must be documented throughout – including a complete, traceable audit trail. This is essential to ensure transparency, integrity and traceability. A future-proof system must also ensure data integrity and enable audit-compliant management.

It is also crucial to identify and assess risks at an early stage. The system must provide mechanisms for risk analysis and measure planning. At the same time, standardized workflows should ensure consistency and thus prevent compliance violations. Finally, a clear assignment of roles with defined responsibilities and a transparent distribution of tasks is essential for regulatory traceability and internal efficiency.

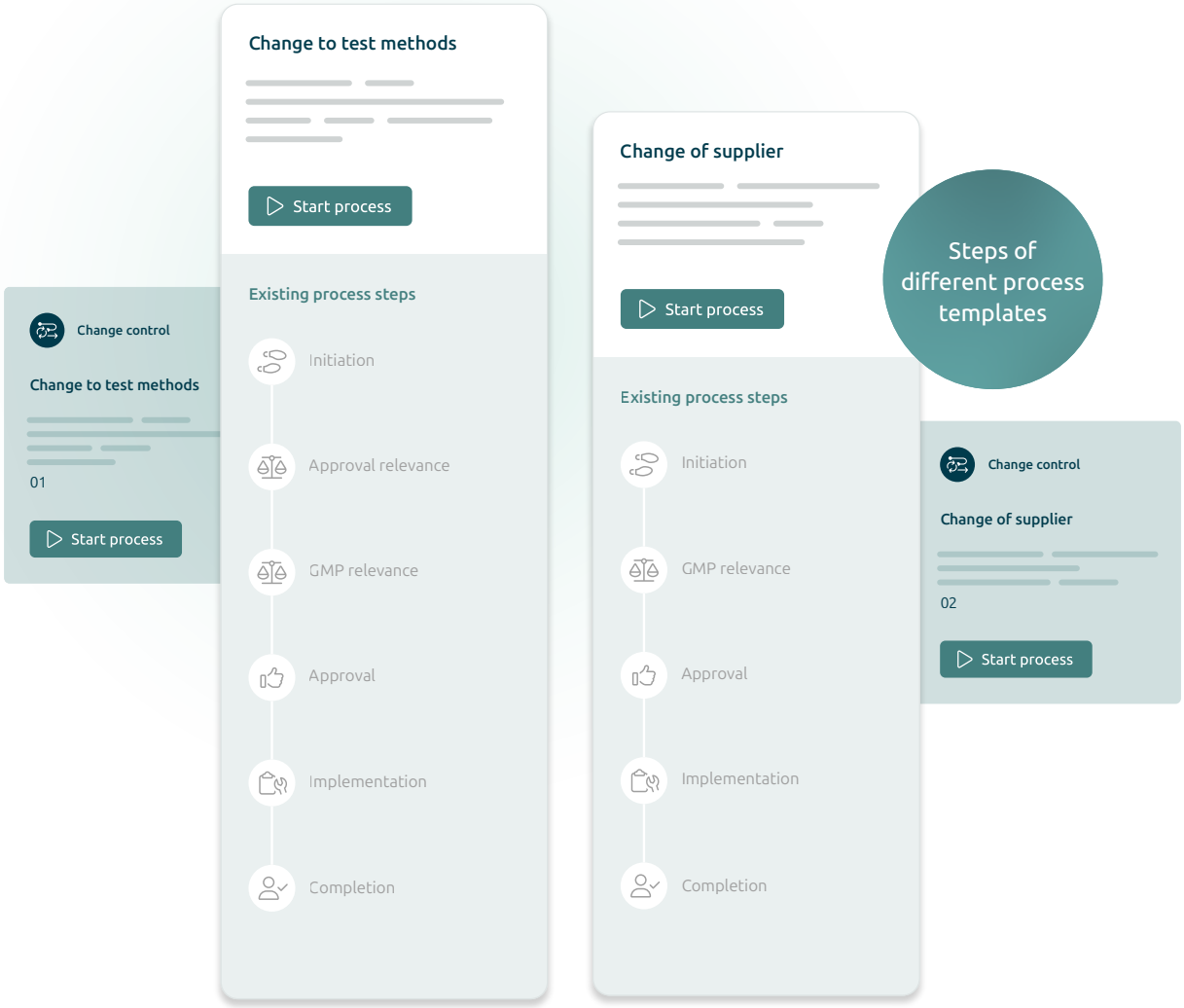
engamp® | change control meets these requirements by providing a structured, compliant and digital representation of the entire change process – from recording and implementation through to completion.

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® | change control** takes into account the requirements of the following regulations (excerpt):

- EU-GMP Guideline, Annex 11
- FDA 21 CFR Part 820
- ISO 13485:2016, Chapter 7.3
- ISO 17025
- EMA ICH Guideline Q10, Chapter 3.2



Scope of services

engamp® | change control covers the entire change process digitally and supports companies in efficiently managing quality-relevant changes.

Fixed process steps

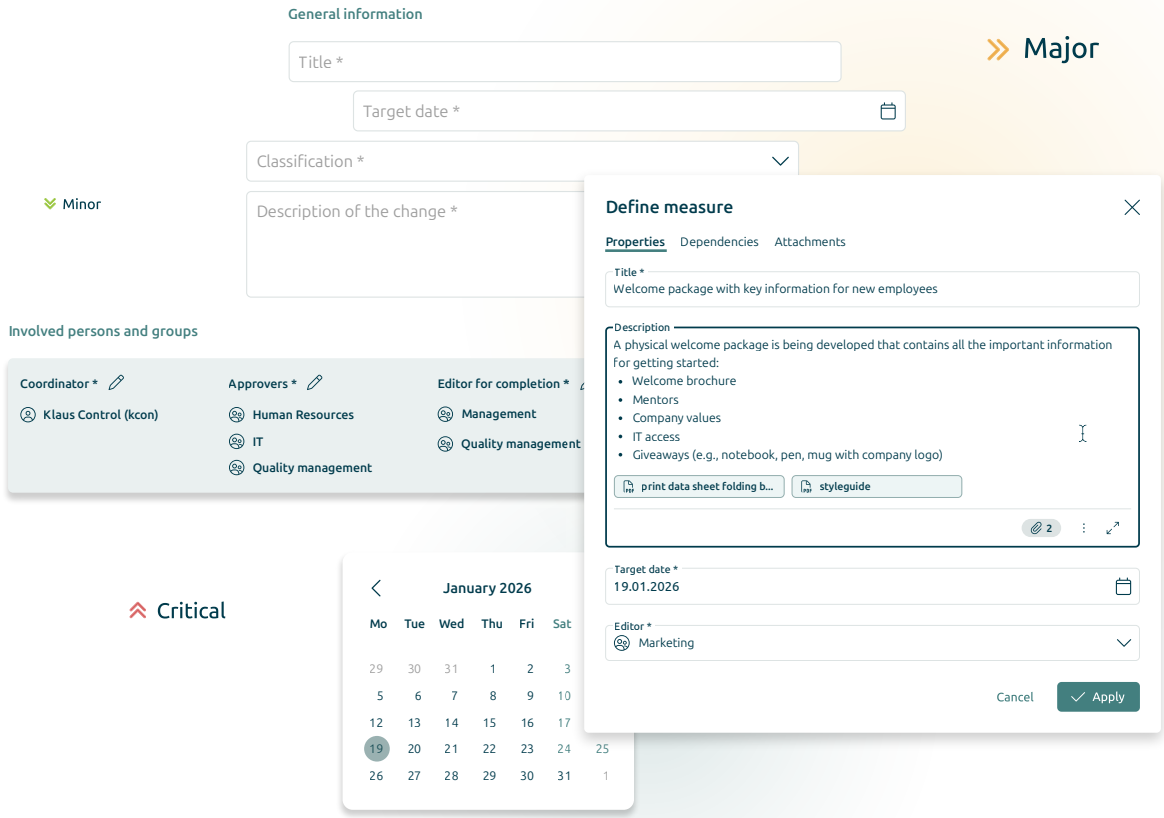
- Initiation
- Approval
- Implementation
- Completion

Optional process steps

- Initial evaluation
- Relevance evaluation
- Collection of measures
- Effectiveness check

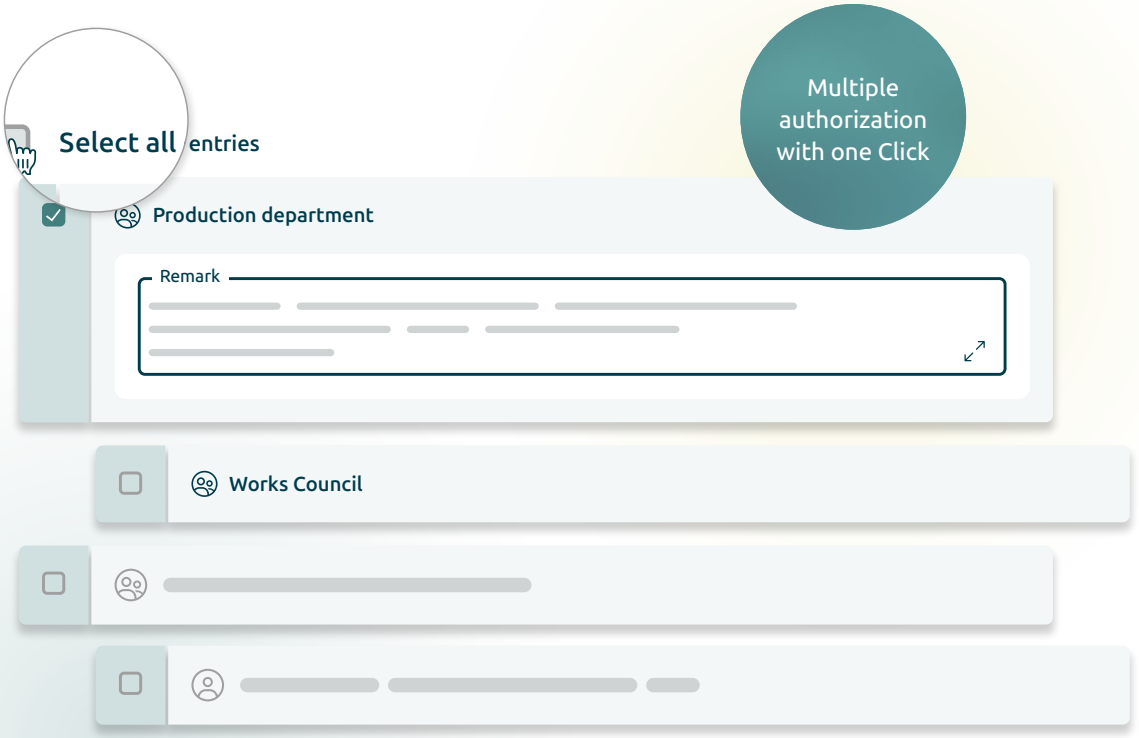
Initiation – sound basis for your planned changes

In the first step, changes can be recorded and described in detail. The criticality of the change is classified. A risk evaluation is used to evaluate potential impacts. Necessary measures can be defined and assigned to individual editors. The chronological list of measures enables transparent, comprehensible documentation of all planned activities. Approvers can be named and addressed directly in the system.



Other features in this context

- Recording and evaluation of changes with target date, actual/target and criticality
- Risk evaluation
- Allocation of measures
- Documentation of the reason for and scope of the change



Approval – Compliant decisions

The entire change project, including all measures and the resulting risks and improvements, is evaluated by the responsible approvers. They can confirm the change or reject it with reasons and thus cancel the change process immediately. The **engamp® | change control** ensures a formal decision, as required in a regulated environment.

Other features in this context

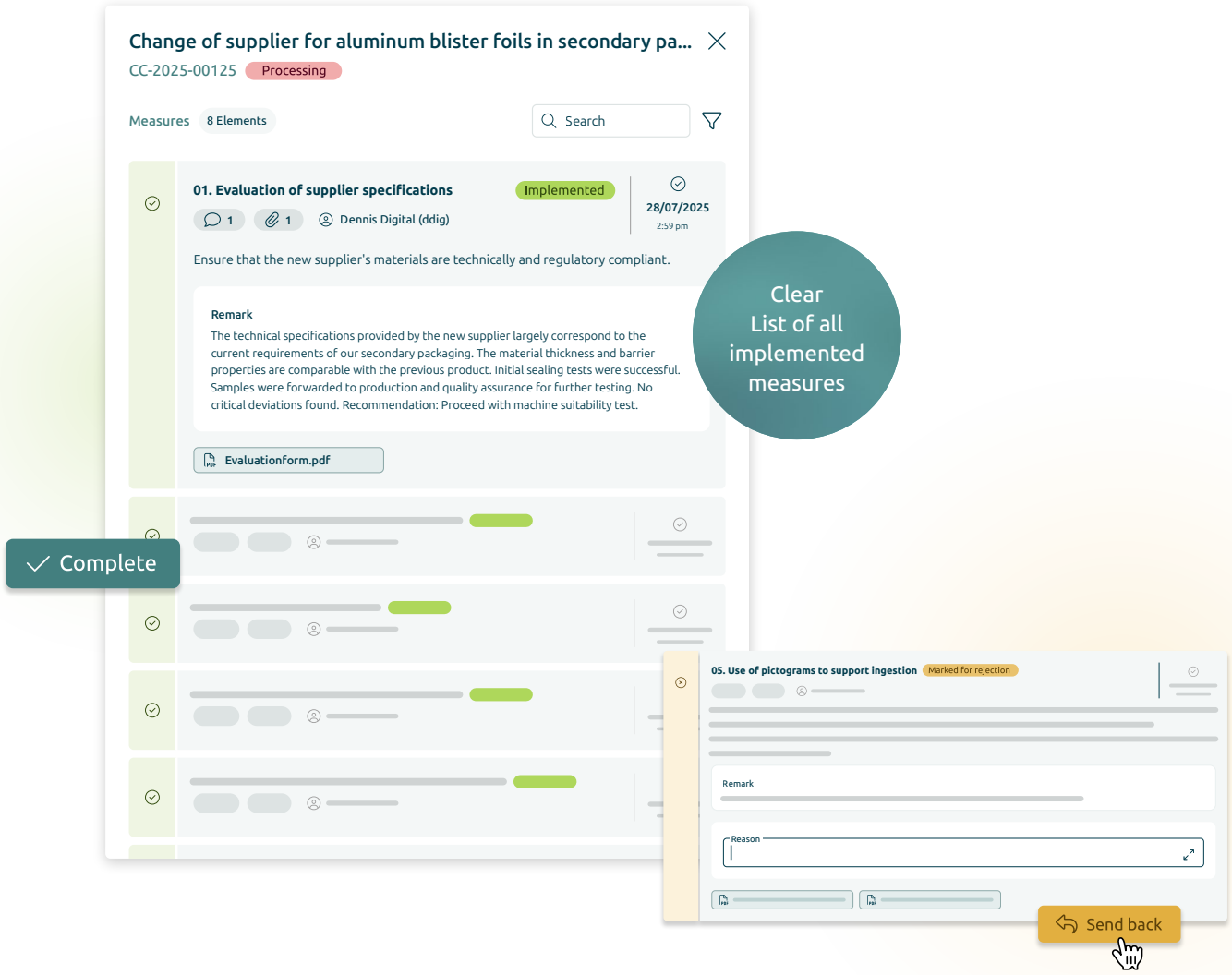
- Cross-role multiple approvals with one click
- Input option for the justification of the decision
- Complete documentation of all approvals with time stamp

Implementation – control of all measures

In the implementation step, the defined measures are carried out and documented in the system. It is possible to comment on and adjust the status of each measure. This allows you to keep track of the current implementation status at all times. Points that have already been edited can be rejected for reworking. Filter functions provide a focused overview of the status of your process.

Other features in this context

- Implementation and documentation of defined measures
- Monitoring progress
- Comments, status adjustment and rejection of measures
- Filter functions for a focused overview of the implementation status

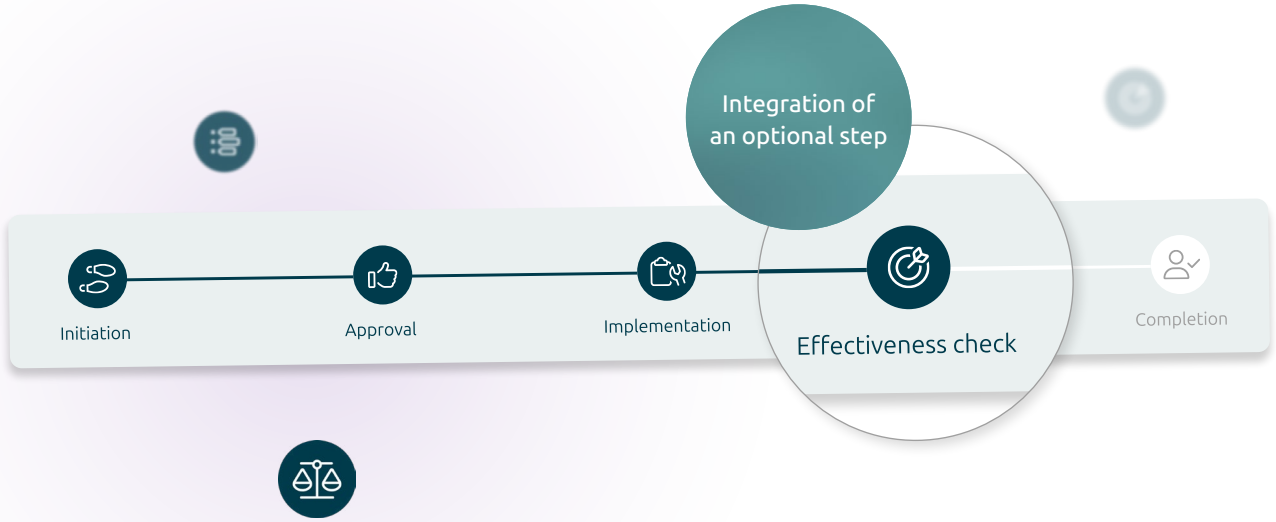


Completion – The last step of the change

After the implementation, a final evaluation is carried out to validate the effectiveness of the change. This validation is a central component of the Change Control process and is also documented in an audit-compliant manner. If necessary, measures can be sent back for processing. Formal completion only takes place after a positive evaluation.

Other features in this context

- Validation of the effectiveness of the change
- Audit-compliant documentation of the evaluation
- Decision on completion or renewed processing



Optional steps – for more flexibility

To increase process flexibility, additional, optional steps can be integrated into the workflow. These can be easily activated as needed, providing even more precise control of the change process.

Initial evaluation
Preliminary review of the change request for completeness and significance.

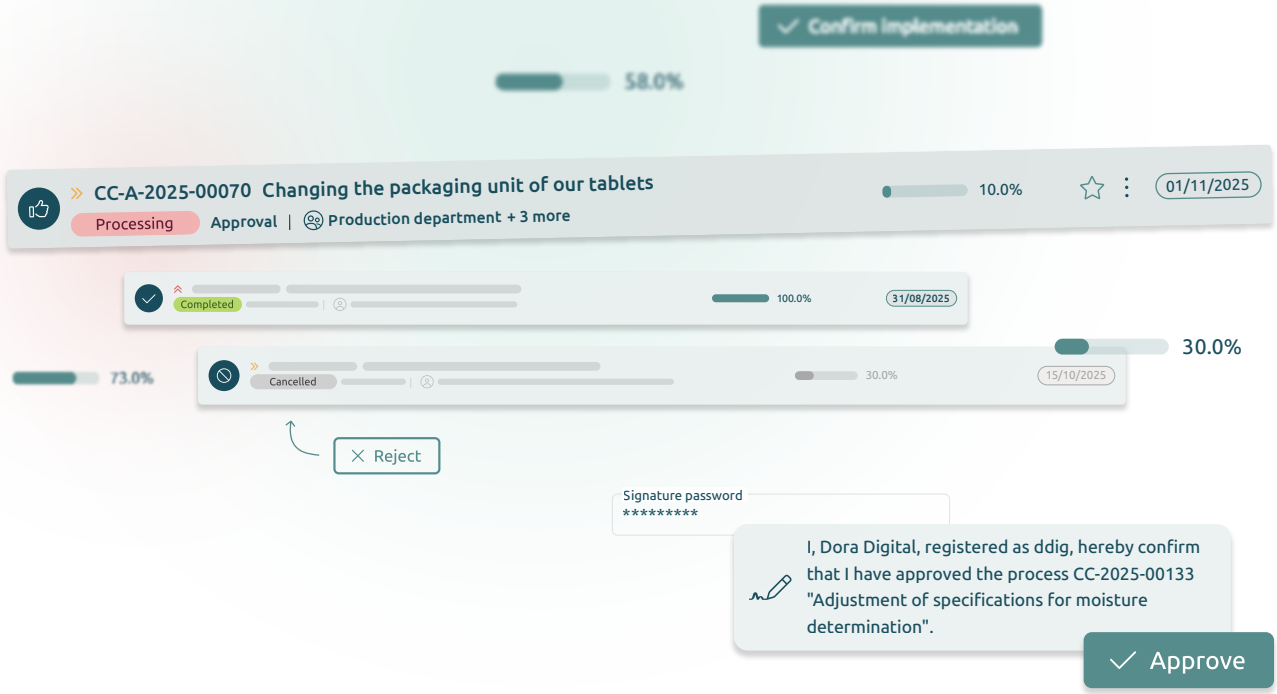
Relevance evaluation
Evaluation of the significance of the change for GMP, customers, approval and / or registration of a product.

Collection of measures
Structured collection and evaluation of potential implementation measures.

Effectiveness check
Formal evaluation of the effectiveness of measures implemented to meet the objectives of the change.

Other features in this context

- Access via mobile, tablet or desktop
- Activating and deactivating mandatory fields
- Configurable access at user or group level



Additional core functions

Cross-step functions

The software enables the configuration of individual process templates, allowing standardized and adaptable workflows to be established. Roles are assigned on a user-specific and step-by-step basis – for QA, production or development, for example. All ongoing and completed change processes can be viewed at any time via the central process overview and used for management reviews or external audits. Other functionalities include a complete audit trail, electronic signatures in accordance with 21 CFR Part 11, mandatory field checks for quality assurance of entries, visual progress indicators, security queries when exiting input masks and protection against parallel processing. The context-sensitive help makes it easier to get started and use on a daily basis.

Other features in this context

- Adding attachments
- Forwarding tasks between editors
- Redirecting processing steps
- Process control by a coordinator who has special rights to monitor and manage the entire process
- Escalation monitoring

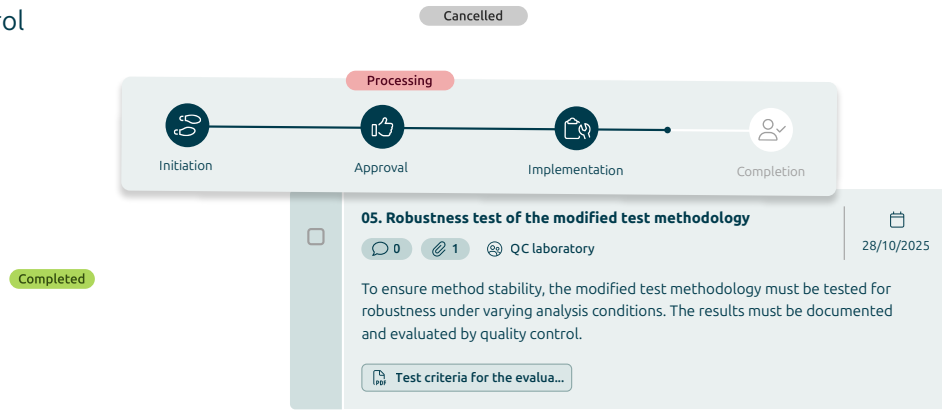
Advantages

Summarized for you

engamp® | change control is a fully integrated, digital solution for the implementation of changes in regulated companies. The software can be flexibly adapted to existing company processes and helps to efficiently meet regulatory requirements, minimize risks and sustainably improve transparency and traceability within the company.

Benefit from:

- Consistent compliance security
- Efficient and transparent process control
- Adaptability to your processes



Request a non-binding demo now

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