



**engamp<sup>®</sup>**  
**supplier qualification**

Efficient supplier  
qualification in the life  
sciences industry



# Content

Introduction	3	<a href="#">↗</a>
Basic principle	4	<a href="#">↗</a>
Objective	5	<a href="#">↗</a>
Regulatory requirements	6	<a href="#">↗</a>
5 essential aspects	7	<a href="#">↗</a>
<p>'Single point of truth' for the status of your suppliers Clear structure for all important details All documents on the status of qualification at your fingertips Documented qualification process Efficient planning and documentation of your audits</p>		
Advantages	12	<a href="#">↗</a>



In this white paper, we present **engamp® | supplier qualification** – a software solution that supports companies in the life science industry in the structured, compliant and efficient qualification and evaluation of suppliers.

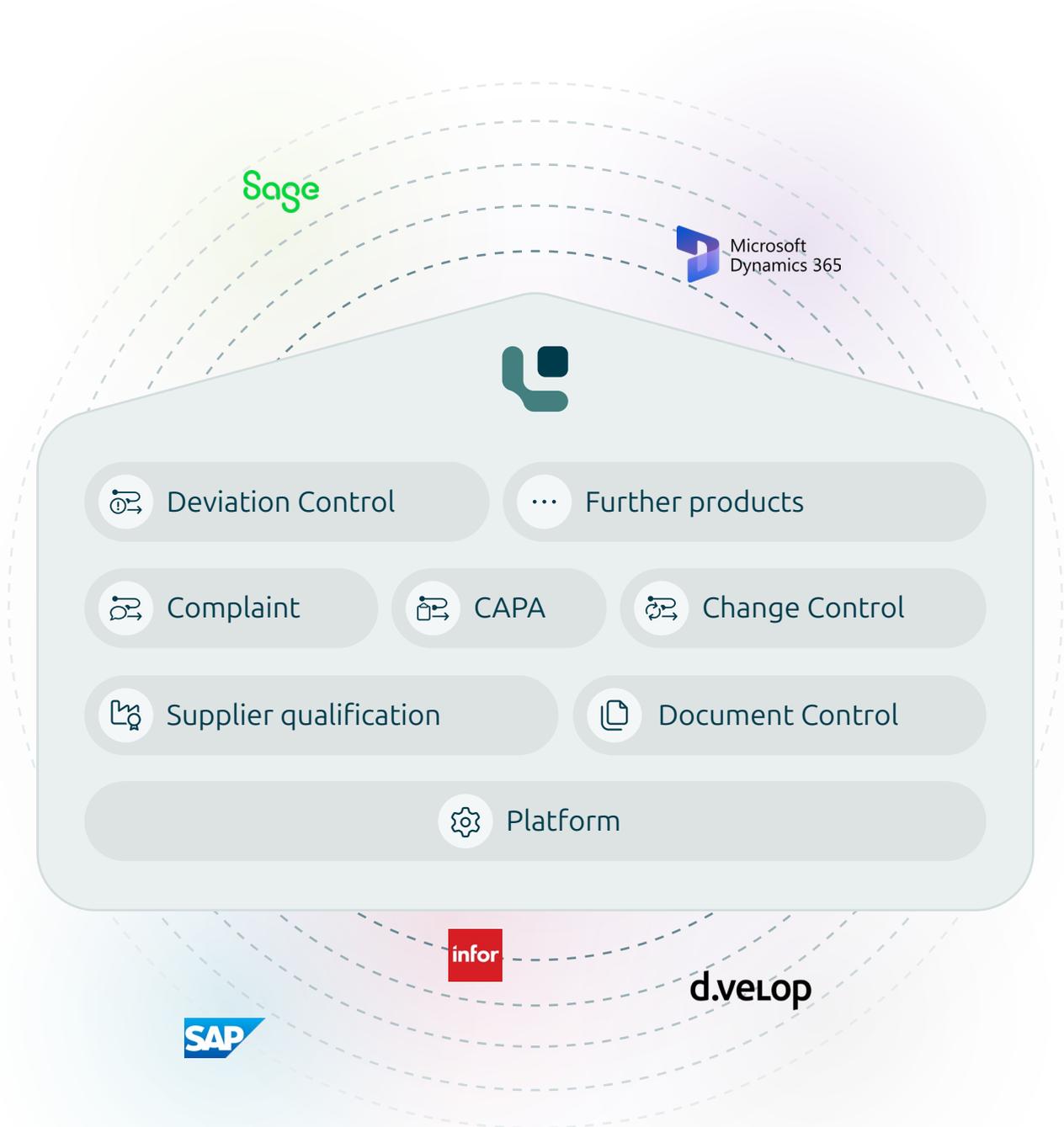
## Introduction

Supplier errors cost money, time - and trust. With **engamp® | supplier qualification** you can prevent this. Keep an eye on which suppliers are qualified at all times - without Excel chaos or a flood of e-mails.

An electronic procedure efficiently optimises the supplier qualification process by documenting risk-based procedures and providing an up-to-date overview of the status of your suppliers. This central source of information allows you to react quickly to changes and ensure compliance with quality standards.

During the development of the **engamp® | supplier qualification**, the applicable regulations, guidelines and standards were taken into account as well as practical experience. In close cooperation with experts from the life sciences industry, a module has been developed that realistically and efficiently depicts the process.

Use this brochure to see for yourself how **engamp® | supplier qualification** reduces the administrative effort. By saving time and resources, you can increase your company's efficiency and minimise the risk of quality defects at the same time.



# 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.



The qualification of suppliers is an essential component of the QM system to ensure product quality.

# Objective

## Requirements for efficient supplier qualification

The services provided by suppliers have a direct impact on product quality. The aim of supplier qualification is therefore to document that the purchased services are provided at the same level of quality as specified in the company's own quality management system.

The **engamp® | supplier qualification** fulfills this requirement through the risk-based definition of measures and the maintenance of a document dossier. The activities during the qualification process are fully documented in the audit trail, thus maximising transparency and traceability.

As a central source of information, the status of a supplier for a specific service is available to all authorised interested parties in the company and thus guarantees that services are only ordered from qualified suppliers.



# Regulatory requirements

When developing our digitalisation solutions, we take into account the regulations, guidelines and standards from the regulated environment. Our many years of experience in the development of software for electronic quality management systems ensures consistent compliance with standards.

Our solution **engamp® | supplier qualification** in particular takes into account the requirements from the following regulations (excerpt):

- Ordinance for the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients § 11
- GMP Guideline, Chapter 1 & 5
- FDA 21 CFR 820.50
- ICH Q10 Section 2.7
- MDR 2017/745 Article 10 (9)d
- ISO 13485:2016 Section 7.4.1



# 5 essential aspects

## 'Single point of truth' for the status of your suppliers

The digitalisation of supplier qualification enables all authorised parties in the company to query the status of suppliers. Changes are immediately visible – giving you a reliable basis for deciding which companies to place an order with.

Different filter and search options allow you to search for individual suppliers as well as display the supply chain for a material or a list of all external services for an end product.

The image illustrates the process of exporting a supplier list. It shows a 'Qualifications' table with columns for supplier name, status, and valid until date. An 'Export' button is highlighted. A dialog box titled 'Export 102 elements' allows selecting the file format (PDF) and contents (Supplier, Manufacturer, Version, Supplier type, Supplier ID, Risk class, Process owner, Valid until date). The resulting 'Supplier list' report shows a list of suppliers with their details and status.

**Export 102 elements**

Select file format \*  
PDF

Select contents

- Supplier
- Manufacturer
- Version
- Supplier type
- Supplier ID
- Risk class
- Process owner
- Valid until date

Cancel **Export**

**Supplier list**  
102 elements

**AB Pharma Logistik KG | DEU - Radeberg** Qualified  
Supplier type: Refrigerated storage of return samples  
Version: 1.0 | Supplier ID: 88304885 | Risk class: 1 - critical | Process owner: Georg Müller (gmu01)  
Valid until date: 12/05/2028

**Chemische Fabrik Maltarino GmbH | DEU - Köln** Qualified  
Supplier type: Manufacturer of auxiliary materials  
Version: 2.0 | Supplier ID: 108570713 | Risk class: 2 - major | Process owner: Georg Müller (gmu01)  
Valid until date: 15/02/2028

**Lyoservice GmbH | AUT - Zell am See** Qualified  
Supplier type: Manufacturer of active ingredients  
Version: 1.0 | Supplier ID: 44940739 | Risk class: 1 - critical | Process owner: Tanja Liebstöckel (tli01)  
Valid until date: 05/11/2025

**Sterilisationservice Pharma KG | DEU - Ehrenkirchen** Qualified

### Other features in this context

- Quick filter by status and risk class
- Filter by individual search terms
- Visual representation of the supply chain to an end product
- Export of the complete or filtered supplier list
- API for status queries from external systems



## Clear structure for all important details

The status of a supplier is clearly displayed with all the important details. The colour coding of the status and the indication of the risk class and end of validity give you an overview of the key points.

The services provided by the supplier are assigned to the supplier with the full address, right down to the individual material numbers. Further properties provide information on the status of the contractual agreement, supplier evaluation and more and the affected end products.

The screenshot displays a supplier profile for 'Pharma Packaging | DEU - Rüsselsheim' with ID '245751561' and a 'Qualified' status. A callout box provides a detailed overview of the supplier's role and key metrics. The callout includes the manufacturer's description, process owner information, and various control buttons. To the right, a table lists material numbers and their corresponding elements.

**Supplier status at a glance**

**Pharma Packaging | DEU - Rüsselsheim**  
245751561 Qualified

**Manufacturer of printed secondary packaging, supplier of auxiliary materials + 3 others**

Process owner  
**Hauke Haien (hhai)**

**New version** **Lock**

Material number	Elements
5344337505	Alpha Naxasin
54037181	

Version 1.0  
Valid until 12/08/2027  
Reference date 12/08/2023  
Risk class supplier >> 2 - major  
Audit no

### Other features in this context

- Visual differentiation of the status
- Representation of the manufacturer in addition to the supplier
- Display of the individual services
- Master data import from your ERP in case of a larger number of values
- Responsive display on mobile devices



## Quick access to all documents on the status of the qualification

In the **engamp® | supplier qualification**, a specific document dossier documents the current status of the supplier and allows direct access to proofs, certificates, contracts and other documents.

You transfer the measures derived from your risk evaluation to the configuration of the risk classes and supplier types and thus specify a package of tasks for each qualification. In this way, the application ensures that each supplier is qualified in accordance with the risk evaluation.

For controlling documents, the **engamp® | document control** is available without system interruption.

Document dossier for qualification

Pharma Packaging | DEU - Rüsselsheim  
245751561 Qualified

Qualification **Documents** Audit trail

Add document

Drag and drop file here

Upload file Link file

6 🔍 ⌵ ⌶

- GDP certificate  
Certificates 31/08/2027
- Wholesale approval for human medicinal products  
Certificates 15/06/2028
- Supplier self-disclosure  
Declaration
- Distribution license for the wholesale of veterinary medicinal pr  
Certificates
- Questionnaire SQM

Self-disclosure

Certificate

### Other features in this context

- Risk-based specification of the required documents
- Storage via drag & drop in the application
- Audit-compliant storage
- Document archiving without redundancies
- Management of the validity of proofs



**Set circulation** Lyoservice AG Processing

Select circulation  
One-step circulation

**Circulation steps**

1 Processing

Process Peter (ppet)

Head of production

+ Add editor

Additional information  
Here is some information. 0 / 5000

**Approve**

Login password \*  
\*\*\*\*\*

Signature password \*  
\*\*\*\*\*

**Integrated electronic signature**

**Process Peter**  
Process owner

**The processing has been completed and the qualification is ready for acceptance.**

Release  Reject

I, Process Peter, hereby confirm that I have blocked the qualification "Lyoservice AG".

## Documented qualification process

Only the persons responsible for this can approve or lock a supplier. Once all measures have been implemented, the employee completes the qualification process and submits it to the person responsible for approval.

The quality-relevant information, including the documents, is available for this decision. All relevant actions are documented in the audit trail with time stamps and employees.

If a supplier needs to be locked, the status can be corrected immediately. After expiry of the validity period, re-qualification is carried out with the creation of a new version of the qualification.

### Other features in this context

- Integrated GxP-compliant electronic signature
- Signature circulation with multiple recipients possible
- Authorisation concept according to application roles
- Indication of the reason for locking
- Versioning



## Efficient planning and documentation of your audits

If an audit is required for the qualification of a supplier, plan and document this directly in **engamp® | supplier qualification**. Indicate whether the audit will be carried out in writing, on site or by a third party. You select the members of the audit team from the group of people provided.

The documents are created according to the template and filed for the audit. Since they are linked to the qualification, they are also visible there in the dossier.

The screenshot displays the 'Overview' section of the engamp interface. It features a calendar for May 2025 with the 13th highlighted. A teal circle highlights the 'Optimisation of audit planning' feature. Below the calendar, there are two panels: 'Upcoming deadlines' and 'Audit details'. The 'Upcoming deadlines' panel lists tasks such as 'Change of supplier pipettes' (16/05/2025), 'Change of supplier glass ampoules' (19/05/2025), and 'Procurement guidelines'. The 'Audit details' panel shows an audit for 'Meditec GmbH' on 09:00 am - 5:00 pm, with a 'DATE' button. Below it, a 'Pharma Packaging' audit is listed with ID 79805648 and an 'ACCEPTANCE' button. On the left, there are images of an 'Audit report' and a 'Certificate' document.

### Other features in this context

- Different audit types
- Assignment of the audit team with indication of the role
- Annual audit plan
- Schedule optimisation



# Advantages

## Summarized for you

The **engamp® | supplier qualification** is a digital solution for the qualification of suppliers in a regulated environment. It is a central source of information and supports documented compliance with the measures based on risk evaluation.

### Benefit from:

- Increased efficiency through an electronically managed process
- Centrally available information on the status of each supplier
- Assurance of your product quality

Lupin Ltd | IND - Aurangabad

01/07/2026

Qualified 1.0 | Manufacturer of active ingredients + 5 more

MediSwiss AG | CHE - Zurich

Processing 0.1 | Contract laboratories + 1 more

MedSupply Dynamics | DEU - Wuppertal

01/07/2026

Acceptance 1.0 | Service provider for GMP-relevant consultin + 1 more

## Request a non-binding demo now

**Georg Langbehn**

Georg.Langbehn@digital-ls.de

+49 2542 20201-29

+49 152 29217318

www.digital-ls.de

 **Make an appointment now**

