

Quality doesn't delay supply. **The email bottleneck does.**

See how your quality team can move beyond emails, spreadsheets and manual processes to create a smarter, more scalable approach for collaborating between CMOs and MAHs.

A quality event, such as a change control or a deviation, needs to cross from the manufacturer through to every marketing authorisation holder. Today it makes that journey on countless email threads, PDF attachments and manual spreadsheets. The Quality Bridge puts it in one collaborative workspace: a private review thread for each party, an owner and a date on every open step, and a complete audit trail. Nothing waits quietly in an inbox.

Spend your oversight on judgement, not on forwarding.

Replaces the email chain

Not your QMS. The regulated record stays exactly where it already lives, and no internal procedure has to change.

One workspace, private threads

Several MAHs on one change control, each in a thread only they can see. No MAH is told another MAH is in the workspace.

Owner and date on every step

Overdue steps are chased from the workspace, automatically, rather than by someone remembering to send an email.

THE PROBLEM

Approvals between companies run painfully on email. Supply waits while this happens.

Every company in the chain runs a capable quality management system, and every one of them stops at its own boundary. Nothing spans the gap between them, so the work crosses by email, attachment and spreadsheet — outside every system, with no shared status and no shared trail. That gap is where the delays happen.

Fragmented

The same quality event is exported from one QMS, attached to an email, filed in a shared drive and re-keyed into another QMS at the far end.

Untracked

Nobody can say where a request is without opening a mailbox. Chasing status is a job someone does by hand, every week.

Reconstructed

The evidence exists in three companies' mailboxes. Answering "show me" means rebuilding the story from forwarded threads, days or weeks after the question was asked.

WHY IT COSTS MONEY

A quality event that stalls holds up production, delays market access and puts orders at risk. A variation that misses its window can escalate from a Type IA notification to a fee-bearing Type IB.

WHAT MAKES IT DIFFERENT

Built for the space between companies.

Every internal QMS manages quality inside one organisation and stops at its edge. This is the layer that spans the two companies either side of a quality event — or three, when an intermediary sits between them. It is the part nobody owns today.

The record stays where it belongs

The platform never becomes the regulated system of record and never applies a signature. It replaces the email chain, not the QMS on either side of it, so there is no need to update internal procedures.

Extraction assists. People decide.

Extraction shortens the time to understand a request. Every field is confirmed by a person, and every regulated decision stays with a qualified person.

The CMO's document stays the document. We carry it across.

Four steps, in the order a change control moves. Nothing is re-keyed, nothing is re-signed, and nothing leaves the workspace.

1 Submit

The CMO uploads the change control or deviation export straight from its own QMS. No re-keying and no new system of record. The workspace carries the CMO's own QMS reference, unchanged, so the same number tracks it on both sides, and the export itself is kept as the source that every later step points back to.

2 Extract and verify

The key regulated fields are read off the export: the affected products, the proposed change, the regulatory impact, the variation type and the action plan are identified and pre-populated. A person at the CMO checks each field, corrects anything that needs correcting, and only then does the change control go anywhere. Extraction shortens the time to understand a request; it never decides.

3 Review and decide

Product entitlements, drawn from the quality agreements, decide which MAHs a change control can go to. It can be shared with several MAHs at once, each in its own private thread. Questions are numbered, answers are attached to the question they answer, and every cycle stays in the workspace. Approving a change control means signing the CMO's own document with the signature the MAH already uses and uploading the signed copy. Rejection needs no signature, only a reason.

4 Evidence

Every action in the workspace is logged with who, what and when, and filtered so that each viewer sees only their own thread. The evidence pack puts the change control, the questions, the amendments and the signed decision into one print-ready document, so the answer to "show me" takes a minute rather than a week of searching three companies' mail servers.

Search

One box searches references, products, descriptions, questions, document names and audit entries. A MAH's search never matches another MAH's thread.

Audit trail

Every action logged with who, what and when, and filtered per viewer, including the value a date or a field was changed from.

Bottlenecks

For whoever holds the licence: everything that has stalled, who it is sitting with, at what stage, and for how long.

THE PARTIES

Four roles on one workspace.

Each party sees the workspace from where it sits, and only what it is entitled to see.

CMO

Raises the change or the deviation, answers questions, records investigation steps and confirms implementation.

Intermediary

Sets up the company profiles, users and product entitlements, and watches for whatever has stalled. On business-to-business change controls and on deviations, reviews and approves in its own right.

MAH

Acknowledges receipt, asks questions, and approves or rejects a change control. On a deviation, accepts the investigation and rules on the batch.

EU release site

Sees the change controls and deviations affecting the products it releases, and confirms it has read each one.

THE TWO KINDS OF QUALITY EVENT

CHANGE CONTROL

Direct or business-to-business

On a direct change control the MAH asks the CMO. On a business-to-business one the intermediary asks the CMO and the MAH asks the intermediary; the two never deal with each other directly. Review dates can be agreed and reminders sent. After the decision the CMO records the date the change went live. A change control can be amended only with a stated reason, and every amendment is numbered and notified. It can be withdrawn, with a reason, and its history stays. Once it is closed, no further comment can be added.

DEVIATION

Always through the intermediary

A deviation runs CMO to intermediary to MAH; the MAH never deals with the CMO directly. Five states carry it: Under Creation, Under Investigation, Under Review, Investigation Accepted, Closed. While it is under investigation, each open step carries an owner and a due date, and a standing summary at the top of the workspace says what has been established so far. When the CMO declares the root cause found, the investigation report goes up with it. The intermediary decides, field by field, what each MAH is told, and the workspace shows plainly what was withheld. The MAH accepts the investigation and rules on the batch.

MOMENTUM

Every open step has an owner, a date and a state everyone can see.

Production blocked by an unapproved change control is a supply problem before it is a quality one. Reminders come from the workspace rather than from someone remembering to send one: once a step is past its agreed date it is chased automatically, and again every fortnight until it lands. The licence holder sees every change control in flight, who it is sitting with, at what stage, and whether it is at risk, stuck or past an agreed date. Nobody has to ask, and nothing waits quietly.

Where the signature sits, where the record sits, and what protects both.

Not the system of record

The regulated record stays in your QMS. The platform holds the shared, attributable trail of the approval alongside it.

No signature of its own

The MAH signs its partner's document with the signature it already uses. We store the signed copy and the decision record.

Designed for validation

A GAMP 5 Category 4 configured product, with a clean split of responsibilities between you and us.

THE CUSTOMER OWNS

Your intended use

User requirements specification · Testing sign-off · Acceptance and release for use · SOPs and work instructions for your intended use

WE OWN

The configured product

Functional and configuration specifications · Configuration test evidence · Product user documentation · A documented change-management process

ITEM	STATE	DETAIL
Hosting	By go-live	Hosted in the European Union. No customer data leaves the EU.
Encryption	By go-live	TLS 1.2 or higher for every connection; data and documents encrypted at rest.
Access control	By go-live	Every action is permitted by role and by company. A user sees only their own company's workspaces and threads, and one MAH can never see another MAH's thread.
MFA and SSO	By go-live	Multi-factor authentication available to every user and enforceable by the licence holder for its own users and for invited partner users; SAML 2.0 single sign-on for customers who run their own identity provider.
Data integrity	By go-live	Extraction is advisory; a person confirms every field. Every action is time-stamped and attributable; amendments are numbered, with every earlier version kept.
Backup and testing	By go-live	Daily encrypted backups with a tested restore procedure; independent penetration test at least annually and after any material change.
Incident notification	By go-live	Customers notified without undue delay and within 72 hours of a confirmed personal-data breach, as the GDPR requires.
Exit	By go-live	Every workspace, document, thread and audit trail exportable in open formats, at no charge, at the end of the contract.

The platform is pre-release, so every item above is committed for the first production release.

References: GAMP 5 (second edition) Category 4 · EU GMP Annex 11, Computerised Systems · ALCOA+ principles for data integrity. A supplier quality pack is available to quality and validation teams on request.

WHO IT'S FOR

Built for the companies whose quality processes cross a boundary.

CMOs

The same change control goes to many customers, and you absorb the rework when it stalls at any of them. Raise it once, from your own QMS export; every MAH reviews in its own thread; every decision comes in against one change control.

MAHs

You receive high volumes from many manufacturers. Each one arrives with the key fields already structured and the affected products identified. You acknowledge it under your own internal reference, ask your questions, and decide.

When there is an intermediary

A company between the two is another link in the same chain, not a fixture. It reviews and approves in its own right, and watches for whatever has stalled across every CMO in its network.

WHERE IT FITS

What it deliberately does not do.

It is not the system of record

The regulated record stays in your QMS.

It applies no signature

The signed document is yours, produced with the signature you already use, and uploaded as evidence.

It does not replace your eQMS

Those manage quality inside your company. This is the handoff between companies, which none of them was built to cover.

The licence can sit anywhere along the chain: most often with the intermediary connecting its CMOs and MAHs, but a CMO or a MAH can hold it directly too, when they are the one driving the need to close the gap.

You are not stuck with the email chain.

Most quality teams have never seen this done any other way, so the useful half hour is not a demo — it is a walkthrough using a change control shaped like the ones you actually handle: your parties, your fields, your decision points.

30 minutes, on a call • Your own change control, not a canned demo • No preparation needed

Request a walkthrough →

www.thequalitybridge.com/contact



The collaborative workspace for the quality processes that cross company boundaries in pharmaceutical contract manufacturing.