The True Cost of Spreadsheet Quality Management

How fragmented quality records create hidden labor, delayed investigations, rework, and audit-readiness risk.

QUALITY WHITE PAPER | SEPTEMBER 2026

PREPARED FOR QUALITY LEADERS IN FOOD AND BEVERAGE, SPECIALTY CHEMICALS, ADVANCED MATERIALS, PERSONAL CARE, INDUSTRIAL BIOTECHNOLOGY, AND BATCH OR PROCESS MANUFACTURING

uncountable

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WHO THIS IS FOR

A practical report for quality leaders in food and beverage, specialty chemicals, advanced materials, personal care, industrial biotechnology, and batch or process manufacturing.

The cost is carried by people, not by the software

Spreadsheets are useful tools. They are flexible, familiar, inexpensive, and often indispensable for local analysis. The issue is not that a quality team uses Excel. The issue begins when spreadsheets, paper forms, email threads, shared folders, PDFs, and disconnected software become the de facto system for managing deviations, CAPAs, complaints, document changes, approvals, audit findings, and corrective actions.

That arrangement can appear inexpensive because the software itself is inexpensive. Its real cost is carried elsewhere: in the people who reconcile versions, rebuild evidence trails, chase approvals, compile reports, investigate issues across several systems, and prepare manually for audits. These costs rarely appear together in a budget. They are absorbed into the daily work of quality, laboratory, operations, regulatory, and manufacturing teams.

For a quality leader, the practical question is not simply whether spreadsheets are still "working." It is whether the current operating model can reliably support the level of traceability, speed, consistency, and accountability the organization now requires.

A quality event is rarely self-contained. A deviation may require the investigator to locate the relevant batch record, test result, raw material, specification revision, standard operating procedure, production context, prior complaint, supplier record, approval history, and related change control. If those items are distributed across systems and files, the investigation begins with a search. The team spends time reconstructing the evidence before it can understand the issue.

That matters operationally. Delayed access to evidence can prolong investigations, product holds, disposition decisions, retesting, and corrective action closure. It also makes it harder to identify recurring patterns across products, sites, suppliers, batches, or process changes. In an audit, the organization may be able to produce records eventually, but only after a concentrated and disruptive effort to demonstrate what happened, who made a decision, which version of a document applied, and what evidence supported the conclusion.

The principles behind this challenge are well established. The U.S. Food and Drug Administration (FDA) defines data integrity as the completeness, consistency, and accuracy of data, and describes complete, consistent, accurate records through the ALCOA framework: attributable, legible, contemporaneously recorded, original or a true copy, and accurate. The agency also treats relevant audit trails as part of the associated record, not as an optional feature that sits outside it.[1] The UK Medicines and Healthcare products Regulatory Agency (MHRA) similarly describes an audit trail as metadata that allows an organization to reconstruct the history of a record, including who acted, what changed, when it changed, and why.[2]

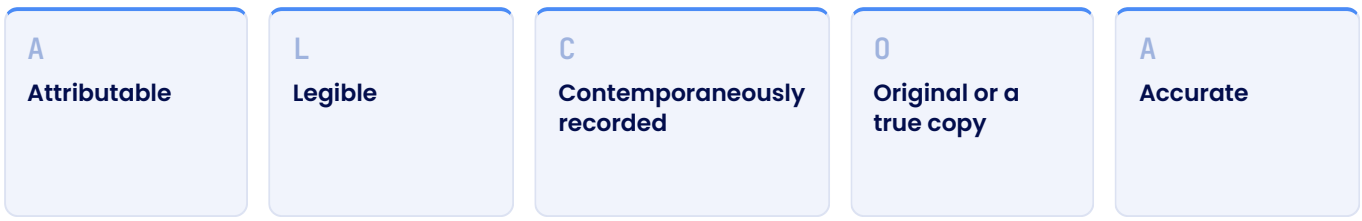

Fig. 1 The ALCOA framework as the FDA describes complete, consistent, accurate records. Relevant audit trails form part of the associated record.

Those expectations apply most directly in GxP-regulated environments. But the underlying business principle is relevant to any organization that must demonstrate product quality, investigate deviations, meet customer requirements, maintain controlled procedures, or explain its decisions during internal and external audits.

This report provides a way to identify the hidden cost of spreadsheet-led quality management. It does not offer a single universal cost figure, because the implications differ by product, industry, quality-event volume, regulatory environment, labor model, and customer commitments. Instead, it shows where the cost accumulates and provides a practical method for estimating it using the organization's own data.

The outcome is not necessarily an immediate technology decision. The first outcome is visibility: an evidence-based understanding of how much manual work, delay, and avoidable exposure the current quality process creates.

CHAPTER 1: THE "SPREADSHEET QMS" IS USUALLY NOT ONE SPREADSHEET

A model that emerges rather than one that is chosen

Most organizations do not deliberately choose to run quality through a single workbook. The model emerges over time.

A team creates a deviation tracker to make open issues visible. Another spreadsheet follows to track CAPAs. Document-control records sit in a shared folder. Approval requests move through email because email is convenient and familiar. Test results are generated in laboratory instruments, a LIMS, or exported reports. Batch and lot information sits in an ERP, manufacturing, or production record. Supplier information may be stored in procurement systems. Reporting for management review is assembled in a monthly or quarterly workbook.

Each tool may solve a legitimate local need. The problem emerges in the connections between them.

A quality manager may have a deviation record in one place, a CAPA action plan in another, an SOP register elsewhere, and the supporting evidence scattered across laboratory data, production records, shared-drive documents, and inboxes. To understand what happened, the team has to assemble a narrative manually.

That process is often invisible when operations are steady. It becomes visible when there is an out-of-specification result, a customer complaint, a supplier issue, a process deviation, a document change, an internal audit, or an external inspection. At that point, the organization needs more than a status field in a spreadsheet. It needs to demonstrate a trustworthy history.

Fig. 2 The eight places one quality process ends up living. None of them was chosen as the quality system; together they became it.

Consider a routine event. A QC test result falls outside an approved specification. The investigator needs to know whether the result relates to the sample, the method, the instrument, the raw material, the batch, the formulation, the process conditions, the specification itself, or a recent controlled change. They may also need to confirm which SOP version was in effect, whether the correct personnel were trained, whether related deviations occurred previously, and whether an earlier CAPA addressed a similar issue.

Fig. 3 What one investigator may have to locate before the investigation can begin. In a fragmented model each item is found and validated separately.

In a connected operating model, the event and its evidence can be reviewed together. In a fragmented model, the investigator must find and validate every component separately. The quality record may be present, but the context that makes it useful is distributed.

This is why the issue is better understood as a connection problem than as a spreadsheet problem. Spreadsheets do not inherently create weak quality processes. But when they become the mechanism for connecting critical records manually, they turn quality work into a labor-intensive reconstruction exercise.

CHAPTER 2: THE HIDDEN LABOR BEHIND MANUAL QUALITY MANAGEMENT

Small tasks, repeated across every event

The cost of a spreadsheet-led quality process is rarely a dramatic, one-time expense. It is a steady accumulation of small tasks that are repeated across events, products, sites, and audit cycles.

A quality team may spend a few minutes confirming that the document in a shared folder is current. It may spend another few minutes checking whether an approval was completed, locating an old email thread, or updating a status report for a management meeting. A laboratory analyst may be asked to re-export a result. A production supervisor may need to confirm batch context. A quality manager may have to reconcile a CAPA tracker against a deviation log before sharing a report.

None of those activities appears especially costly in isolation. Together, they can become a significant administrative layer on top of the work of investigating quality issues and preventing their recurrence.

2.1 Where the hours go

The first source of hidden cost is duplicate entry. A single quality event often has several representations. It may appear in a deviation register, a CAPA tracker, a customer-complaint log, a management-review report, a document change record, an audit evidence folder, and an email chain. When the event status changes, each representation must be updated or reconciled. The result is not necessarily poor performance by the people involved. It is a predictable consequence of managing one event across multiple disconnected records.

The second source is evidence retrieval. Quality events depend on context. A CAPA may need the original deviation, the supporting test data, the relevant specification, a procedure revision, an approval record, and the evidence used to verify effectiveness. If that context is not available from the event itself, someone has to retrieve it manually. This work increases the time between identifying an issue and reaching a defensible conclusion.

The third source is approval and follow-up work. Paper, email, and spreadsheet processes often rely on individual knowledge and persistence. Someone must remember which review is outstanding, determine who has authority to approve a decision, send reminders, and escalate overdue actions. A digital status field may show that a task is open, but it does not automatically establish whether the underlying evidence is complete, whether the latest document applies, or whether a related quality event has changed the risk assessment.

The fourth source is reporting. Management teams need to know what is open, overdue, recurring, high risk, or trending in the wrong direction. If quality data is held in several trackers, local templates, or systems with inconsistent definitions, reporting requires extraction, reconciliation, and interpretation before it can be trusted. The work of creating the report can become as demanding as the work of acting on its findings.

The fifth source is institutional dependence. In a small or stable organization, one or two experienced people may know where records are stored, which spreadsheet is authoritative, and how a local process really works. As sites, products, headcount, or regulatory obligations grow, that knowledge becomes harder to transfer and govern. The quality system may still appear functional, but it increasingly depends on individuals rather than on a repeatable operating model.

01	**Duplicate entry**	One event represented in a register, a tracker, a complaint log, a report, a change record, an evidence folder and an email chain
02	**Evidence retrieval**	Context that is not held with the event has to be found by hand before a defensible conclusion can be reached
03	**Approval and follow-up**	Reviews, reminders and escalations that depend on individual knowledge and persistence
04	**Reporting**	Extraction, reconciliation and interpretation before management data can be trusted
05	**Institutional dependence**	A process that works because particular people know where the records are

Fig. 4 Five sources of hidden labor. None looks costly in isolation; together they form an administrative layer on top of the quality work itself.

This is one reason that a spreadsheet-led process can appear efficient until it is tested by turnover, growth, acquisition, a major quality event, or an audit. The cost has been present all along; it simply has not been measured.

Delay changes what the quality team can do

A quality event should focus the organization on a decision: what happened, what is affected, what action is necessary, and how can recurrence be prevented?

In fragmented environments, the investigation often begins somewhere else: with a search.

The investigator searches for the correct record. They search for the current specification. They search for the relevant test result. They search for the latest SOP and then determine whether that was the version in effect when the event occurred. They search for the production record, batch history, supplier information, related changes, previous deviations, prior CAPAs, and the person who can explain an undocumented decision.

The search may involve laboratory systems, folders, emails, shared drives, paper binders, spreadsheets, ERP data, production records, and conversations with people in different functions. Even when the records exist, the time required to retrieve and reconcile them can delay the investigation.

The operational cost is not only staff time. Delay changes the quality team's ability to act.

A slower investigation can prolong product holds and disposition decisions. It can lead to additional testing while the organization tries to establish whether the issue is isolated or systemic. It can delay corrective action because the root cause is not yet sufficiently understood. It can also increase the likelihood that a similar issue occurs before the first event is fully resolved.

THE PURPOSE OF CAPA

CAPA focuses on investigating, understanding, and correcting discrepancies while attempting to prevent recurrence.

The FDA's quality-system guidance makes the purpose of CAPA clear: it is not merely a recordkeeping exercise. CAPA focuses on investigating, understanding, and correcting discrepancies while attempting to prevent recurrence. The agency describes a quality-system approach in which deviations from written procedures are justified and documented, and in which organizations can trace the history of a product in relation to personnel, materials, equipment, and processes as appropriate.[3]

The FDA's guidance on pharmaceutical quality systems also emphasizes that CAPA should address complaints, product rejections, nonconformances, recalls, deviations, audits, regulatory inspections, and trends from process-performance and product-quality monitoring. It calls for a structured investigation intended to determine root cause, with the level of effort and documentation proportionate to risk.[4]

Those expectations are written for pharmaceutical quality systems, but the operational lesson travels well. A corrective action is only as strong as the organization's ability to understand the evidence surrounding the event. When evidence is fragmented, the quality process becomes slower, less consistent, and more dependent on manual reconstruction.

For manufacturers outside GxP-regulated sectors, the equivalent pressure may come from customer audits, GFSI requirements, ISO-based quality systems, contractual traceability obligations, high-specification products, or internal governance standards. The language may differ, but the challenge remains: an organization must be able to demonstrate not only that it recorded an issue, but that it investigated it with adequate evidence, made a controlled decision, and followed through effectively.

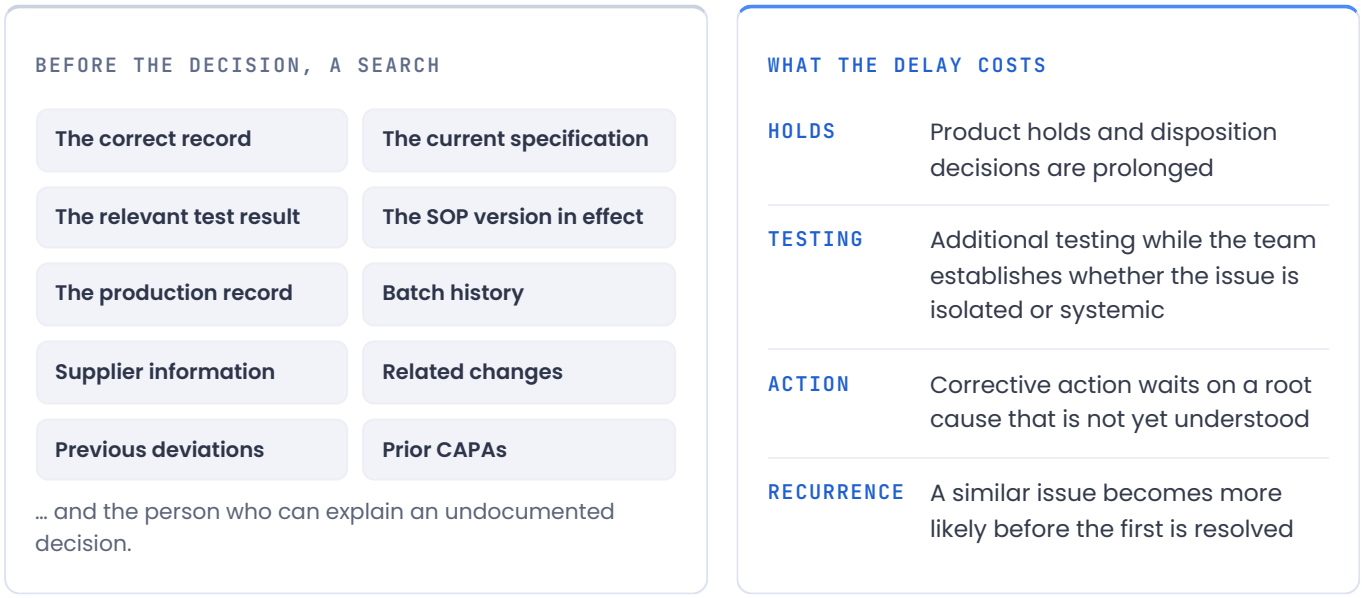

Fig. 5 The investigation starts before the analysis does. Time spent locating evidence is time the decision waits.

Reconstructing a trustworthy sequence of events

Many organizations think about audit readiness as a pre-audit activity. The audit date appears on the calendar, the quality team begins compiling records, document owners are asked to confirm current versions, and evidence is gathered into folders or binders.

That approach can work. It can also become expensive, disruptive, and difficult to sustain.

Audit readiness is not fundamentally about producing documents. It is about reconstructing a trustworthy sequence of events. An auditor, customer, or internal reviewer may need to understand what happened, what information was available at the time, who made a decision, which procedure applied, what changed afterward, and whether the organization verified the effectiveness of its actions.

The more that record history has to be assembled manually, the more audit preparation becomes a project.

This is where audit trails matter. The MHRA describes an audit trail as metadata associated with the creation, modification, or deletion of GxP records. It notes that the audit trail should allow reconstruction of activities and preserve the original information rather than obscuring it.[2] The FDA similarly explains that audit trails include records that track the creation, modification, or deletion of data, and that organizations should review audit trails that capture changes to critical data as part of review of the associated record.[1]

For a quality team, the practical implication is straightforward. A final version of a spreadsheet may not answer every question that arises during review. If information changed, the organization may need to establish what the prior value was, why it changed, who changed it, when the change occurred, and whether that change was reviewed appropriately.

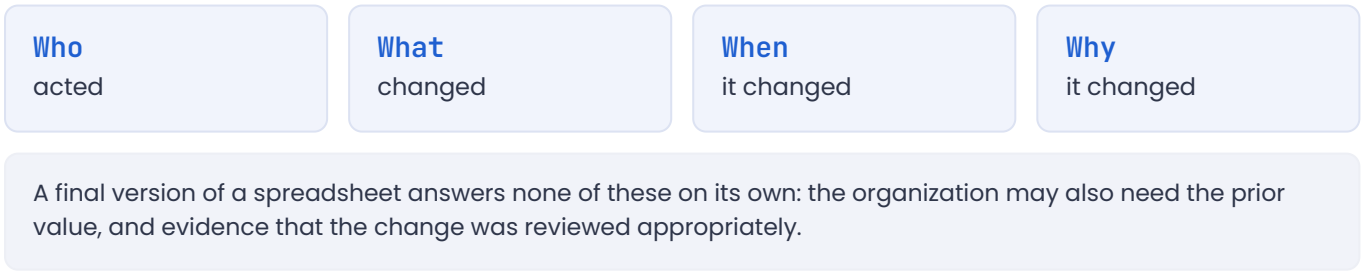

Fig. 6 What an audit trail has to allow the organization to reconstruct, as described by the MHRA and the FDA.

In a well-governed environment, the organization can retrieve that information without turning the audit into an investigation of its own records. In a manual environment, the evidence may be distributed across file versions, emails, meeting notes, signatures, change logs, and the memory of people who were involved.

The burden is especially acute when audit requests cross functional boundaries. Quality may own the deviation record, but the supporting data may belong to QC, R&D, operations, engineering, regulatory, procurement, or a supplier-management function. If each group maintains its own local records, the quality team becomes the coordinator responsible for proving that those records form a coherent whole.

That coordination takes time. It also creates risk. A record can be technically available but still be hard to retrieve, difficult to interpret, incomplete in context, or inconsistent with another source. The more effort required to make the record understandable, the greater the chance of missed detail, delayed response, or uncertainty during review.

Audit readiness, then, should not be measured only by whether the organization can assemble documents. It should be measured by whether the organization can explain its quality decisions quickly, consistently, and with evidence that is accessible when needed.

Fig. 7 Audit requests cross functional boundaries. The coordination is the cost, and it is where detail is missed.

CHAPTER 5: THE COST OF RECURRENCE AND REWORK

What the organization does not see early enough

The most visible costs of fragmented quality records are often administrative: the hours spent on updates, reporting, document searches, and audit preparation. But the more consequential costs can come from what the organization does not see early enough.

Quality events rarely occur in complete isolation. A complaint may relate to an earlier supplier issue. An out-of-specification result may follow a change in raw material, a new manufacturing condition, an equipment adjustment, or a specification revision. A recurring deviation may be distributed across sites, product lines, or teams in ways that are not obvious when records are separated.

When a quality organization cannot connect events to their relevant product, process, material, and change history, it becomes harder to identify patterns. The team may close each event individually without recognizing that the same underlying issue is recurring. It may implement corrective actions that address the immediate symptom but do not account for the wider context.

This is the point at which the cost of spreadsheet-led quality management moves beyond administration. It can contribute to retesting, extra inspection, rework, repeated investigations, delayed release decisions, scrap, customer dissatisfaction, and a continued cycle of corrective activity.

The American Society for Quality defines cost of quality as a method for determining how an organization's resources are used for prevention and appraisal activities, as well as internal and external failures. Its examples of failure-related costs include rework or rectification: correcting defective material or errors.[5] That framework is useful here because it widens the conversation beyond the immediate cost of a quality-system tool.

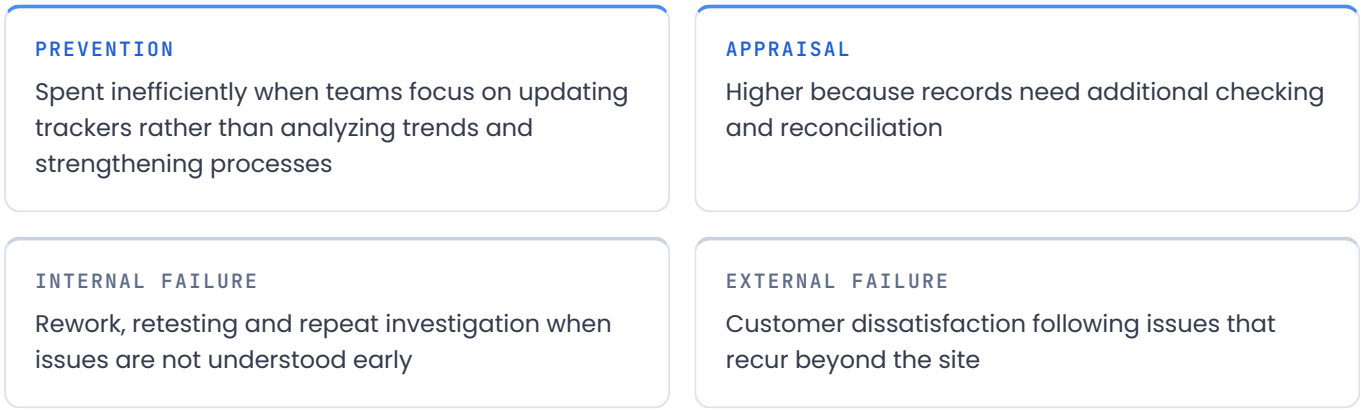

Fig. 8 Where manual coordination lands in the cost-of-quality framework defined by the American Society for Quality.

A process that relies heavily on manual coordination can create costs in all parts of the quality equation. The organization may spend more on appraisal because records need additional checking and reconciliation. It may incur internal-failure costs when issues require rework, retesting, or repeat investigation. It may incur prevention costs inefficiently when teams focus on updating trackers rather than analyzing trends and strengthening processes.

The aim is not to claim that spreadsheets directly cause every quality issue. Quality failures are complex and may involve materials, methods, people, equipment, environment, suppliers, or process design. The relevant point is narrower: when information is fragmented, it is more difficult to investigate efficiently, identify relationships, and prevent recurrence.

A connected quality operating model does not eliminate the need for expertise, judgment, or root-cause analysis. It gives those activities a stronger evidence base. It reduces the amount of time spent locating records and increases the amount of time available to understand what the records mean.

A complaint	←	An earlier supplier issue
An out-of-specification result	←	A raw material change, a new manufacturing condition, an equipment adjustment, or a specification revision
A recurring deviation	←	The same issue distributed across sites, product lines, or teams

- Each connection is invisible when the records sit apart, so every event is closed on its own terms.

Fig. 9 What a connected record makes visible. Patterns of this kind are what separate a closed event from a solved one.

CHAPTER 6: WHY SCALE EXPOSES THE WEAKNESS

More quality data, less confidence in it

A manual quality process can be manageable in a small, stable environment. One team may use a common spreadsheet. A small number of people may understand the workflow. The same quality manager may oversee the documents, approve the actions, and know where historical evidence is stored.

The model becomes more difficult as complexity grows.

New sites may adopt different templates. Acquired businesses may bring their own quality processes. Product portfolios expand. New raw materials and suppliers are introduced. The organization serves more regions, customers, or regulatory environments. Quality data increases, but its structure and governance do not necessarily keep pace.

The consequences often appear in reporting first. Leadership asks for a view of open CAPAs, recurring deviations, audit findings, overdue actions, product trends, or site performance. The quality team can usually provide an answer, but only after manually consolidating different sources, checking definitions, resolving duplicate records, and confirming that the report reflects the latest status.

The problem is not simply that reporting takes longer. It is that management may be making decisions from data that is delayed, inconsistently defined, or difficult to validate.

This creates a common paradox. The organization has more quality data than ever, but less confidence in its ability to use that data. It may have dozens of trackers, hundreds of records, and extensive documentation, while still relying on individual knowledge to answer basic questions.

QUESTIONS A GROWING ORGANIZATION STRUGGLES TO ANSWER

- Which SOP was current when this event occurred?
- Which batch, lot, or specification was affected?
- Which actions are overdue, and what risk do they represent?
- Can we show a complete history without asking several people to search their local records?
- Is this CAPA linked to a previous deviation or a related complaint?
- Are we seeing the same issue at another site?
- Has the corrective action been verified as effective?

Fig. 10 Seven questions from the paper. A quality system should make them easier to answer as the organization grows.

A quality system should make those questions easier to answer as the organization grows. If growth makes them harder to answer, the system is creating operational drag.

CHAPTER 7: QUANTIFYING THE TRUE COST

A calculation built from the organization's own work

There is no single universal cost of spreadsheet-led quality management. A food and beverage manufacturer, a specialty chemicals producer, a medical-device company, and an industrial materials organization will face different event volumes, labor structures, compliance requirements, product risks, and customer obligations.

That does not mean the cost cannot be measured. It means the most credible calculation begins with the organization's own work.

The goal is not to produce an inflated ROI claim. It is to make the hidden labor and delay in the current process visible.

7.1

Start with a sample of real events

Start with a sample of real events. Choose recent deviations, CAPAs, complaints, audit findings, change controls, or nonconformances. For each one, trace the process from initial identification to closure.

How long did it take to create the record? How many systems, trackers, folders, or emails did the investigator need to search? How much time was spent confirming the correct document version? How much time was spent requesting records or context from another function? How many reminders were required to obtain review or approval? How much time was spent reconciling records for a report, review meeting, customer request, or audit? How often did the team need to repeat a test, recheck a record, or revisit an investigation because the first evidence set was incomplete?

A basic labor calculation can be expressed as:

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Annual manual quality-work cost  =  ( annual quality events × additional manual
                hours per event ) × blended hourly labor cost
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For example, imagine an organization that handles 240 quality events per year. Through a sample review, it estimates that each event requires an extra 2.5 hours of manual administration, document retrieval, evidence reconciliation, reporting, and follow-up because records are fragmented. If the blended hourly labor cost across quality, laboratory, and operational personnel is $65, the direct annual labor cost is:

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240 × 2.5 × $65  =  $39,000
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That calculation should be treated as illustrative, not as an industry benchmark. The value lies in the organization's own numbers.

It is also intentionally conservative. It does not include the labor required to prepare for audits, the cost of extended holds, the operational impact of delayed disposition, retesting, rework, management reporting, or the cumulative cost of recurring issues that were not identified early enough.

7.2

A fuller estimate

A fuller estimate can separate the cost into five categories:

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Total annual cost = event administration + evidence retrieval + audit
  preparation + reporting and reconciliation + rework and recurrence
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The first four categories are generally measurable through time studies, process mapping, and staff interviews. The final category should be handled with greater care. Rework and recurrence are real costs, but their relationship to the quality system may be indirect. The organization should use its own event history to estimate where fragmented information delayed action, limited trend visibility, or created repeated effort.

The most useful conclusion may not be a single dollar figure. It may be a clear operational insight: "Our quality team spends a material share of its time reconstructing evidence rather than preventing problems."

That is the beginning of a credible business case.

CHAPTER 8: WHAT A STRONGER OPERATING MODEL LOOKS LIKE

Reducing the effort spent proving what happened

The purpose of improving quality operations is not to eliminate human judgment. Quality work will always require expertise, investigation, risk assessment, and decision-making. The purpose is to reduce unnecessary effort spent on finding, reconciling, and proving information after the fact.

A stronger quality operating model brings quality events together with the evidence needed to understand them.

A deviation should not sit apart from the test result, batch record, raw material, specification, procedure, or process change that gives it meaning. A CAPA should not become an isolated action list detached from the original event, the investigation, the approvals, the related documents, and the effectiveness check. A document revision should not require the organization to manually determine which quality events, products, processes, training records, or specifications it affects.

This does not mean every quality process needs identical workflows. Different products, industries, sites, and risk levels require different approaches. But the underlying principles are consistent.

01	**Governed**	Clear ownership, controlled states, approval requirements, accessible history and visibility of overdue actions
02	**Connected**	The event leads to the product, batch, sample, test, specification, material, document, change and prior history needed to assess it
03	**Reconstructable**	Decisions established without relying on file names, inbox searches or the memory of a few experienced employees
04	**Reported for action**	Timely visibility of open and overdue work, recurring issues, risk patterns and the effectiveness of corrective actions
05	**Scalable**	Consistency that improves rather than degrades as products, people, sites and requirements are added

Fig. 11 Five principles of a stronger operating model. Workflows differ by product, industry, site and risk; the principles do not.

The FDA's CAPA guidance for medical devices describes the need to investigate causes of nonconformities, identify actions to correct and prevent recurrence, verify or validate that those actions are effective, document all activities, and bring relevant quality-problem information to management review.[6] Although the exact obligations vary by sector, the principle is universal: a quality system should help an organization learn from quality events, not merely document that they occurred.

CHAPTER 9: MOVING BEYOND THE SPREADSHEET WITHOUT OVERSIMPLIFYING THE PROBLEM

Map the workflow before you look at software

There is no value in replacing a spreadsheet merely because it is a spreadsheet. The right question is whether the current process gives the organization the controls, traceability, context, and visibility it needs.

For some low-risk, local, and temporary activities, a controlled spreadsheet may remain appropriate. The decision changes when the spreadsheet or collection of spreadsheets becomes central to quality workflows that require reliable approvals, complete histories, consistent execution, and evidence that can stand up to internal review, customer scrutiny, or formal audit.

The transition should begin with workflow mapping, not software features.

Choose one recent quality event and trace it from beginning to end. Include every person, system, document, spreadsheet, approval, and handoff involved in its resolution. Ask which steps add expertise and judgment, and which exist only because the information is disconnected.

The results are often revealing.

WHAT THE MAP SHOWS	WHAT IT MEANS
Significant time spent locating the correct evidence	**An evidence-connection problem**
Manual reconciliation of different versions of the same status	**A record-governance problem**
Approvals that depend on email reminders and individual follow-up	**A workflow-visibility problem**
Audits that require a temporary project to reconstruct history	**An audit-readiness problem**
Recurring issues that are hard to identify across sites, materials, products or process changes	**A quality-intelligence problem**

Fig. 12 Reading the workflow map. Each symptom names an operating-model problem rather than a software gap.

These are not merely technology problems. They are operating-model problems. But technology can play an important role when it helps the organization connect records, standardize workflows, govern changes, preserve history, and make quality evidence accessible in context.

For organizations whose quality events must connect to R&D, QC, manufacturing, specifications, product data, and lifecycle changes, the objective should be more than digitizing isolated forms. It should be building connected quality operations: an environment in which the event and the evidence behind it can be understood together.

Fig. 13 The order the transition follows. Workflow mapping precedes software features.

CHAPTER 10: CONCLUSION

Make the work visible

Spreadsheet-led quality management rarely fails all at once. More often, it becomes gradually more expensive.

The cost appears in administrative repetition, evidence searches, delayed investigations, approval follow-up, audit preparation, manual reporting, and recurring issues that are harder to identify when information is fragmented. These costs are easy to overlook because they are distributed across people and departments rather than concentrated in a single system budget.

The most important first step is to make that work visible.

By mapping a representative quality event, measuring the hours spent on manual coordination, and identifying where evidence must be reconstructed, a quality leader can move the discussion beyond "We have always used spreadsheets" or "The process seems to work." The organization can instead ask a more useful question:

> THE QUESTION WORTH ASKING
>
> **How much time, risk, and quality capacity are we spending because our records do not connect?**

A quality system should help people investigate faster, make better decisions, demonstrate control, and prevent recurrence. When the system requires people to manually assemble the story behind every event, the organization is paying more for quality management than it may realize.

CHAPTER 11: APPENDIX: A PRACTICAL COST-OF-WORK EXERCISE

Five events, one baseline

Choose five recently closed quality events. Use a mixture of deviations, CAPAs, complaints, audit findings, nonconformances, or change controls where possible.

For each event, capture the event type, time from opening to closure, active investigation time, time spent updating trackers or reconciling records, time spent finding supporting evidence, time spent chasing approvals, time spent preparing reports, the number of systems or record sources involved, any repeat testing or duplicated work, and information that was difficult to locate or validate.

CAPTURE FOR EACH OF THE FIVE EVENTS

01 Event type
02 Time from opening to closure
03 Active investigation time
04 Time updating trackers or reconciling records
05 Time finding supporting evidence
06 Time chasing approvals
07 Time preparing reports
08 Number of systems or record sources involved
09 Repeat testing or duplicated work
10 Information that was hard to locate or validate

Fig. 14 The capture sheet for the exercise. Look for common patterns rather than a perfect cost figure.

At the end of the exercise, look for common patterns rather than trying to prove a perfect cost figure. If multiple events required the same kinds of search, follow-up, reconciliation, or reconstruction, those are not isolated inefficiencies. They are features of the current operating model.

A simple annual estimate can then be calculated:

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Annual labor burden = annual event volume × average avoidable manual hours per event × blended hourly labor cost
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Add audit-preparation hours, recurring reporting effort, and clearly attributable rework separately. Keep assumptions transparent. The purpose is to establish a credible baseline for improvement, not to produce an artificially high savings claim.

Fig. 15 The three inputs the baseline needs, and what is counted separately.

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WHITE PAPER

How much time, risk, and quality capacity are we spending because our records do not connect?

Connected quality operations put the event and the evidence behind it in one place, so investigations start with the record rather than a search.

ABOUT UNCOUNTABLE

Uncountable connects R&D, quality, product lifecycle, and project management on one structured data model. Our founding team of MIT and Stanford engineers brings expertise in software development and data analytics.

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