

ComplianceWorxs®

The Record Behind the Decision.

PEOPLE
PROCESS
RECORDS
BETTER OUTCOMES®

Inspection Readiness Starts with the Record

CONFIDENCE TODAY.
A STRONGER
TOMORROW.

Why Authorization Reasoning Matters

CLEARER THINKING.
STRONGER DEFENSES.

The Five Gaps Behind Compliance Exposure

SPOT THE RISKS.
STRENGTHEN THE RECORD.

From DDA to IRR: A Smarter Compliance Journey

SAME PRINCIPLES.
A STRONGER TOMORROW.

How to Answer: Who Authorized This and Why?

PRACTICAL GUIDANCE
FOR REAL-WORLD SITUATIONS.

Special Report:

Preserving the Record Behind Critical Decisions

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COMPLIANCE
BUILDS
TRUST

THE RIGHT
RECORD
A BRIGHTER
TOMORROW

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A MORE COMPLIANT
TOMORROW

Contents

Issue No. 1 is built around one question: can the organization show what was known, who had authority, what was considered, and why the decision made sense at the time?

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Masthead

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Publisher's Letter

Why this magazine exists.

Most life-sciences organizations are very good at preserving outcomes.

They preserve procedures. Deviations. CAPAs. Batch records. Investigations. Approvals. Training records. Change controls.

But there is another layer of the record that is often much harder to find later: **What did we know at the time? Who had the authority to decide? What evidence did they consider? What risks were weighed? Why did the decision make sense when it was made?**

Those questions matter because inspections, investigations, leadership reviews, and quality events rarely happen at the moment a decision is made. They happen later – sometimes weeks later, sometimes months later, sometimes after the people involved have changed roles or left the organization entirely.

At that point, the difference between verification and reconstruction becomes important.

A signature can tell you who approved something. A procedure can tell you what was supposed to happen. A completed record can tell you the outcome. But none of those automatically preserve the reasoning that connected the evidence to the decision.

That is the territory this magazine will explore.

ComplianceWorxs Magazine is not intended to be another publication filled with generic reminders about compliance. Our goal is more practical: to examine the moments where quality decisions are actually made – when evidence is incomplete, timelines matter, risk must be weighed, competing priorities exist, and someone has to exercise judgment.

In this first issue, we begin with a simple premise: **inspection readiness starts with the record.** Not simply the existence of a record, but the ability of that record to explain what happened well enough that another qualified person can understand the decision without having to reconstruct it from memory.

Compliance is ultimately carried out by people making decisions under real conditions. The quality of the record determines how well those decisions survive time, scrutiny, organizational change, and inspection.

Welcome to the first issue of ComplianceWorxs Magazine.

The Record Behind the Decision.

Reconstruction Is Not Verification

A later explanation can be credible. A contemporaneous explanation is stronger.

Verification begins with a contemporaneous record

The reviewer examines what was known, what evidence was available, who participated, who authorized the action, and why the decision was made. The record already exists. The task is to evaluate it.

Reconstruction begins with a question

People search through systems, emails, meeting notes, batch records, investigations, and individual memories to figure out what must have happened.

Sometimes reconstruction is accurate. Sometimes it is incomplete. Sometimes different people remember the same event differently.

The organization may be able to explain what happened without being able to demonstrate that the explanation existed when the decision was made.

The record is being asked to do more

Traditional documentation often proves that a process occurred. Inspection-ready documentation must sometimes do something more: help another person understand the quality of the decision itself.

A strong record should make several things visible: what was known, what was uncertain, what risks were considered, who had authority, and why the chosen action was reasonable.

This does not require an essay. It requires a visible bridge between evidence and conclusion.

A conclusion describes where you landed. Reasoning shows how you got there.

Verification

BEGINS WITH A CONTEMPORANEOUS RECORD



Reconstruction

BEGINS WITH A QUESTION



What a Strong Record Makes Visible

Five elements should survive time, turnover, and scrutiny.

What was known

What evidence was available at the time? Not what was discovered three months later. What did the decision-maker actually know when the decision had to be made?

What was uncertain

Quality decisions are not always made with perfect information. A credible record does not need to pretend otherwise.

What risks were considered

What could go wrong? Which product, process, patient, compliance, or operational risks were relevant? Which were controlled?

Who had authority

Participation and authorization are not the same thing. Many people may contribute expertise. Someone still has to own the decision.

Why the action was reasonable

Statements such as “No product impact,” “Acceptable,” “Proceed,” or “Risk is low” describe conclusions. They do not necessarily explain them.

The stronger record connects the conclusion to the evidence.

That connection is what allows another qualified person to review the decision instead of recreating it.



The Difficult Inspection Question

Who authorized this - and why?

At first, the question sounds easy.

The organization finds the approval. There is the name. There is the date. There is the signature.

But the second half of the question remains: Why?

The answer may be scattered across several places. The investigation contains part of it. An email contains another part. The subject-matter expert remembers a discussion. The batch record shows what happened next.

Each individual piece may be legitimate. But the organization does not have one contemporaneous record that shows the decision as a decision.

The exposure is not “no documentation”

The company may have created a great deal of documentation. The problem is that the documentation preserved the process around the decision better than it preserved the decision itself.

The five questions

1. What decision was actually being made?
2. What evidence was available at the time?
3. What risks and alternatives were considered?
4. Who had authority to authorize the action?
5. Why was the decision considered reasonable?

If answering those questions requires assembling a group of people and reconstructing the event, that is useful information too. It reveals a documentation gap before an inspector does.



Not Every Decision Needs Another Form

The goal is selective preservation, not more bureaucracy.

Life-sciences organizations already struggle with documentation burden.

Adding another form to every workflow would make the problem worse. The goal should be selective: preserve reasoning when the decision is important enough that the organization may later need to explain it.

That may include unexpected manufacturing conditions, significant deviations, batch disposition, product-impact assessments, investigation conclusions, escalation decisions, temporary controls, significant data-integrity questions, or decisions involving competing quality and operational considerations.

The threshold should be based on significance, not paperwork volume.

The practical question

Do not ask: Can we document everything? Ask: **Which decisions would be difficult or consequential to reconstruct later?**

Those deserve stronger records.

Inspection readiness begins before the inspection

If the reasoning behind a decision was never preserved, inspection preparation cannot make it contemporaneous after the fact.

The best time to create an inspection-ready record is when the decision is being made.

Routine

Stay in normal workflow.

No additional form needed.

-  Routine approvals
-  Standard process execution
-  Day-to-day operational decisions
-  Known and expected conditions

SIGNIFICANCE THRESHOLD

Consequential

Preserve stronger reasoning.

Create an inspection-ready record when the decision is made.

-  Deviation or unexpected condition
-  Batch disposition
-  Product impact assessment
-  Escalation decision
-  Temporary controls
-  Investigation conclusion or other significant decision

The Record Should Reduce the Need for Explanation

One test is surprisingly simple: how much verbal explanation does the record require?

A strong record does not eliminate questions. It gives the organization a stable foundation from which to answer them.

A weaker record may require someone to explain: “That is not exactly what happened.” “You have to understand the context.” “The discussion is not captured there.” “The person who made that decision has left.” “We believe this was the rationale.”

Those phrases do not necessarily mean the underlying decision was wrong. They mean the record is carrying less of the evidentiary burden than it could.

Why records reduce explanation

A preserved decision should answer questions before they are asked.

Less reconstruction later



The record behind the decision

Inspection readiness is the accumulated result of thousands of decisions made long before the inspector arrives - some routine, some consequential, some obvious, some made under pressure.

The organization will remember only a fraction of them. Its records will have to remember the rest.

The strongest organizations do not merely preserve what they decided. They preserve enough of the evidence, authority, risk, and reasoning behind important decisions that those decisions can still be understood later.

**Because eventually someone may ask: Who authorized this?
And then: Why?**

The Five Gaps Behind Compliance Exposure

Most compliance exposure does not begin with a missing SOP. It begins with a gap between what happened and what the organization can later prove.



EVIDENCE What did we know?

AUTHORITY Who had the right to decide?

RISK What were we concerned about?

REASONING Why did this action make sense?

CONTINUITY Will the record still explain it later?

The goal is not more documentation.

The goal is better evidence where the decision matters most.

The Evidence Gap

What did the decision-maker actually know?

A record may contain a final conclusion without showing the evidence available when the decision was made.

The problem is not necessarily that the evidence did not exist. It may have existed in laboratory results, batch records, environmental data, deviation records, equipment logs, emails, subject-matter expert input, previous investigations, or trending reports.

The weakness appears when the decision record does not make clear which evidence actually mattered.

What a reviewer may ask

What information did you rely on?

Was that information available before the decision was made?

Which evidence was considered most important?

Weak documentation

No product impact identified.

Stronger documentation

Review of the affected batch record, equipment alarm history, in-process test results, and prior comparable events found no evidence of impact to critical process parameters. These findings supported continuation under documented additional monitoring.

The second example does not merely state the conclusion. It shows the bridge between evidence and action.

The management question

Can we show what was known at the time without rebuilding the record later?

Evidence bridge

What was known should be visible without rebuilding the story.



The Authority Gap

Participation is not authority.

A quality event may involve Manufacturing, Quality, Engineering, Validation, Regulatory, Operations, and senior management.

Many people may contribute information. Several may agree with the outcome. But that does not automatically answer:

Who had authority to authorize the action?

An authority gap occurs when the record shows involvement but leaves ownership ambiguous.

Weak documentation

Team agreed to proceed.

Which team? Who had approval authority? Was the agreement advisory or final?

Stronger documentation

Following review by Manufacturing, Engineering, and Quality, the Head of Quality authorized continuation under the defined interim controls.

That sentence separates input from authorization.

The management question

Can we identify the person who owned the decision without inferring it from job titles, meeting attendance, or signatures elsewhere?

The Five Gaps in this case

This case combines all five.



The Risk, Reasoning & Continuity Gaps

Three gaps that determine whether the decision survives scrutiny.

Risk

A good decision can still look weak later if the record does not show that meaningful risks were recognized and evaluated.

Risk considered low.

Low based on what? Low in relation to what? A stronger record identifies the concern, the evidence used, and any residual control.

Reasoning

Organizations are usually good at recording conclusions. They are less consistent about preserving the reasoning that connects evidence, risk, authority, and action.

Proceed with production.

That states the action. It does not explain why the action was considered appropriate.

Continuity

A continuity gap exists when understanding of an important decision depends on the continued availability of the people who made it.

Warning signs include: "Ask Sarah." "The old Quality Director would know." "There was a meeting about it." "I think there was an email." "That was before we changed systems."

Would this decision still be understandable if everyone involved left tomorrow?

Together

Evidence. Authority. Risk. Reasoning. Continuity. If those answers are visible, the organization has a strong foundation. If they have to be reconstructed, there is exposure.

Three gaps, one exposure

Weak records fail when risk, reasoning, and continuity are not visible.

Risk

What could go wrong?

Reasoning

Why was the action acceptable?

Continuity

Will this still make sense later?

The Inspection Question

Who Authorized This and Why?

Every issue of ComplianceWorxs Magazine will examine one question that appears simple on the surface but exposes much more when asked seriously.

Who authorized this and why?

It tests more than whether a signature exists. It tests whether the organization can connect authority, evidence, reasoning, and accountability in a way that can still be understood after the event.

The easy answer

The Quality Director approved it.

That may be factually correct. But it answers only half of the question. The next word is the one that matters: **Why?**

What the question is really testing

Was the decision made by someone with appropriate authority? What information did that person rely on? Was the decision reasoned or merely asserted? Were meaningful risks considered? Was the decision contemporaneously documented?

A later explanation may be credible. A contemporaneous explanation is stronger.

A signature establishes accountability. Reasoning establishes defensibility.

The Five Gaps in this case

This case combines all five.



The Signature, Meeting & Email Traps

Three places where reasoning often disappears.

The signature trap

A signature proves something important: someone approved the record. It does not automatically prove why that person considered the action appropriate.

The meeting trap

Important quality decisions are often made collaboratively. The weakness appears when the meeting becomes the only place the reasoning existed.

The solution is not to create transcripts of every meeting. It is to preserve the decision that emerged from the meeting.

The email trap

Email frequently becomes an accidental decision system. A thread may contain excellent reasoning, but the rationale may be spread across twenty messages and the final decision may never be clearly stated.

The fact that reasoning existed somewhere does not mean it was preserved well.

A decision should not require digital archaeology.

What should be captured

The decision. The decision-maker. The evidence. The reasoning. The conditions or controls.

Three traps

The record should outlive the meeting, the email thread, and the signature

Signature

Approval proves action, not rationale.

Meeting

Discussion is not preserved decision logic.

Email

Messages scatter context across systems.

A Practical Example

The difference is not word count. It is visibility.

WEAK RECORD

Weak record

Event: Unexpected temperature excursion observed.

Disposition: Continue processing.

Approval: Quality Manager.

Comment: No impact expected.

The form looks complete, but the important questions remain unanswered: why was impact not expected, what data was reviewed, how severe was the excursion, and why was continuation acceptable?

STRONGER RECORD

Stronger record

Decision: Continue processing under enhanced temperature monitoring pending deviation closure.

Evidence: Excursion duration, validated temperature range, equipment trend, in-process data, and prior comparable events.

Reasoning: The excursion remained below the critical threshold and associated process parameters remained controlled.

Control: Enhanced monitoring and confirmatory review before final disposition.

What changed?

Not more words. More visibility.

THE REAL TEST

Could a qualified reviewer understand this decision without calling the people who were there?

If the answer is no, the record may be complete as a workflow but incomplete as evidence.

Case File

When the Record Cannot Support the Decision

Case signal

Repeat findings should trigger review.



What a 2026 FDA warning letter reveals about investigations, Quality oversight, and the danger of incomplete evidence.

In August 2026, FDA issued a warning letter to Jabil Inc. concerning its Pharmaceuticals International manufacturing facility in Cockeysville, Maryland.

FDA cited failures involving investigations, aseptic processing, environmental monitoring, facility conditions, batch documentation, process validation, and Quality Unit oversight.

A quality system becomes vulnerable when the record no longer gives decision-makers reliable evidence on which to act.

FDA inspected the facility from February 23 through March 6, 2026 and later concluded that significant CGMP violations existed.

Among the issues identified were repeated fungal recoveries in aseptic manufacturing areas and a sterility test failure. FDA said the firm did not adequately investigate a failed sterility result involving fungal contamination and that potential contamination routes had not been thoroughly evaluated.

FDA also identified a broader pattern of fungal contamination findings over multiple years, investigations that did not adequately evaluate likely root causes, insufficient CAPA, and an adverse contamination trend that had not been adequately assessed over time.

Source: FDA Warning Letter to Jabil Inc., MARCS-CMS 731037, Aug. 27, 2026.

The Decision Problem

Investigations are decision infrastructure.

Every investigation ultimately supports decisions: should the batch be rejected? Should other batches be assessed? Should production continue? Is CAPA required? Does the facility remain in a state of control?

Those decisions depend on evidence. If the evidence is incomplete, poorly connected, or historically inaccurate, the decision may be based on an incorrect picture of reality.

FDA explicitly criticized the firm's investigational capability and called for scientifically rigorous, well-documented, timely investigations capable of identifying root causes and supporting appropriate CAPA.

That is more than an investigation-procedure problem. It is a decision-quality problem.

The record problem became even clearer

FDA also identified major deficiencies in batch documentation. One batch record documented 12 interventions during sterile filling, while other records indicated that approximately 200 interventions had actually occurred.

If the actual process involved roughly 200 interventions while the batch record showed 12, the reviewer is no longer evaluating the actual manufacturing history. The reviewer is evaluating an incomplete representation of it.

FDA stated that incomplete manufacturing records compromise reliable batch review, investigations, and the maintenance of a state of control.

Why the record problem matters

A reviewer cannot assess the actual history from an incomplete record.

Documented interventions

12

in the batch record



Other records indicated

~200

actual interventions

Same batch. Different apparent history.

What the Quality Unit Could Not See

Authority only works when the underlying record is reliable.

FDA concluded that the Quality Unit had not provided adequate oversight and specifically cited failures to ensure complete intervention documentation, appropriate disinfection studies, and reproducible manufacturing processes.

FDA called for a comprehensive remediation plan ensuring sufficient Quality Unit authority and resources, including oversight throughout operations, complete batch review, investigation oversight, and final Quality Unit decision authority.

A Quality Unit can have formal authority and still be operating with poor information.

The Five Gaps in this case

Evidence: Historical contamination information was not adequately incorporated into some investigations.

Authority: FDA emphasized final Quality Unit decision authority and sufficient resources.

Risk: Repeated contamination signals were not adequately assessed as a combined trend.

Reasoning: Investigative conclusions were challenged because underlying evaluation was insufficient.

Continuity: Knowledge existed somewhere in the organization but was not consistently visible enough to prevent contradictory conclusions.

Source: FDA Warning Letter to Jabil Inc., Aug. 27, 2026.

Five gaps

This case combines all five.



The Boardroom Question

A documentation weakness that persists long enough becomes a management-system problem.

A senior executive does not need to understand every microbiological detail of this case.

Are the people making our most consequential quality decisions seeing a complete and reliable version of what actually happened?

If the answer is uncertain, the organization has a larger problem than record completion. It has a decision-control problem.

What a stronger system would make visible

What happened. What evidence was available. What historical information was relevant. What uncertainty remained. What risk was identified. What alternatives were considered. Who had decision authority. What action was authorized. Why that action was considered appropriate. What controls or follow-up were required.

The takeaway

This case demonstrates why inspection readiness cannot begin when an inspection is announced. By then, the history already exists. The interventions have occurred. The investigations have been closed. The batches have been reviewed. The decisions have been made.

The question becomes whether the record faithfully preserved enough of that history to support what the organization later says happened.

That is the difference between reconstructing a story and producing the record.

Editorial note: This Case File is based solely on FDA's public warning letter. It does not infer facts beyond the published record.

What leadership should ask

Can our most important quality decisions be understood from the record?

- 1 What happened?
- 2 What evidence was available?
- 3 Who had authority?
- 4 What uncertainty remained?
- 5 Why was the action acceptable?

The Record Review

What This Documentation Does

A record can look complete and still leave the most important questions unanswered.

The Record as Written

At first glance, this looks complete.

BATCH EVENT RECORD		BATCH NO. 24A
Event:	During manufacture of Batch 24A, an equipment alarm was observed during processing.	1
Immediate Action:	Operations paused the process and notified Quality.	2
Assessment:	Engineering reviewed the equipment and determined that the alarm was transient.	3
Product Impact:	No product impact identified.	3
Disposition:	Processing may continue.	5
Approval:	Quality Manager — September 14, 2026	4

Document No. DEV-001 | Revision 0

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What the Record Does Not Say

- What actually happened?**
The event is too vague. Key details are missing, such as which equipment, what the alarm indicated, how long it lasted, and at what point in the process the issue occurred.
- What evidence was reviewed?**
The basis for the conclusion is not clear. There is no record of what data, logs, or documents were examined.
- Why was there no product impact?**
The conclusion is not consistent with the documented reasoning. The record does not explain the risk assessment or how product impact was ruled out.
- Who made the decision?**
Approval is shown, but the decision-making process is unclear. It is not evident who evaluated the risk, whether the appropriate authority reviewed it, or what their basis was.
- Why was continuation acceptable?**
The risk and conditions are not described. The record does not explain the risk assessment or what controls were placed on continued processing.

The Five Gaps in This Case

This case combines all five.



Weak Record

Vague event • Hidden evidence • Unclear authority
No visible reasoning • Insufficient risk detail

The Record Doesn't Tell You.

It raises questions unanswered.

CLEARER
THINKING.
STRONGER
DEFENSES.
A HEALTHIER
TOMORROW.

A Stronger Version

More context. A clearer story. A stronger record.

BATCH EVENT INVESTIGATION RECORD		BATCH NO. 24A
Event:	During manufacture of Batch 24A, Mixer M-204 generated a high-torque alarm lasting approximately 40 seconds during the blending stage.	
Immediate Action:	Operations paused processing and notified Quality and Engineering. No additional material was added while the process was paused.	
Evidence Reviewed:	Equipment alarm history, mixer torque trend, motor current, batch process parameters, calibration status, maintenance history, in-process blend data, and two prior comparable alarm events.	
Risk Considered:	The primary concern was whether the alarm indicated impaired mixing sufficient to affect blend uniformity.	
Assessment:	The torque increase remained below the established critical process limit. Motor current returned to the expected operating range after restart. In-process blend results remained within specification.	
Decision:	Continue processing under enhanced torque monitoring for the remainder of the blending step.	
Reasoning:	Available process and equipment data did not indicate loss of mixing capability or impact to the defined critical process parameters. Because the specific cause of the transient alarm had not yet been confirmed, enhanced monitoring was required until completion of the batch.	
Authorized By:	Quality Manager	
Follow-Up:	Engineering investigation required before final batch disposition.	
Document No. QI-4587 Revision 1		Page 1 of 1

What happened

Repeat findings should trigger review.



The Five Gaps in this case

This case combines all five.



The difference is not more documentation.
The difference is visibility.

BETTER RECORDS.
BETTER DECISIONS.
A HEALTHIER TOMORROW.

Executive Perspective

Quality Is a Management System, Not a Department

There is a familiar sentence in regulated manufacturing: “Quality owns quality.” It sounds responsible. It can also be dangerously incomplete.

The Quality Unit has specific responsibilities and authority. Those responsibilities matter. But product quality is created – or compromised – long before a document arrives for Quality approval.

Manufacturing decisions affect quality. Engineering decisions affect quality. Maintenance, supply chain, laboratory, staffing, capital allocation, and management decisions affect quality.

Quality cannot be something an organization delegates to a department. It is a management system.

The difference matters

When an organization treats Quality primarily as a department, a predictable pattern can emerge: Operations performs the work, Engineering solves the technical problem, Manufacturing manages the schedule, management manages the business, and Quality reviews the documentation.

That arrangement can place Quality at the end of decisions it should have influenced much earlier.

The question is not only: Did Quality approve it? The more mature question is: Was the quality system functioning while the decision was being made?

Authority without visibility is weak authority

Giving Quality formal authority is essential. But authority only works when Quality has reliable information.

If interventions are incompletely documented, prior events are hard to retrieve, investigation conclusions are poorly communicated, or trends are not visible across functions, the organization cannot learn – and the same issues are more likely to recur.

Quality as a system

Important decisions are shaped upstream.



The Executive Test

Quality maturity becomes visible when the answer is not obvious.

Executives influence the system whether they intend to or not

Senior leaders shape the conditions under which Quality and Operations work: how aggressively production targets are pursued, how much investigation capacity is funded, when equipment is replaced, how quickly deviations must close, how many experienced Quality professionals are available, and what happens when Quality asks for more evidence.

Those decisions establish incentives. Incentives shape behavior. Culture is not separate from the quality system. It is one of its outputs.

Choose five decisions

Select five consequential quality decisions from the previous quarter and ask: What happened? Who had authority? What evidence did they use? What uncertainty existed? What risk was accepted? Why was the decision reasonable? What happened afterward?

Could we answer these questions from the records alone?

If not, the organization has learned something important.

Quality should survive the org chart

Imagine everyone directly involved in an important decision left the company tomorrow. Would a new Quality leader, auditor, inspector, or executive still understand what happened?

If the answer depends on locating the right person and hearing the story, institutional knowledge has not been adequately converted into organizational evidence.

Quality is not what one department does after the work is complete. Quality is how the organization decides while the work is happening.

The executive test

Choose five important decisions from the last quarter and ask these questions.

- 1 What happened?
- 2 Who had authority?
- 3 What evidence did they use?
- 4 What risk was accepted?
- 5 Why was the decision reasonable?

Five gaps

This case combines all five.



Regulatory Watch

What FDA's 2026 Signals Mean for Quality Leaders

Regulatory developments matter. But not every new guidance document deserves an executive meeting. Regulatory Watch focuses on signals that may change how quality leaders should think about operations.

1. Quality maturity is moving beyond baseline compliance

FDA's Center for Drug Evaluation and Research continues developing its Quality Management Maturity program. FDA describes mature quality-management practices as going beyond baseline CGMP and supporting more reliable manufacturing performance and resilience.

In February 2026, FDA opened a third cohort for evaluation of its prototype QMM assessment protocol.

The emerging question is not only: Are we compliant? It is also: How effectively does our management system sustain quality?

2. FDA keeps returning to Quality Unit authority

Recent 2026 warning letters to K.C. Pharmaceuticals, Reliance Life Sciences, Auriga Research, and Jabil repeatedly emphasize Quality Unit authority, resources, oversight, and the ability to perform required responsibilities.

The repetition matters. The issue is not simply whether an organization has a Quality Unit. The question is whether Quality can actually exercise its authority when consequential decisions are being made.

Look beyond the organization chart. Ask what happens when Quality says no - or asks for more evidence.

Sources: FDA CDER QMM program page; FDA warning letters dated Aug. 12, Aug. 18, and Aug. 27, 2026.

Three signals to watch

FDA is looking past paperwork toward the effectiveness of the management system.

Quality maturity

Beyond baseline
CGMP

Quality unit authority

Real operating
authority matters

Reliable records

Weak evidence
weakens decisions

Regulatory Watch

Reliable records remain fundamental to reliable decisions.

3. Data and record integrity are decision issues

FDA's August 2026 warning letter to Auriga Research criticized incomplete and non-contemporaneous laboratory documentation and called for comprehensive remediation of documentation systems and Quality Unit capability.

Data integrity is sometimes discussed as a records problem. But unreliable data creates a decision problem. If the underlying record cannot be trusted, neither can the decisions made from it.

What we are watching

Quality Management Maturity. Quality Unit authority. Management oversight. Data and record integrity. Risk-based inspection approaches.

The recurring theme is more consequential than paperwork: can the organization demonstrate that its quality system actually works?

For leaders

A useful response is not to create more forms. It is to strengthen the connection between reliable evidence, clear authority, management oversight, learning, and consequential decisions.

Inspection readiness should become an operating condition rather than an inspection-preparation project.

Source note

FDA, CDER Quality Management Maturity (updated 2026). FDA Warning Letters: K.C. Pharmaceuticals Inc., Aug. 12, 2026; Auriga Research Pvt. Ltd., Aug. 12, 2026; Reliance Life Sciences Private Limited, Aug. 18, 2026; Jabil Inc., Aug. 27, 2026.

The magazine will continue to distinguish published regulatory facts from ComplianceWorxs editorial interpretation.

Reliable records support reliable decisions

Data integrity is consequential because decisions inherit the strength of the record.



Decision of the Quarter

Would You Continue the Batch?

A commercial batch is in the middle of a validated blending operation.

Twenty-eight minutes into the blend, the mixer generates a high-torque alarm. The event lasts approximately 40 seconds. The operator stops the equipment according to procedure.

The torque value exceeded its normal operating range but remained below the validated critical limit. Engineering reviews the equipment. No mechanical failure is immediately identified. The mixer restarts normally.

In-process results collected before the event are within specification. No post-event blend sample is yet available. This product is currently experiencing supply pressure. Manufacturing recommends continuing the batch. Quality must decide.

Decision A - Continue immediately

The excursion remained below the validated critical limit and there is currently no evidence of product impact.

Decision B - Reject the batch

May be premature without additional evidence.

Decision C - Continue conditionally

Allow processing to continue under defined additional controls while preserving the event for investigation and requiring additional evidence before final batch disposition.

Our analysis

Based only on the facts provided, Decision C is the most defensible direction. Not because continuing is automatically safe, and not because the batch must ultimately be released.

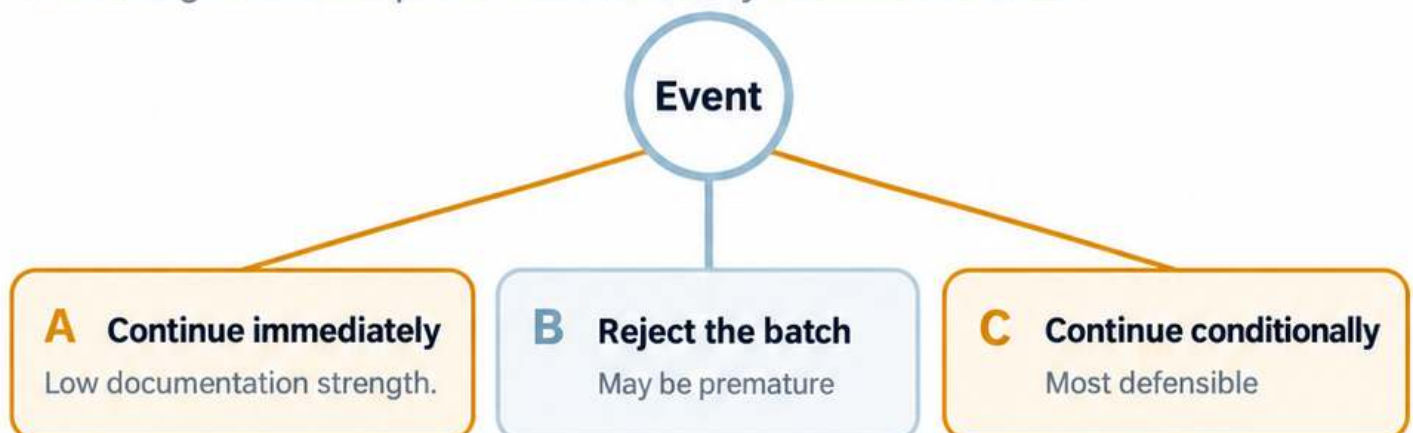
The available evidence does not yet demonstrate that rejection is necessary. But unresolved uncertainty makes an unconditional continuation weaker than a bounded continuation accompanied by additional controls and investigation.

The decision should preserve the uncertainty rather than pretend it has already been resolved.

Ask your team.

Decision paths

The strongest answer preserves uncertainty and adds controls.



The 60-Second Decision Record Check

Before closing a consequential quality decision, ask five questions.

1**EVIDENCE****What do we know?**

Can we identify the material evidence available at the time?

☐

YES

☐

NO

2**AUTHORITY****Who is making the decision?**

Is the accountable decision-maker explicit?

☐

YES

☐

NO

3**RISK****What are we protecting against?**

Does the record identify the material risk or uncertainty being managed?

☐

YES

☐

NO

4**REASONING****Why does this action make sense?**

Can another qualified person follow the connection between evidence and conclusion?

☐

YES

☐

NO

5**CONTINUITY****Will this still make sense later?**

Could someone understand the decision without calling the people who were there?

☐

YES

☐

NO

One final question:

If an inspector challenged this a year from now, what would we wish we had written down today?

Source Notes & Partner Directory

Issue No. 1 uses public regulatory material as evidence and keeps commercial partners separate from editorial conclusions.

Primary regulatory sources

- FDA** Quality Management Maturity - 2026 program updates
- FDA** Jabil Inc. Warning Letter, MARCS-CMS 731037 - Aug. 27, 202
- FDA** Reliance Life Sciences Warning Letter, MARCS-CMS 730801 -
- FDA** Auriga Research Warning Letter, MARCS-CMS 730694 - Aug.
- FDA** K.C. Pharmaceuticals Warning Letter, MARCS-CMS 729870 -

fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity
fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-let

Founding partner directory

Validation & Qualification	FOUNDING PARTNER SLOT AVAILABLE
Regulatory Consulting	FOUNDING PARTNER SLOT AVAILABLE
eQMS / Quality Technology	FOUNDING PARTNER SLOT AVAILABLE
Laboratory & Analytical Services	FOUNDING PARTNER SLOT AVAILABLE
Legal / Regulatory Practices	FOUNDING PARTNER SLOT AVAILABLE
Training & Workforce	FOUNDING PARTNER SLOT AVAILABLE
CDMO / CRO Services	FOUNDING PARTNER SLOT AVAILABLE
Cybersecurity / Data Integrity	FOUNDING PARTNER SLOT AVAILABLE

Advertising principles

- Maximum ~20% of the issue.
- Advertising is visually labeled and separated from editorial.
- Topic sponsorship does not grant editorial approval rights.
- CW may decline advertisers that conflict with reader trust.

Five gaps

This case combines all five.



The record behind the decision.

What would your records reveal under scrutiny?

ComplianceWorxs helps life-sciences organizations identify where consequential decisions are difficult to defend later - and preserve the evidence, authority, risk, and reasoning behind those decisions while the context is still fresh.

Start with the Decision Defensibility Assessment

Find where your organization may be relying on reconstruction instead of a preserved record.

- ✓ No purchase required.
- ✓ Designed for qualified life-sciences professionals.
- ✓ A practical first look at the Five Gaps.

complianceworxs.com/decision-defensibility-assessment →

What will the assessment reveal?

A clear view of where key elements may be missing, incomplete, or difficult to defend.



Evidence

What was known, and when?



Authority

Who made the decision?



Risk

What risks were considered?



Reasoning

Why this path was chosen?

COMPLIANCEWORXS

People | Process | Records | Better Outcomes