unifize

From scramble to ready

How Applechem slashed audit prep time with Unifize

SECTION 1

Executive summary

Applechem is a small but highly specialized chemical technology company operating at the intersection of cosmetic science, pharmaceutical-grade regulation, and modern sustainability expectations. With just 18 employees, Applechem designs and manufactures functional ingredients - thickeners, rheology modifiers, pigment dispersants, and performance additives - that quietly determine how consumer products feel, behave, and perform in the hands of millions of end users.

While Applechem's size suggests simplicity, its operational reality is anything but simple.

The company serves customers ranging from early-stage indie skincare brands to global multinationals such as Estée Lauder and Chanel. It manufactures ingredients that must comply not only with cosmetic regulations, but also with FDA 21 CFR, ISO 9001, and, critically, ICH Q7 CGMP standards typically reserved for pharmaceutical-grade active ingredients. Products such as zinc oxide and titanium dioxide significantly increase Applechem's compliance burden well beyond that of most cosmetic ingredient suppliers.

For years, Applechem had strong processes on paper and a deeply knowledgeable team executing them. What it lacked was a practical way to run its quality management system as part of daily work, rather than as a parallel, documentation-heavy obligation that required constant manual oversight.

Before Unifize, Applechem relied almost entirely on Excel spreadsheets, Word documents, shared folders, and email to manage document control, change control, corrective actions, risk assessments, raw material validation, and supplier quality. While this approach technically "worked," it came at a high cost:

- Quality processes stalled because approvals fell through the cracks
- Corrective actions lingered for months unless an audit forced attention
- Meetings multiplied just to keep everyone aligned
- Quality leaders spent more time chasing updates than improving systems

The result was not non-compliance, but unsustainable friction. The quality system was becoming so resource-intensive that it actively discouraged use, undermining the very purpose it was meant to serve.

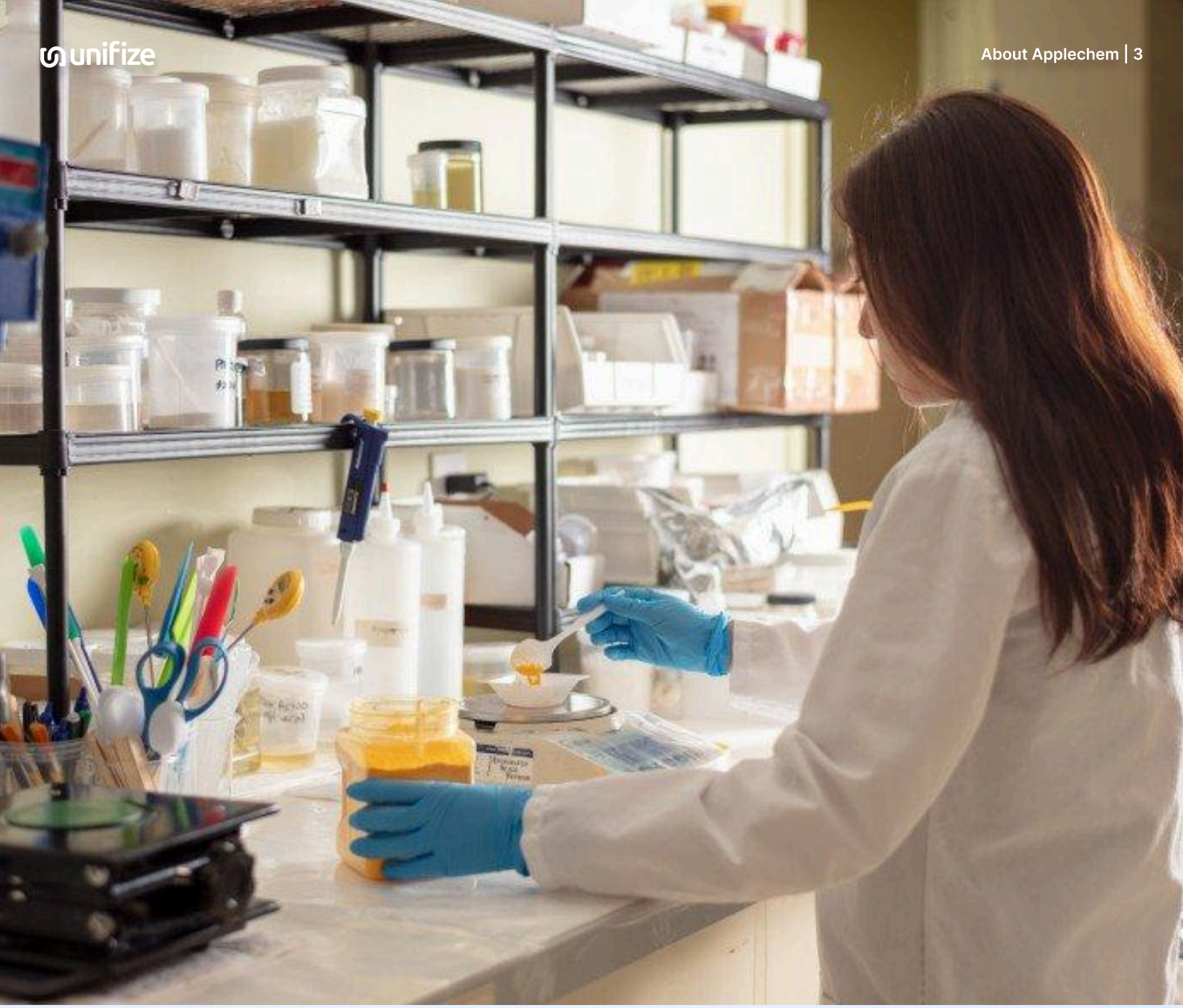
Unifize changed that dynamic.

Rather than replacing Applechem's processes, Unifize embedded them directly into day-to-day workflows, tying conversations, documentation, approvals, and accountability together in one shared system. Within weeks, Applechem had operationalized document control and change control. Within months, corrective actions, risk assessments, and raw material validation were running faster, with far greater visibility and ownership.

The impact has been tangible:

- Reduced approval cycle times reduced from 3–8 months to ~2 weeks
- Reduced corrective actions cycle time
- A dramatic reduction in meetings, email chasing, and manual follow-ups
- A measurable “quality of life” improvement for a small team wearing many hats

This case study explores how Applechem - a company with strong fundamentals but limited bandwidth - used Unifize to transform quality from a managerial burden into a living, collaborative operating system that scales with the business.



SECTION 2

About Applechem

Industry: Cosmetics Location: Parsippany, New Jersey, USA

Applechem is a research-driven chemical technology company focused on developing and manufacturing functional ingredients for the personal care and cosmetics industry. Its products are not the finished lotions, shampoos, or sunscreens consumers buy, but the invisible components that make those products work.

Thickeners that control viscosity.
Rheology modifiers that determine flow and texture.
Pigment dispersants that ensure consistency and stability.

These ingredients directly influence how a product pours, spreads, foams, feels on the skin, and performs over time. In other words, Applechem operates at the sensory and functional core of consumer experience.

Company size, structure, and footprint

Applechem employs 18 people and operates out of a single facility in Parsippany, New Jersey. The site currently spans approximately 18,000 square feet, housing:

- Corporate and administrative offices
- R&D laboratories
- Manufacturing operations
- Warehousing and logistics

At the time of Unifize adoption, Applechem was already preparing for growth, with plans to expand the facility to ~42,000 square feet to support increased manufacturing, R&D capacity, and inventory needs.

Like many small specialty manufacturers, Applechem's lean structure means that individuals wear multiple hats. There is no excess capacity - every role matters, and every inefficiency compounds quickly.

Customers and markets

Applechem's customer base spans a wide spectrum:

- Early-stage indie brands developing niche skincare and suncare products
- Mid-sized consumer brands looking to modernize formulations
- Global multinationals such as Estée Lauder and Chanel, with rigorous supplier expectations

This diversity creates constant tension between speed, customization, documentation depth, and regulatory rigor. What satisfies an indie brand's timeline may fall short of a multinational's audit expectations, and Applechem must be able to operate confidently at both ends of that spectrum.

Regulatory and quality environment

As a cosmetic ingredient manufacturer, Applechem must comply with the U.S. Food, Drug, and Cosmetic Act. But its regulatory obligations go significantly further.

Applechem operates under:

- ISO 9001:2015 quality management requirements
- CGMP standards
- ICH Q7, due to the manufacture of materials classified as active pharmaceutical ingredients (APIs), such as zinc oxide and titanium dioxide

ICH Q7 represents Applechem's highest compliance burden. Unlike standard cosmetic GMPs, it requires:

- Long-term stability testing
- Deep documentation of manufacturing controls
- Pharmaceutical-grade rigor applied to products that may ultimately be used in topical cosmetics

For a company of Applechem's size, meeting these expectations is not just a compliance exercise; it is a resource and capital challenge. The systems, equipment, and documentation rigor required are typically found in much larger pharmaceutical organizations.

Leadership and quality ownership

At the center of Applechem's operations is Wilson Lin, one of the company's longest-tenured employees, with nearly 18 years of service.

Wilson wears several critical hats simultaneously:

- Head of Marketing
- Owner of Regulatory Affairs
- Leader of Quality Assurance operations

In many organizations, these functions are siloed. At Applechem, they converge in one person, by necessity and by design.

Wilson's path into quality leadership did not begin in chemistry or manufacturing. It began in finance.
Before Applechem, Wilson worked at American Express and in boutique financial planning firms. The work was structured and competitive, but deeply transactional. He quickly realized it wasn't where he wanted to spend his career.

What he wanted was simpler and more human: to work directly with customers, to sell products he believed in, and to be part of an industry built on long-term relationships rather than zero-sum competition.

The personal care and cosmetics industry offered exactly that. Its impact is enormous, yet the ecosystem behind them is surprisingly small and collaborative, especially on the supplier side. Innovation is shared, reputations matter, and success is often mutual rather than adversarial.

That environment suits Wilson. He enjoys helping customers solve real formulation problems and seeing those solutions translate into better-performing products. Though his work is largely invisible to consumers, its effects are tangible in how products feel, perform, and improve daily routines.

This perspective shapes how Wilson approaches quality.

He is not a bureaucratic quality leader. He does not see quality systems as paperwork engines or compliance theater. He is pragmatic, systems-minded, and openly allergic to busywork, especially work done only to satisfy an audit.

Wilson believes deeply in the purpose of quality management systems: to surface issues early, control risk, document decisions, and enable continuous improvement. But he is equally clear-eyed about how traditional systems fail in practice, particularly in small, growing companies. When systems are rigid, manual, or disconnected from daily work, they get used late, inconsistently, or only under pressure.

At Applechem, with a lean team where everyone wears multiple hats, there is no bandwidth to chase approvals or babysit processes. Any system that depends on reminders, heroics, or constant follow-up is fundamentally unsustainable.

That realism - not ideology - is what shaped Wilson's expectations. He wasn't looking for a system to replace good processes. He was looking for one that would let those processes actually run as part of everyday work.

Why Wilson cared and what "winning" looked like

Wilson's frustration wasn't that Applechem lacked good processes. It was that executing those processes had become too resource-intensive.

Wilson's personal definition of success was not "passing audits."
It was making compliance part of everyday work, without increasing headcount or friction.

His personal wins came in the form of:

- Fewer follow-up emails and reminder chains
- Approvals that moved without escalation
- Conversations that stayed attached to the work itself
- Being able to trust that if something was open, it was visible, and owned

Unifize appealed to Wilson precisely because it did not promise to fix bad processes. Instead, it promised to reduce the friction between good processes and real work.

For someone who had spent years compensating for system gaps through sheer effort, that promise mattered.

SECTION 3

Operational complexity & why quality was hard at Applechem

COMPLEXITY 1

Pharmaceutical-grade regulatory burden in a cosmetic business

Although Applechem serves the cosmetics and personal care industry, several of its core ingredients - most notably zinc oxide and titanium dioxide - are classified as active pharmaceutical ingredients (APIs) under U.S. regulations.

That classification pulls Applechem into ICH Q7 CGMP, a standard designed for drug manufacturers.

This creates a fundamental mismatch:

- The scope of requirements resembles pharmaceutical manufacturing
- The resources available resemble a small specialty chemical company

Under ICH Q7, Applechem must manage:

- Extensive process validations
- Extensive change control for even minor process adjustments
- Long-term and ongoing stability testing
- Rigorous deviation, corrective action, and risk assessment workflows
- Deep traceability between raw materials, processes, and finished outputs

For large pharma companies, these activities are distributed across dedicated QA, validation, regulatory, and documentation teams. At Applechem, they are handled by a small group of people wearing multiple hats, often in parallel with customer-facing and operational responsibilities.

Quality wasn't optional, but it was expensive in time, attention, and cognitive load.

COMPLEXITY 2

Innovation-driven product development with high failure tolerance

Applechem is not a commodity manufacturer. Its value lies in solving hard formulation problems driven by evolving consumer and regulatory trends:

- Sulfate-free surfactants
- Biodegradability requirements
- Microplastic bans (especially from the EU)
- Sustainability expectations from multinational customers

Each new product begins as a scientific hypothesis. Polymer chemists explore molecular structures, test performance across different surfactant systems, and iterate repeatedly. Many candidates fail before one succeeds.

When a candidate shows promise, complexity accelerates:

- Lab-scale success must translate to manufacturing scale
- Scale-up often reveals new failure modes
- Processes must be reworked, revalidated, and re-documented
- Regulatory and quality documentation must evolve in parallel

Every iteration introduces:

- New documents
- New approvals
- New risks
- New change controls

This creates constant motion inside the quality system. When quality tooling is static, rigid, or manual, it becomes a bottleneck rather than an enabler.

COMPLEXITY 3

A wide customer spectrum with conflicting expectations

Applechem serves both:

- Indie brands prioritizing speed and flexibility
- Global multinationals demanding audit-ready rigor

This duality forces quality to operate at two speeds simultaneously.

For enterprise customers, Applechem must demonstrate:

- Controlled document revision histories
- Robust change control and deviation management
- Traceability and investigation rigor
- Evidence of continuous improvement

For smaller customers, Applechem must still move quickly, adapt formulations, and support rapid iteration. Without a single system of record, this tension expressed itself as:

- Duplicate documentation
- Parallel tracking methods
- Context switching between “fast” and “formal” modes

Quality had to stretch, and the tooling did not stretch with it.

COMPLEXITY 4

Existing quality systems were manual, fragmented, and fragile

Before Unifize, Applechem's quality management system ran almost entirely on:

- Excel spreadsheets
- Microsoft Word documents
- Shared file servers
- Email threads

This applied to:

- Document control
- Change control
- Corrective actions
- Risk assessments
- Raw material validation
- Supplier documentation

While this approach technically met ISO 9001 requirements, it introduced structural weaknesses:

- No real-time visibility into status
- No automated reminders or accountability
- No single place where conversation and documentation lived together
- Heavy dependence on individuals to remember and follow up

As volume increased, the system became person-dependent rather than process-dependent.
If the right person was busy or on vacation, work stalled.

COMPLEXITY 5

Approvals, ownership, and accountability broke down at scale

One of the most painful failure modes was approvals.

In theory, approvals existed.
In practice:

- Change controls could linger 3–6 months
- Corrective actions stalled unless audits forced attention
- Documentation revisions piled up silently

No one was ignoring quality. People were simply busy.

Without automated ownership, reminders, and escalation:

- Tasks fell between roles
- Accountability blurred
- Progress depended on manual chasing

This wasn't negligence; it was structural.

COMPLEXITY 6

Cultural overcompensation through meetings

Applechem is a highly collaborative company. To compensate for poor system visibility, the team relied heavily on:

- Frequent meetings
- Verbal check-ins
- Status updates
- Escalation discussions

Over time, this became cultural muscle memory.

Meetings weren't inefficient because people talked too much - they existed because there was no shared system showing the truth of the work.

As complexity increased, so did meetings. Ironically, the more collaborative the company became, the harder it was to move quickly.

Non-conformances at Applechem - execution failures, not product failures

Applechem's quality challenges did not primarily manifest as defective products, safety incidents, or regulatory enforcement actions. There is no evidence of chronic field failures or systemic breakdowns in product quality. Instead, Applechem's non-conformances lived in a quieter, more dangerous place: the execution layer of the quality management system itself.

Before Unifize, many of Applechem's issues would best be described as latent process non-conformances - conditions that violated the intent (and sometimes the letter) of ISO 9001 and CGMP requirements, even if they were not always formally logged as NCs.

This distinction matters.

What these non-conformances looked like in practice

From Wilson's experience and day-to-day operation of the QMS, recurring issues included:

- **Change controls remaining open for months**
  Changes were identified, discussed, and sometimes even implemented, but the formal change control record lagged behind execution.

- **Corrective actions that lingered until audits forced closure**
  Issues were known, but without system-level enforcement, they competed with operational priorities and drifted.

- **Documentation updates not completed in real time**
  SOPs, validation records, and supporting documents were often revised after work had already moved on.

- **Approvals delayed due to lack of visibility**
  No one could easily see what was waiting on whom, or how long something had been stalled.

- **Raw material validation steps progressing unevenly**
  Vendor qualification, questionnaires, reviews, and sign-offs were tracked manually, making handoffs fragile.

None of these looked catastrophic individually. Collectively, they created audit risk, operational drag, and constant background stress.

Why weren't these issues always logged as “NCs”

A critical insight at Applechem was that the system itself made non-conformances harder to see, not easier to capture.

Because quality was managed through Excel, Word, shared folders, and email:
- There was no consistent trigger that forced an issue to be logged
- There was no single place where deviations naturally surfaced
- “Open” and “closed” were often subjective judgments
- The effort required to formally document an NC was itself a deterrent

In effect, the QMS allowed problems to exist between the cracks - acknowledged informally, discussed verbally, but not always recorded with the rigor regulators expect.

This does not indicate negligence. It indicates tooling misalignment.

Root causes: system design, not people

When viewed through a root-cause lens, these non-conformances shared a common profile.

Primary root causes included:
- **Manual systems with no enforcement**
  Excel and Word could record information, but could not enforce sequence, ownership, or completion.

- **No real-time visibility**
  There was no dashboard or queue showing what was overdue, blocked, or aging.

- **Implicit ownership**
  Responsibility lived in people’s heads or emails, not in the system.

- **Approval processes with no escalation**
  If someone was busy, work simply waited, sometimes indefinitely.

- **Bandwidth constraints in a small team**
  Quality work competed with R&D, manufacturing, and customer demands every day.

- **Audit-driven urgency**
  As Wilson openly acknowledged, issues often moved fastest when an auditor was coming.

Crucially, operator error was not the dominant factor. The same people, working harder, would not have solved the problem. The system itself allowed drift.

Why this mattered more than product defects

From a regulatory perspective, process non-conformances are often more dangerous than isolated product failures.

They:
- Accumulate silently
- Create inconsistent records
- Undermine confidence in the quality system as a whole
- Surface at the worst possible moment - during audits or investigations

Wilson recognized that continuing this way would eventually force Applechem into one of two paths:
- Add headcount just to manage the system, or
- Change the system so it could manage itself

Why Applechem chose Unifize

Applechem, and especially Wilson, was not looking for “an eQMS.”
He was looking for a way to run quality continuously, without adding headcount or turning quality into a separate administrative job.

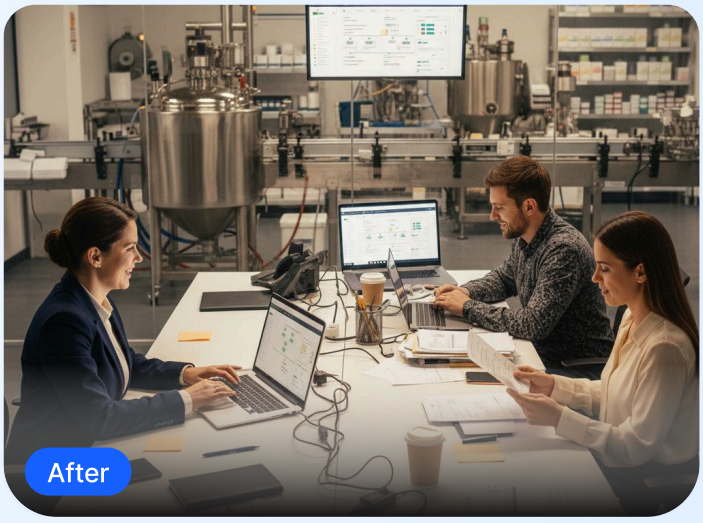
Traditional enterprise systems like MasterControl were immediately ruled out: they were expensive, rigid, and designed for organizations with large, dedicated QA teams to administer them.

Lower-cost QMS tools fared no better. While cheaper, they still carried the same fundamental problem: rigidity. They forced Applechem to contort its existing, working processes to fit the software, recreating the same compliance-over-usability tradeoff Wilson was trying to escape.

Unifize stood apart because it approached quality differently. It treated quality as a collaborative workflow rather than a document repository, tied conversations directly to the process itself, and embedded ownership, reminders, and accountability into everyday work. Most importantly, Unifize did not promise to fix bad processes. It promised to make good processes executable. That distinction is what made the decision clear.

SECTION 4

Challenges and solutions



Manual, fragmented QMS execution → One collaborative system of record

Challenge (Before)

Applechem's quality management system was distributed across Excel trackers, Word documents, shared file servers, and email. Document control, change control, corrective actions, risk assessments, and raw material validation all had their own artifacts, folders, and communication threads.

There was no single place where someone could answer basic questions like:

- What quality actions are currently open?
- Who owns them?
- What's waiting on approval?
- How long has it been stuck?

Instead, the answers lived in people's inboxes, personal spreadsheets, or institutional memory. Keeping everything aligned required constant meetings and follow-ups, which scaled poorly as the business grew.

Solution (After)

Unifize became Applechem's single, collaborative system of record for quality. Documents, change controls, corrective actions, and validation workflows now live in a single shared environment, with conversations, context, and documentation tied directly to each record.

Instead of stitching together the state of quality work manually, teams can see it directly - reducing ambiguity, duplication, and reliance on tribal knowledge.

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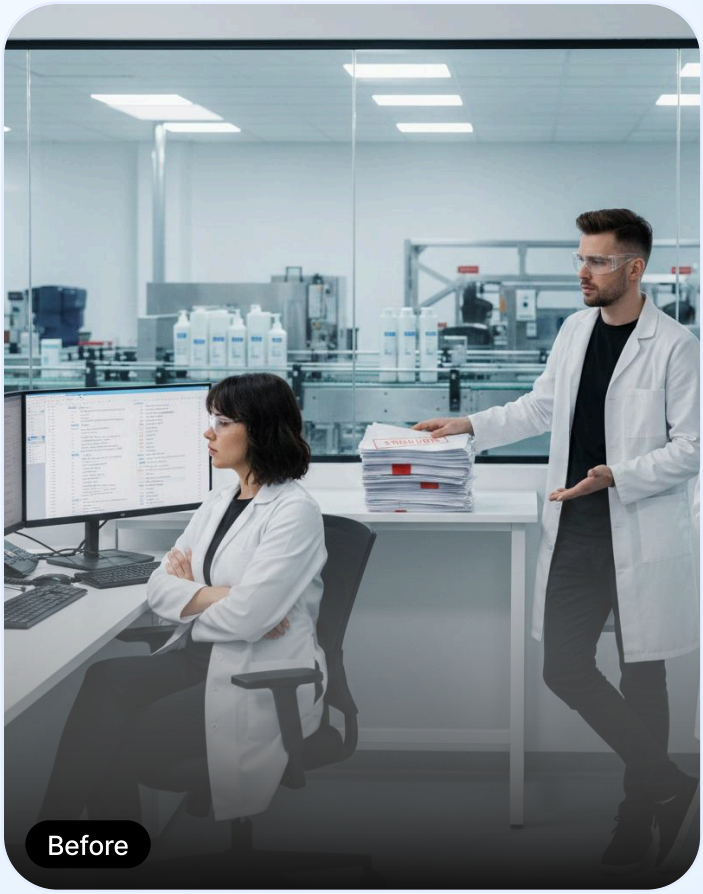

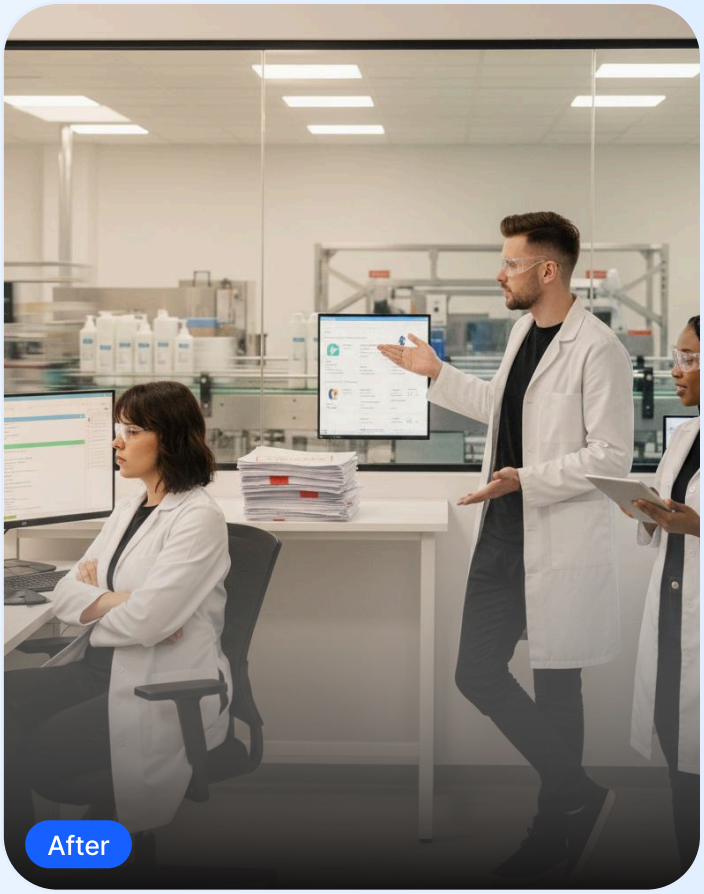

Approval bottlenecks and stalled progress → Embedded ownership and automation

Challenge (Before)

Approvals were one of the most fragile points in Applechem's QMS. Change controls, SOP revisions, and corrective actions could remain open for weeks, months, or even longer, not because of disagreement, but because no system was actively enforcing ownership or follow-up.

Approvals depended on someone remembering to chase an email or raise the issue in a meeting. In a lean organization where everyone wore multiple hats, that approach inevitably broke down.

Solution (After)

Unifize embedded explicit ownership, due dates, and automated reminders into every workflow. Approvals are now tied directly to the step they unlock in the process, making it unambiguous who needs to act and when.

This shifted approvals from a passive, email-driven activity to an active part of the workflow. Variability collapsed, and approval timelines moved from unpredictable months to consistently measured weeks, without adding management overhead.

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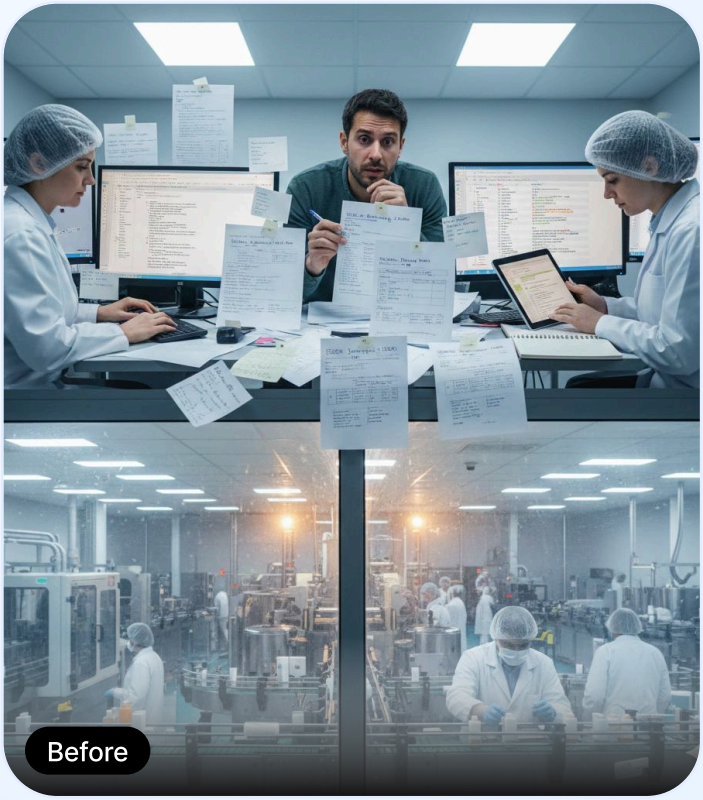

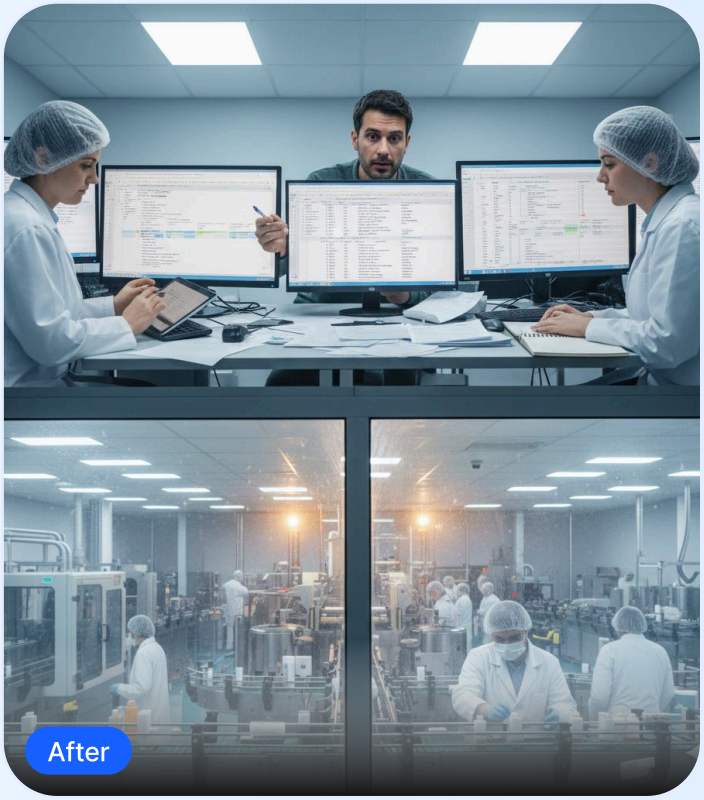

Documentation lag and backfilling → Real-time documentation tied to execution

Challenge (Before)

Documentation often lagged behind reality. SOP updates, change control records, and corrective action documentation were frequently completed after work had already progressed, increasing audit risk and cognitive load.

This wasn't a discipline problem - it was a usability problem. Capturing documentation in real time using Word, Excel, and shared drives added friction to already busy days.

Solution (After)

With Unifize, documentation is captured as part of the work itself. Change controls link directly to affected SOPs, conversations happen next to the record, and decisions are documented in context as they are made.

This reduced the need for backfilling, improved traceability, and turned documentation into a natural byproduct of execution rather than a separate administrative task.

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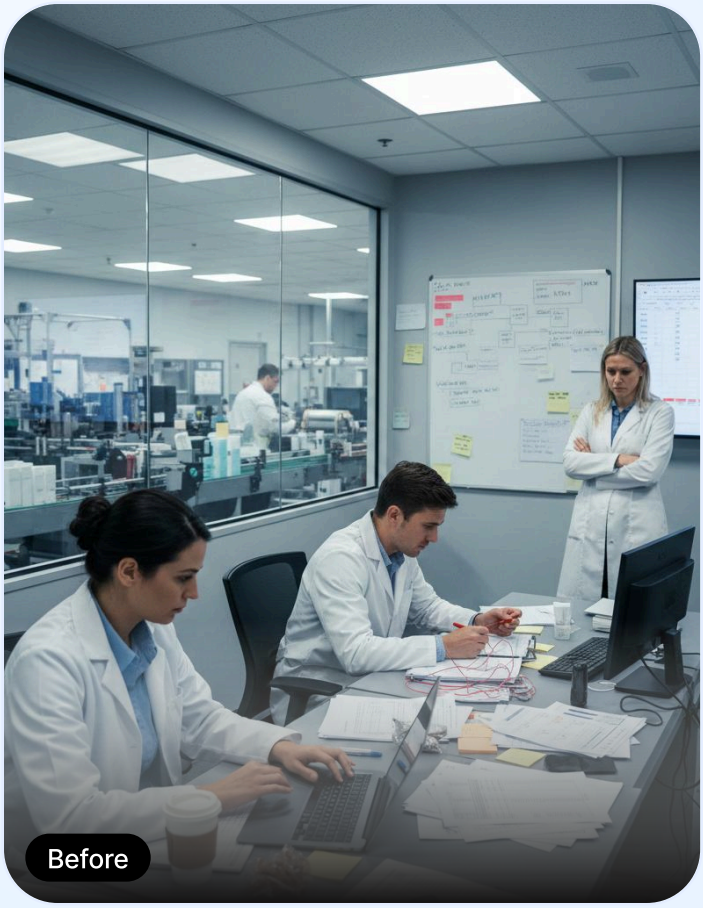

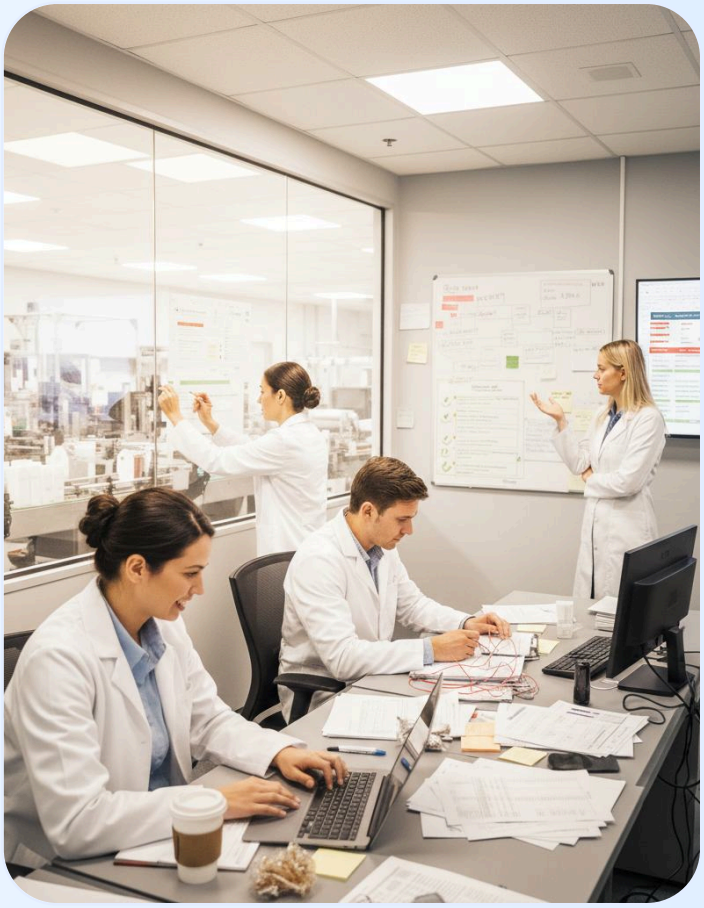

Corrective actions that dragged on → Structured, visible investigations

Challenge (Before)

Corrective actions and risk assessments were difficult to manage, especially when they spanned departments or involved external parties. Without a shared workspace, updates were scattered across emails, calls, and meetings.

As a result, corrective actions could take 2 to 3 months or longer, often moving fastest only when an audit created external pressure.

Solution (After)

Unifize provided a structured, shared workspace for investigations. Ownership, action items, and status are visible in one place, and internal and external stakeholders can contribute directly to the same record.

This reduced corrective action cycle times from months to a few weeks, while improving the quality, completeness, and auditability of investigations.

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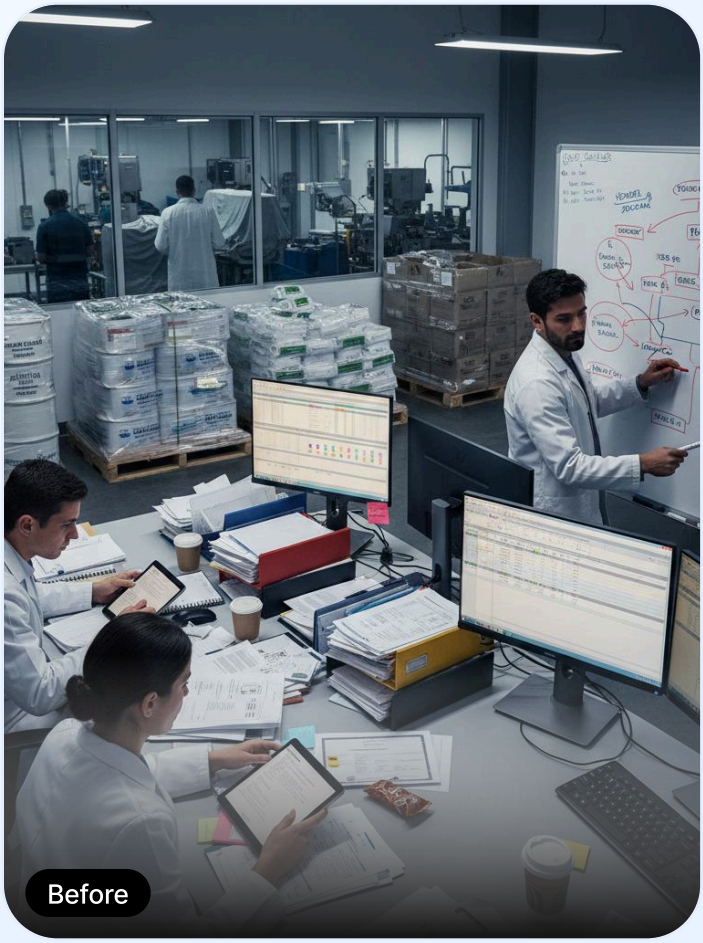

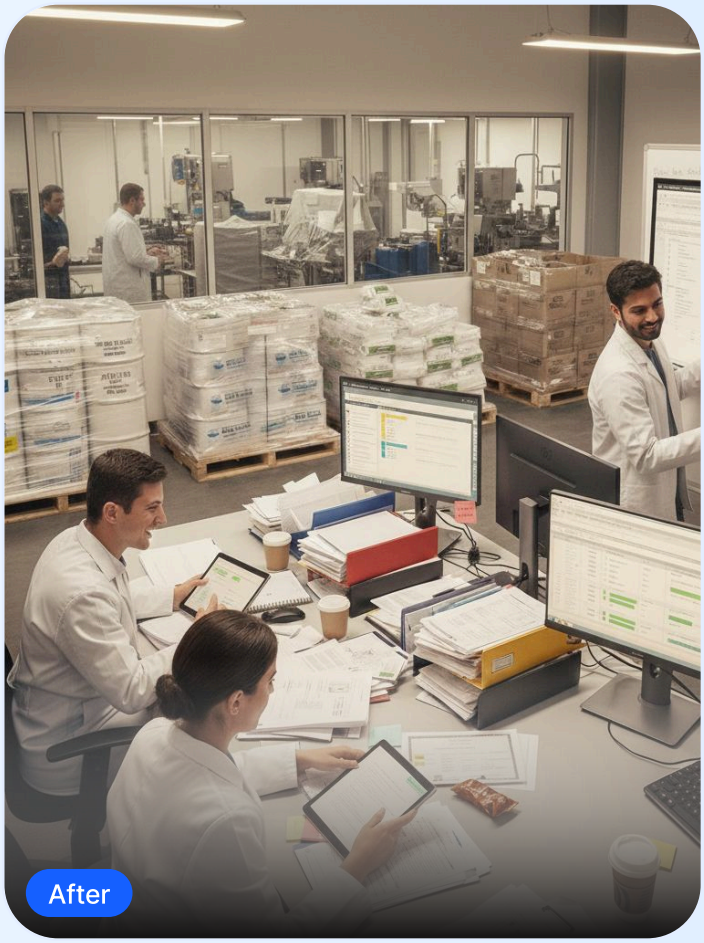

Raw material validation complexity → Stage-gated, checklist-driven workflows

Challenge (Before)

Raw material validation involved multiple steps: vendor qualification, questionnaires, documentation review, and approvals. Tracking progress manually meant steps were often completed out of sequence, with handoffs relying on emails or meetings to move work forward.

Each transition between stages required additional coordination just to signal readiness.

Solution (After)

Unifize transformed raw material validation into a stage-gated, checklist-driven workflow. Each stage has a defined owner, required inputs, and approvals, making progress visible at a glance.

This allowed R&D, QA, and leadership to work in parallel where appropriate, while ensuring that no critical validation step was skipped or forgotten.

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Meeting-heavy coordination → Visibility-driven collaboration

Challenge (Before)

Because there was no real-time visibility into quality work, Applechem relied heavily on meetings to stay aligned. Status updates, escalations, and approvals often required synchronous discussions simply to understand where things stood.

Over time, this became cultural muscle memory - collaboration equaled meetings.

Solution (After)

With Unifize providing live visibility into ownership, status, and history, many of these meetings became unnecessary. Stakeholders can log in, review the record, read the conversation, and act immediately.

Collaboration didn't disappear; it became asynchronous, contextual, and far more efficient.

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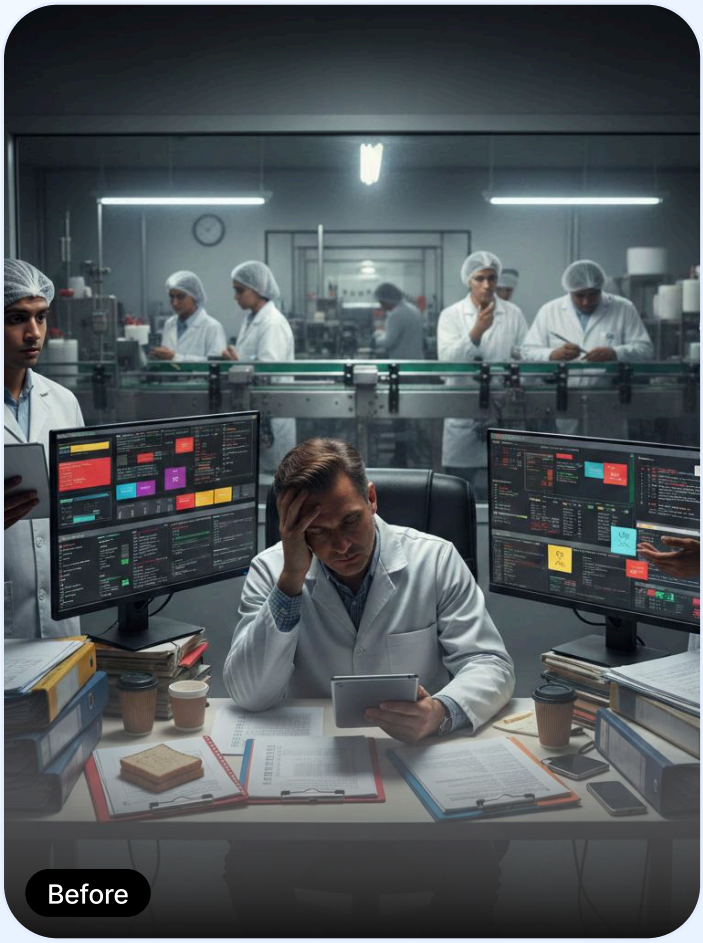

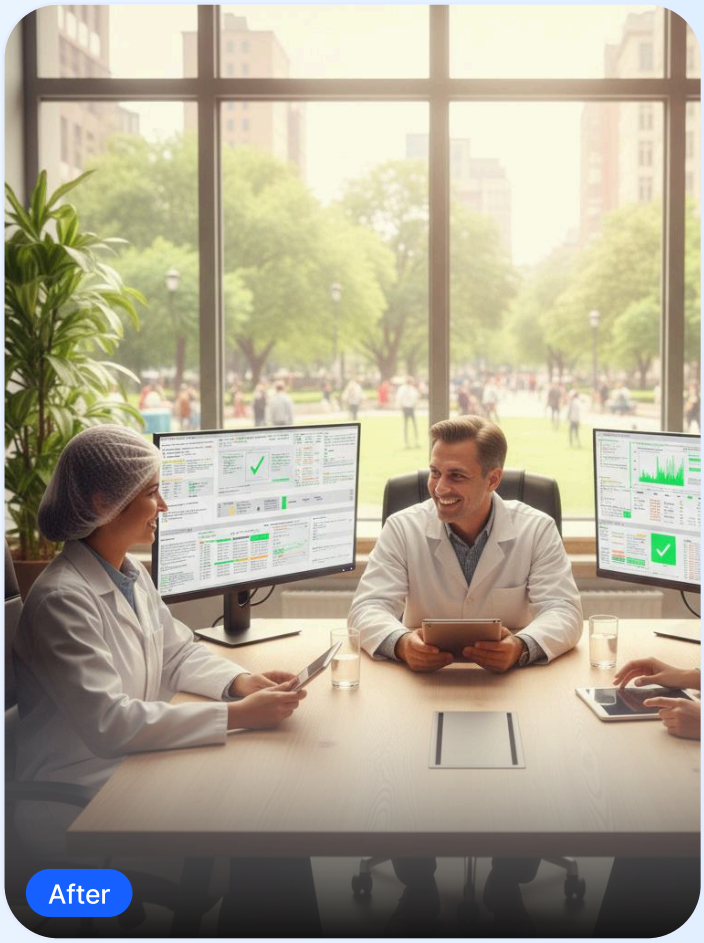

Quality as an active management burden → Quality embedded into everyday work

Challenge (Before)

Actively managing the QMS required constant attention. Without dedicated resources, quality leadership became reactive and audit-driven, dependent on individual vigilance rather than system behavior.

This created stress and made sustained compliance harder than it needed to be.

Solution (After)

By embedding accountability, visibility, and documentation directly into workflows, Unifize reduced the need for constant oversight. Quality no longer depends on heroics or manual supervision.

For Wilson and the broader team, this represented a meaningful quality-of-life improvement, not just a process improvement.

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SECTION 5

Applechem's connected quality workflows in Unifize

Once Applechem consolidated its quality processes into Unifize, the most meaningful shift was not digitization, but operability. Instead of running quality through Word files, Excel trackers, email threads, and meetings, Applechem now executes documentation, approvals, investigations, and validations inside a single shared environment.

Every workflow - documents, change controls, corrective actions, risk assessments, raw material validations, and approvals - lives in Unifize and is connected through shared ownership, conversation, and visibility. The sections below outline how Applechem actually runs its quality system day to day inside Unifize.

SECTION 5.1

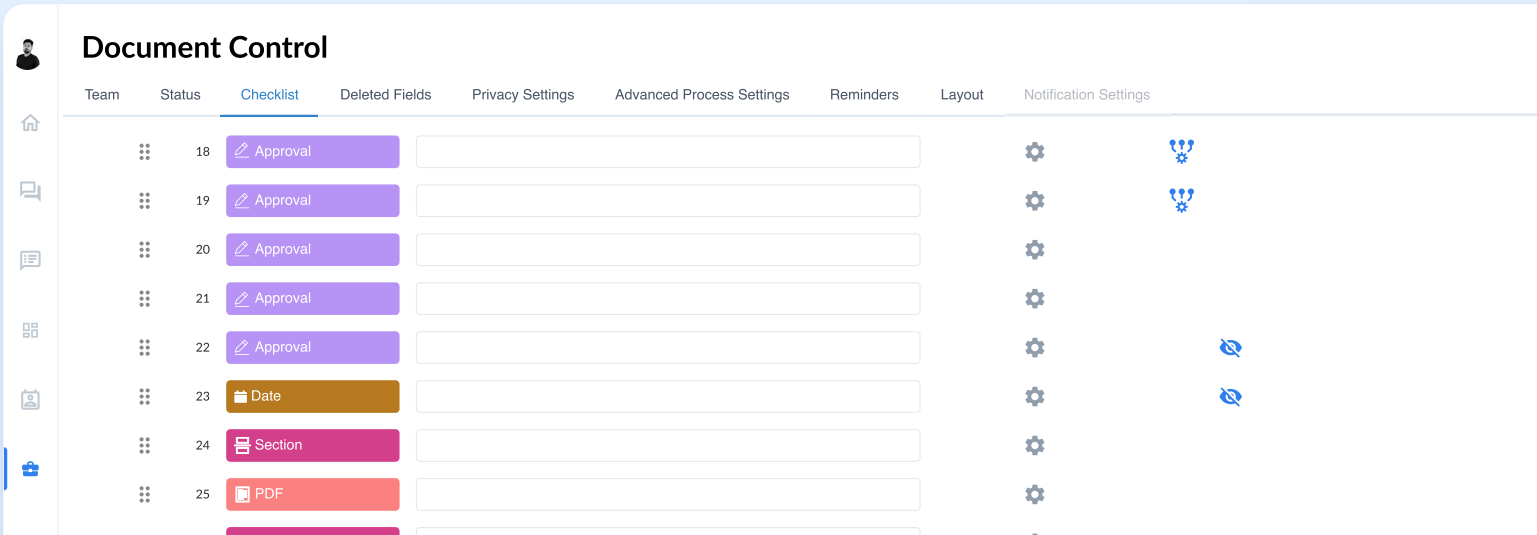
Document control: the backbone of Applechem's QMS

Document control is the foundation of Applechem's quality system and was the first workflow migrated into Unifize.

How document control works in practice

Applechem maintains hundreds of SOPs and quality documents in Unifize, including:

- Manufacturing procedures
- Quality control and testing procedures
- Validation protocols and reports
- Change control–related documentation
- Regulatory and compliance support documents



Each document record in Unifize includes:

- Document type, category, and owner
- Current revision and full revision history
- Required approvers and approval status
- Attached files for each revision
- A conversation thread capturing discussion, rationale, and clarifications

Rather than replacing files in shared folders, revisions are managed through a controlled workflow. When a document changes, Unifize ensures the correct reviewers are notified, approvals are captured, and the updated revision becomes the single source of truth.

For audits, this means Applechem no longer assembles documentation reactively. The evidence of control - what changed, when, why, and who approved it - is already there.

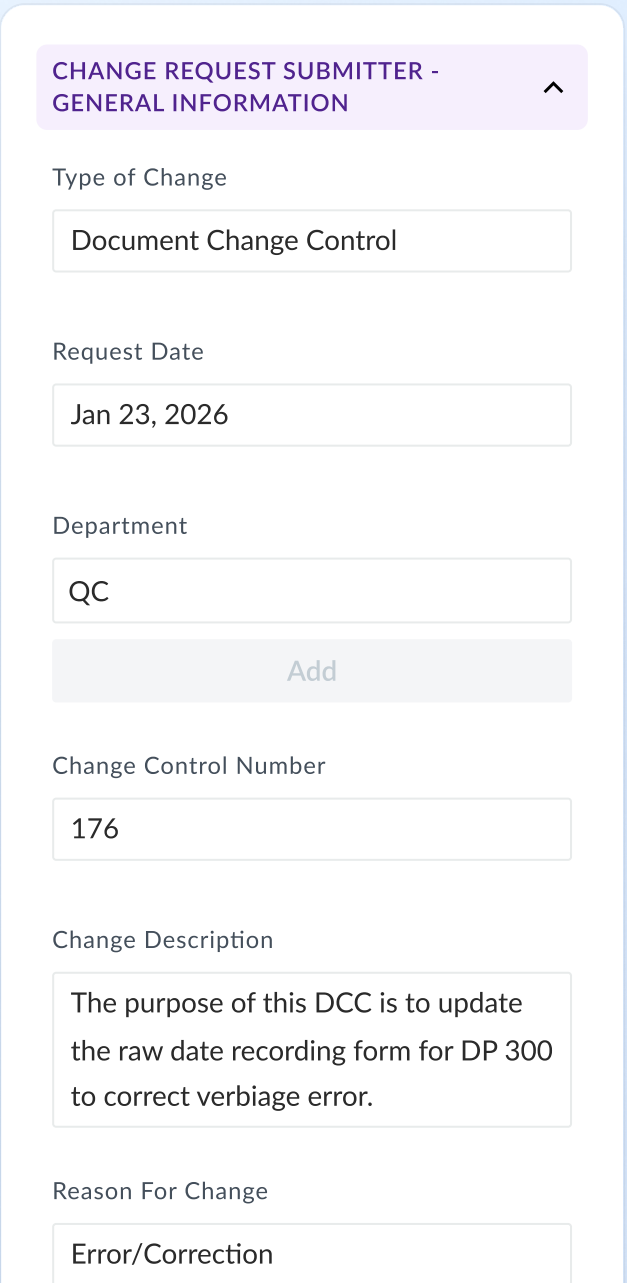
SECTION 5.2

Change control: linking improvements directly to SOPs

Change control is one of the most resource-intensive parts of Applechem's QMS, particularly under ISO 9001 and ICH Q7 CGMP requirements.

How change control works in Unifize
Each change control record captures:

- The proposed change and business or quality justification
- The SOPs and documents impacted (linked directly from Document Control)
- Risk assessment and downstream considerations
- Assigned owners and approvers
- A shared conversation thread for discussion and clarification



Approvers review the change in context, alongside the affected documents, rather than interpreting redlined Word files in isolation. As discussion unfolds, updates to the change record happen in real time, reducing confusion and follow-up meetings.

Because change controls are visible in a centralized list, quality leadership can see:

- Which changes are open
- How long they've been open
- Who they're waiting on

This has removed one of the biggest friction points in continuous improvement.

SECTION 5.3

Corrective actions and investigations: managing issues as shared work

Corrective actions and risk assessments are where Applechem sees the most day-to-day collaboration across departments.

How corrective actions are captured

Each corrective action record in Unifize includes:

- Description of the issue or deviation being investigated
- Immediate containment actions
- Root cause analysis
- Risk assessment and potential downstream impact
- Corrective and preventive actions
- Owners, due dates, and required approvals

Supporting evidence - documents, screenshots, supplier input, or updated SOPs - can be attached directly to the record.

Collaboration inside investigations

Instead of coordinating investigations through email and meetings, all discussion happens next to the record itself. Internal stakeholders from QA, R&D, manufacturing, and leadership collaborate in a shared thread. When external parties (e.g., suppliers or contract manufacturers) are involved, they can be looped in without fragmenting the conversation.

This has shortened corrective action cycle times from months to weeks and significantly improved documentation quality.

SECTION 5.4

Raw material validation: stage-gated workflows with clear ownership

Raw material validation is a critical quality process at Applechem, touching regulatory, R&D, QA, and leadership. How validation workflows are structured

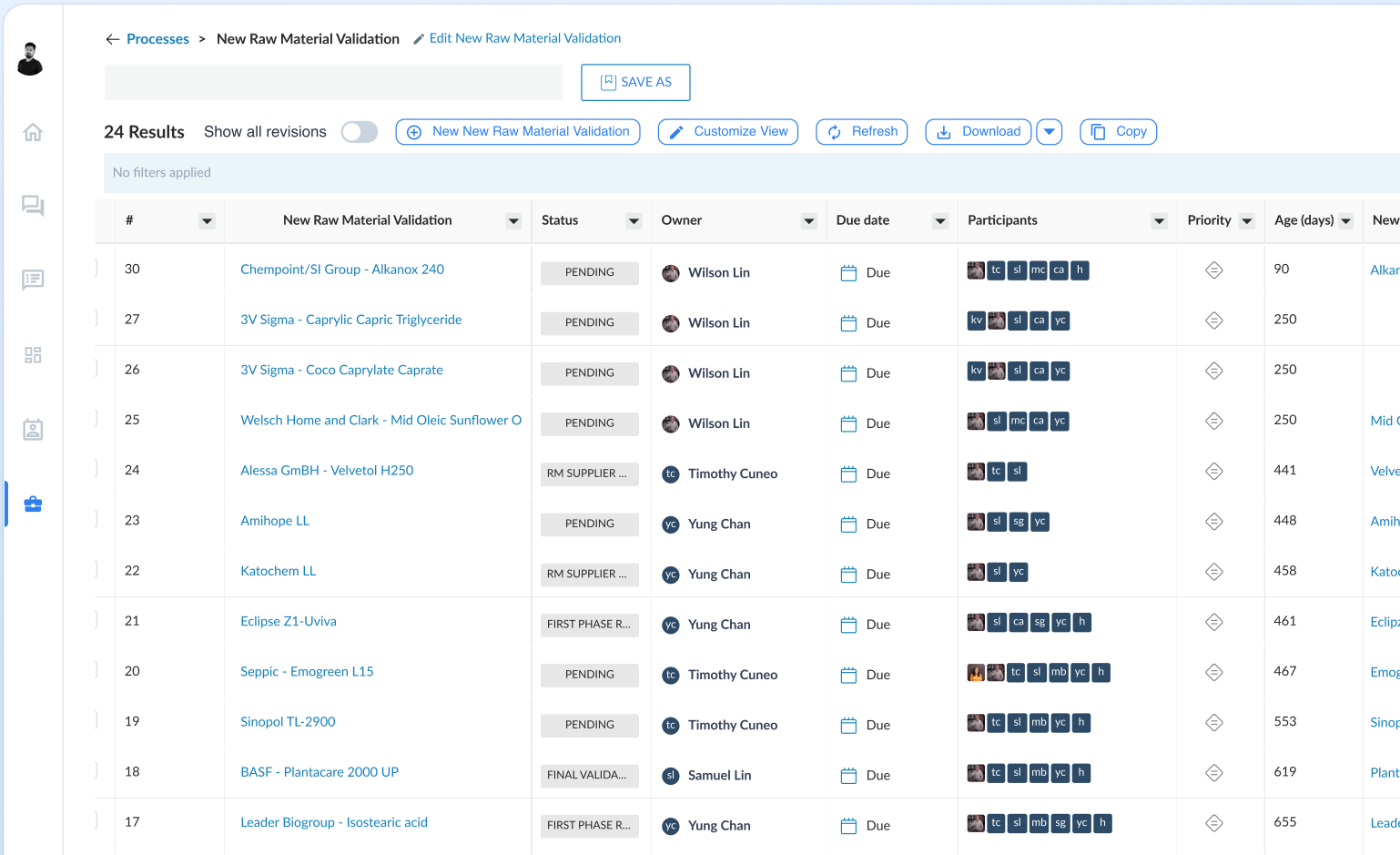
Each raw material validation record includes:

- Supplier qualification steps
- Required regulatory and compliance documentation
- Review and approval stages
- Assigned owners for each stage
- Automated notifications as work progresses

Validation is executed as a stage-gated workflow, meaning:

- One stage must be completed and approved before the next begins
- Ownership transfers automatically between stakeholders
- Everyone can see the current stage and what remains outstanding

This replaces manual checklists and eliminates the need for meetings just to move validation forward.



SECTION 5.5

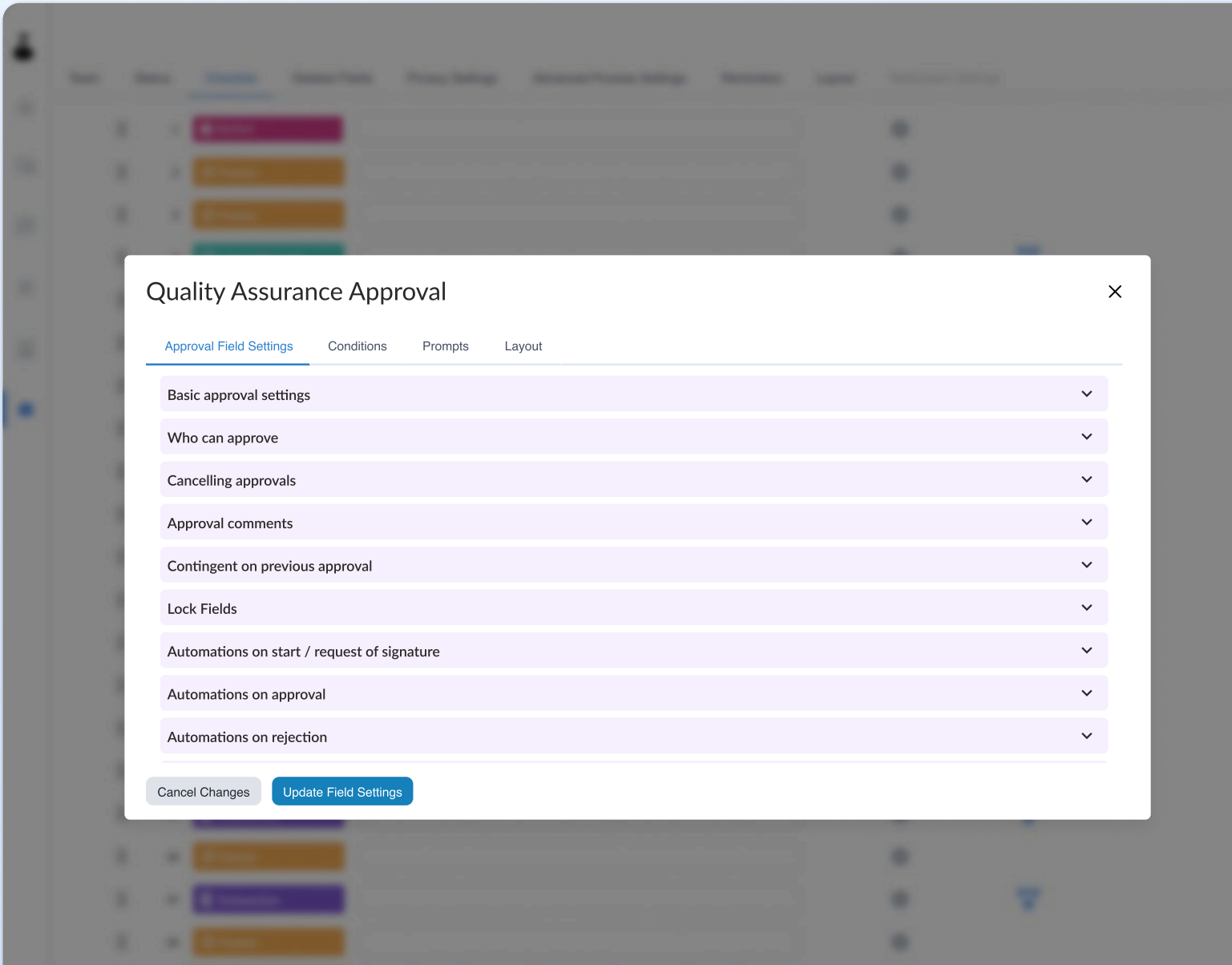
Approvals and accountability: making ownership explicit

Across documents, change controls, corrective actions, and validations, Applechem uses Unifize to enforce explicit ownership.

Every workflow step has:

- A clearly assigned owner
- A due date
- Automated reminders and escalation

This removes ambiguity about responsibility and prevents work from silently stalling. Approvals that once lingered for months now move consistently, without manual chasing.



SECTION 5.6

Dashboards and real-time visibility

Unifize's dashboards give Applechem leadership and quality teams a live view of what is happening across the QMS.

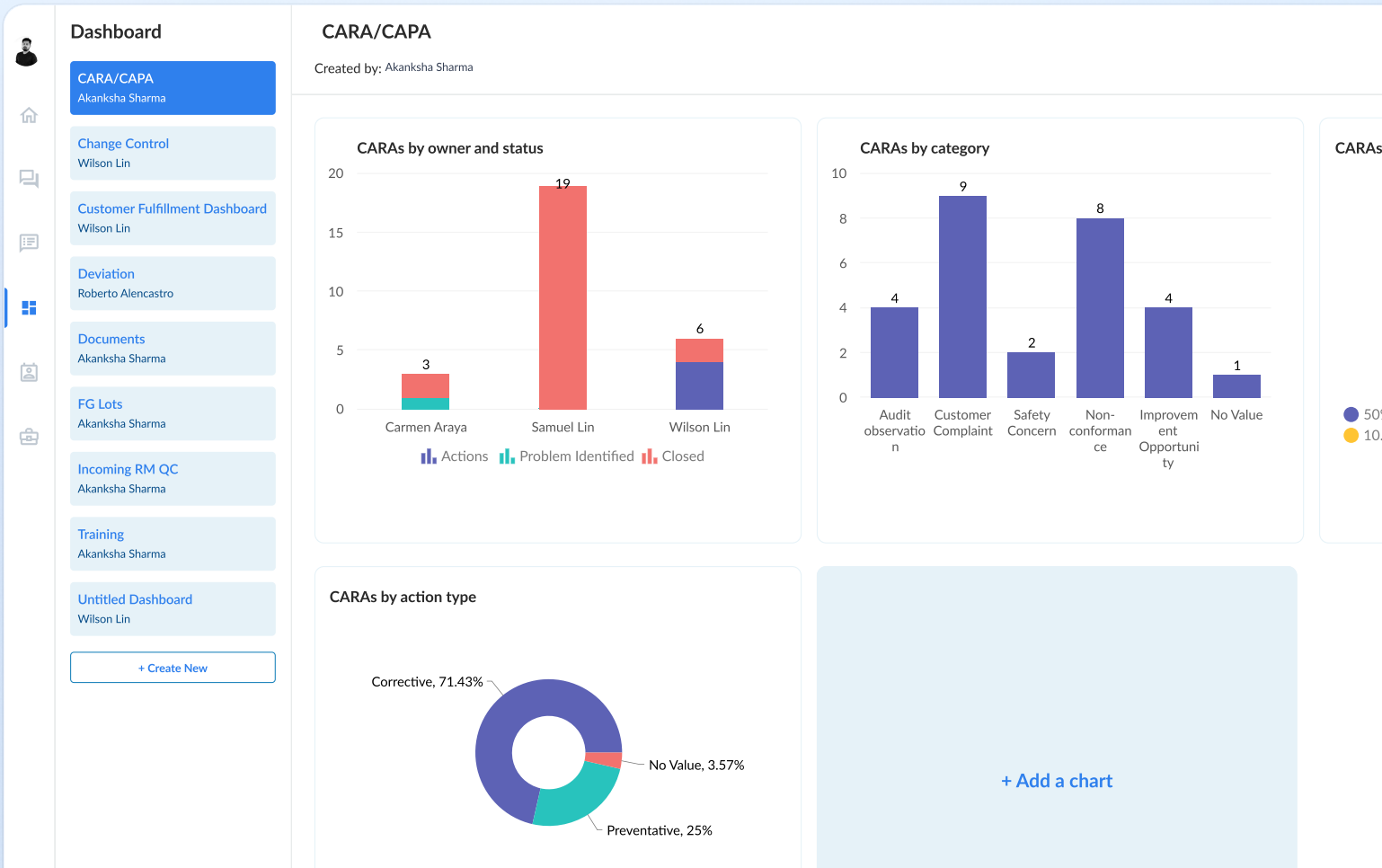
Dashboards Applechem uses

Applechem tracks:

- Open and closed corrective actions
- Aging approvals and overdue items
- Change controls by status
- Document revisions and approval activity
- Raw material validation progress

Dashboards update automatically as work happens. Users can click into any tile or chart to open the underlying record, keeping analysis and action in the same system.

This has shifted leadership conversations from "Can someone pull the status?" to "What needs attention right now?"



SECTION 5.7

How quality work feels different day to day

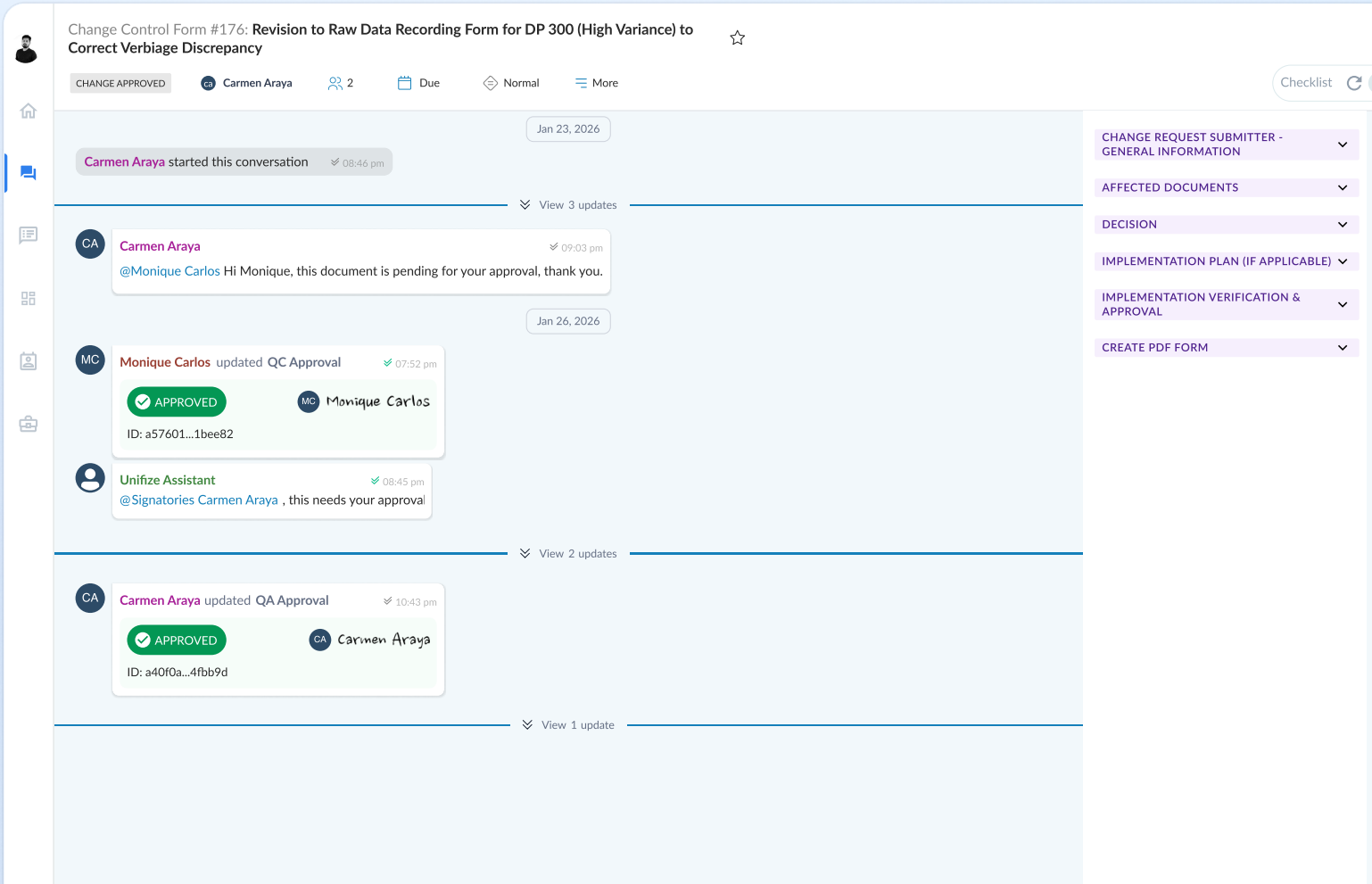
Taken together, these workflows have fundamentally changed how quality operates at Applechem. Quality no longer depends on:

- Memory
- Manual follow-up
- Constant meetings
- Document revisions and approval activity
- Raw material validation progress

Instead, it is:

- Visible by default
- Embedded in daily work
- Executed with less stress and less overhead

For Wilson and the team, this represents a genuine quality-of-life improvement. The quality system now supports the business instead of competing with it.



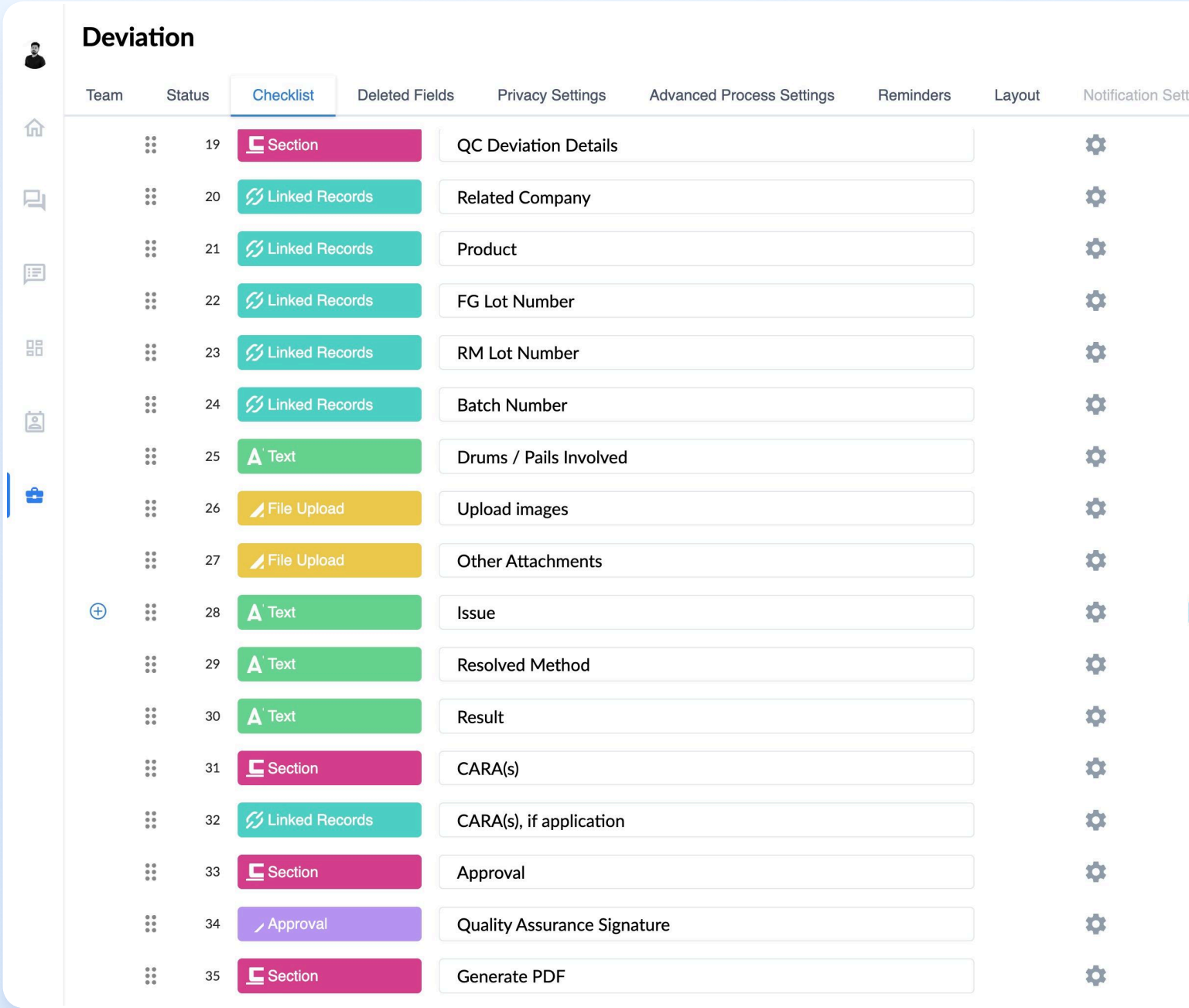
SECTION 5.8

The connective tissue

What makes Applechem's use of Unifize effective is not any single workflow, but how they connect:

- Change controls link to documents
- Corrective actions link to investigations and risk
- Validations link R&D, QA, and leadership
- Dashboards reflect live execution, not static reports

Applechem's QMS now behaves like a system: coherent, transparent, and resilient as the company grows.



SECTION 7

Outcomes & Impact

Outcome / Workflow	Before Unifize	After Unifize	Impact
Approval timelines	Highly variable; approvals often lingered for weeks or 3–6+ months due to lack of visibility and follow-up	Embedded ownership, due dates, and automated reminders drive consistent movement	**Approval cycles reduced to ~2 weeks in most cases, without manual chasing**
Corrective action cycle time	Investigations stretched 2–3 months or longer, especially when cross-functional or involving external parties	Centralized investigation records with shared context and ownership	**Corrective actions now typically close in weeks instead of months**
Audit readiness	Audit prep required manual document searches and evidence compilation; ~30+ minutes per request	Documentation, approvals, and history are always current and traceable	**Audit requests resolved in minutes, not hours; readiness is continuous**
Documentation timeliness	Documentation frequently lagged execution; backfilling common	Documentation captured as work happens, tied to workflows	**Reduced backfilling; improved traceability and confidence in records**
Meeting load	Heavy reliance on meetings for status updates and coordination	Live system visibility replaces most status discussions	**Up to 90% reduction in recurring status-related meetings**

Outcome / Workflow	Before Unifize	After Unifize	Impact
Cross-functional visibility	Status lived in emails, spreadsheets, and people's heads	Real-time visibility into ownership, status, and aging	**Faster alignment, fewer handoffs, less ambiguity**
Early-stage product development speed	18–24 month cycles typical; manual handoffs between stages	Quality, regulatory, and R&D work aligned earlier via shared workflows	**~30% faster from ideation to pre-commercialization; targeting ~40% as adoption matures**
Quality metrics visibility	Many signals (aging approvals, stalled actions) were felt but not measurable	Dashboards show open/closed actions, aging items, and trends	**Enables proactive management instead of reactive cleanup**
Headcount impact	Managing quality required significant manual oversight	System-driven execution reduces management burden	**No additional headcount required to support growth**
Quality of life for QA leadership	High cognitive load, constant follow-ups, audit-driven stress	Work progresses without heroics or constant supervision	**Meaningful quality-of-life improvement without lowering standards**

SECTION 7

Implementation journey - From mapping to mastery

While the exact dates are internal, Adaptive's journey with Unifize followed a clear progression from foundational control to continuous improvement.

Process mapping and gap assessment

The implementation began with a close examination of Applechem's existing quality processes. The team reviewed core SOPs across document management, change control, corrective actions, raw material validation, lot release, and supplier qualification.

The goal was not to redesign processes from scratch, but to identify where execution routinely broke down in practice:

- Where work stalled waiting for approvals
- Where handoffs relied on memory or email
- Where documentation lagged behind decisions
- Where visibility disappeared between steps

This gap assessment clarified that the issue was not what Applechem was doing, but how those processes were being executed day to day.

Configuring Unifize to mirror real workflows

With those gaps identified, Applechem configured Unifize to reflect its actual operating rhythm.

The initial configuration focused on:

- Document control, establishing a centralized master library with structured revision and approval workflows
- Change control, linking improvements directly to impacted SOPs and processes
- Corrective actions and risk assessment, enabling structured investigations with embedded ownership
- Audit management and supplier quality, creating a single place to manage findings, follow-ups, and documentation

Electronic signatures were enabled to support Part 11–style expectations, ensuring that approvals and sign-offs were both compliant and operationally simple.

Crucially, Unifize was configured to adapt to Applechem's processes, not the other way around.

Data migration and cleanup

Rather than migrating everything at once, Applechem focused on migrating what mattered most. Key SOPs, specifications, validation documents, and historical quality records were moved into Unifize first. This ensured that:

- Active work could continue without disruption
- Future changes would be anchored to clean, controlled records
- Audits could reference a consistent, centralized system of truth

The migration process also surfaced outdated or redundant documents, which were cleaned up as part of the transition rather than carried forward.

Training and cross-functional rollout

Training emphasized how work would change, not just where to click.

Rather than positioning Unifize as "another system to update," Applechem framed it as the place where quality work now happens. Cross-functional teams were onboarded with a focus on:

- Capturing discussions directly inside records instead of email
- Using workflows to move work forward rather than meetings
- Relying on system visibility instead of manual follow-ups

Because the workflows mirrored existing processes, adoption was faster than anticipated. Teams began using Unifize for core quality activities within weeks, not months.

Iterative refinement and adoption

Implementation did not end at go-live.

As teams began using Unifize in real scenarios, workflows were refined based on feedback:

- Field layouts were adjusted for clarity
- Approval sequences were tuned to reduce friction
- Notifications and ownership rules were refined

This iterative approach ensured that Unifize continued to fit Applechem's day-to-day reality as usage expanded.

Over time, the system moved from being "new software" to being invisible infrastructure, simply how quality work gets done.

SECTION 8

Executive takeaway

Applechem did not adopt Unifize to fix broken quality processes. The company already had a strong foundation, deep regulatory knowledge, and a culture that cared about doing things right. The challenge was execution: running a pharmaceutical-grade quality system with a lean team, without letting documentation, approvals, and coordination overwhelm day-to-day work.

By embedding Unifize into its existing workflows, Applechem transformed quality management from a manual, burdensome process into an operational system. Approvals became predictable, corrective actions occurred continuously rather than in bursts, documentation stayed current, and visibility replaced meetings as the primary coordination mechanism. Most importantly, this shift happened without adding headcount or compromising rigor.

For Applechem, the value of Unifize is not automation for its own sake. It is the ability to make good processes executable every day, under real operational pressure, in a growing, highly regulated business. That capability has improved audit readiness, reduced friction across teams, accelerated early-stage development, and delivered a meaningful quality-of-life improvement for those responsible for maintaining compliance.

This case demonstrates that modern quality systems need not be rigid, resource-intensive, or disconnected from real work. When quality is treated as a collaborative workflow rather than a repository, even small, complex organizations can operate with enterprise-grade discipline, without enterprise-grade overhead.