

From fragmented specs to 50% lower testing costs

Adaptive Health's connected quality journey with Unifize



SECTION 1

Executive summary

Adaptive Health is a US-based nutraceutical and wellness company behind some of the most recognizable condition-specific supplement brands on the market, from men's vitality and joint health to digestive, sleep, and heart health products. Many of these brands are manufactured at Biovation Labs, an FDA-registered, GMP-compliant contract manufacturer that Adaptive acquired to bring its supply chain closer to home.

Before Unifize, the path from product idea to finished bottle was far more complex than any label suggested. Product development, quality, and manufacturing teams were spread across Adaptive's brand organization, Biovation Labs, and other contract manufacturers. Specs lived in legacy PLM and EQMS tools, ingredients and lots were tracked in ERP and CM systems, and quality events were scattered across spreadsheets, email, and point solutions. Connecting a complaint to a lot, a lot to a spec, and that spec back to its ingredients could take hours of digging.

The risk wasn't just inefficiency. Adaptive operates in a tightly regulated, high-scrutiny environment: dietary supplement GMPs (21 CFR Part 111), NSF and retailer audits, plus marketplace expectations from platforms like Amazon and major retailers. Every product must be backed by the right clinical rationale, manufactured under control, tested to the right limits, and supported by clean documentation. Fragmented systems made it hard to be confident that every step from concept to post-market surveillance had truly been completed and documented.

Unifize changed that. Today, Adaptive Health use Unifize as the connected backbone for their product lifecycle and quality operations. Finished Product Specification Packets (FPSPs) sit at the center, tying together formulations, ingredients, manufacturing formulas (MMFs/MMRs), packaging, artwork, testing requirements, and lot-release rules. Around that core, Non-Conformances (NCs), Deviations, Out-of-Specification (OOS) results, Complaints, CAPAs, and supplier records form a continuous feedback loop across brands and manufacturing sites.

The impact is tangible:

- ✓ Lot release at the manufacturing site has gone from taking days of back-and-forth to being completed in minutes, because all the necessary test results, specs, and approvals are orchestrated inside Unifize.
- ✓ Monthly testing costs at Biovation Labs have been reduced by roughly half (from about \$146k to about \$65k over a two-month window) as better visibility enabled more targeted sampling and fewer unnecessary tests.
- ✓ Ingredient verification for Adaptive's QA team now takes about half the time it used to, with checklist-driven workflows and centralised documentation replacing manual hunts through folders and systems.

Beyond the numbers, teams at Adaptive now work from one "source of truth" for specs, lots, and quality events. Product development, QA, Legal, Marketing, retail partners, and contract manufacturers all collaborate on the same conversations and records. Instead of chasing missing steps, they can focus on making better decisions about formulations, claims, and continuous improvement.

This case study walks through that transformation: the complexity of Adaptive's portfolio and manufacturing footprint, the specific pain points that led them to Unifize, how the platform was implemented, and the results they've seen in both measurable outcomes and day-to-day culture.



**ADAPTIVE
HEALTH**

SECTION 2

About Adaptive Health

 **Industry:** Nutritional Supplements

 **Location:** Charlotte, North Carolina, USA

Adaptive Health is a nutraceutical and wellness business focused on science-backed dietary supplements sold through a mix of direct-to-consumer subscriptions, e-commerce, and major retail partners. Its portfolio spans men's health, joint health, digestive and sleep support, heart and circulatory health, blood sugar management, mood, and healthy aging—through brands like Nugenix, Instaflex, Super Beta Prostate, Peptiva, and physician-endorsed lines such as Dr. Sinatra, Dr. Whitaker, and Dr. Williams.

Many of these brands are manufactured at Biovation Labs in Salt Lake City, Utah, a vertically integrated, FDA-regulated contract manufacturer that Adaptive brought into the group to pull manufacturing, quality, and formulation closer to the brand organization. Biovation manages raw-material sourcing and qualification, blending, encapsulation and tableting, softgels, stick packs, packaging, in-house and external testing, and final distribution for Adaptive's brands as well as major retailers. Adaptive operates through FDA-registered, GMP-compliant, NSF-certified US facilities, so every product has to stand up to 21 CFR Part 111, retailer audits, and marketplace scrutiny. Specs, change histories, and documentation are what keep products on shelf and make audits repeatable instead of traumatic.

When Mikala Hukka joined Adaptive about six years ago, the brand-side operation was still small - around twenty people - with no formal product development or quality team. Her job was to build quality into the DNA of how new products were conceived and launched, not just sign off at the end. Natalie Jones brought the formulation and product-development lens, caring deeply that the formula, the label, the clinical rationale, and the regulatory story all lined up from day one through to end of life. Erica Bennerman sat closest to the firing line: raw-material verification, finished-good release, artwork and label checks, SOP and documentation control - exactly the places where small misses become big problems in front of an auditor or customer.

All three cared about seeing the whole story of a product. But they were trying to do that across too many disconnected systems: specs and change control in legacy eQMS and shared folders, lots and batches in ERP and CM systems, NCs and deviations in spreadsheets or point tools, approvals and clarifications buried in email and chat. That fragmentation hurt them in very specific ways: Mikala couldn't be sure every step from concept to launch was actually done, not just assumed; Natalie was constantly fighting version confusion as more SKUs and channels were added; Erica could spend close to an hour per raw material or finished-good lot hunting for CoAs and approvals, carrying the stress of knowing a missed file or outdated spec might only surface in a mock recall or live audit.

The turning point didn't start at Adaptive - it started next door, at Biovation. Biovation's quality team, led by Jesse Kolstad, had already moved on to Unifize to get away from rigid, file-cabinet-style eQMS tools and to create absolute traceability from raw materials to finished goods on the plant floor. When that implementation showed it could tie specs, raw-material lots, batches, tests, and NCs together in a single collaborative system, and in the process cut testing costs roughly in half and shrink lot-release times from days to minutes, it gave Adaptive a concrete answer to the pain they were living with.

Extending Unifize onto the Adaptive side meant Mikala, Natalie, and Erica could finally work in the same connected environment that was already delivering results at Biovation. Quality, product development, and manufacturing now look at the same FPSPs, the same raw-material records, the same NCs, and mock-recall drill results, and have their conversations on top of that shared data instead of scattered in inboxes. What began as a 20-person brand team with no formal PD or quality function, and a busy GMP plant each fighting their own tool sprawl, has become a single Adaptive–Biovation quality organization managing product lifecycle and quality as one continuous, shared operation.

SECTION 3

Operational complexity & why quality was hard

Managing quality at Adaptive wasn't just about checking a finished bottle on a line. It meant orchestrating a multi-brand, multi-site ecosystem where each product carries its own formulation, clinical rationale, regulatory obligations, and supply chain.

Before Unifize, that ecosystem ran on a patchwork of tools. Specs and formulas lived in a legacy PLM/EQMS (e.g., MasterControl) or in scattered documents; ingredient and lot data sat in ERP and CM systems; NCs, deviations, OOSs, and complaints were tracked in separate EQMS tools, spreadsheets, and email. To answer a basic question like "What happened with this lot?" someone might have to open half a dozen systems and chase people for missing pieces.

Biovation Labs felt that pain first. Their quality team had already outgrown file cabinets and a traditional eQMS and needed something that could tie lot release, testing, and NCs together in real time. They piloted Unifize on the manufacturing side, replacing MasterControl for key processes and using it to link specs, lots, and test results. When that pilot cut lot-release cycle times from days to minutes and helped reduce monthly testing costs from about \$146k to roughly \$65k, it became the proof point that a more connected approach could work at scale.

That success is what ultimately drove the decision to extend Unifize into Adaptive's brand organization. Instead of buying another point solution, the Adaptive team chose Unifize because it could act as a combined PLM + QMS + MES-adjacent backbone: FPSPs at the center, with NCs, deviations, OOSs, complaints, CAPAs, lots, and suppliers all connected around them. The migration followed a deliberate path: mapping how work actually flowed across Adaptive and Biovation, standing up FPSP/MMF control, importing key specs and lot history, then layering in NC/Deviation/OOS/Complaint workflows and supplier quality. Over time, Preventive Maintenance, CMMS, and broader brands were added, turning Unifize into the default place where work happens rather than an "extra system" to update.

This was the backdrop against which Adaptive's existing complexity became hard to manage with fragmented tools.

SECTION 3.1

Brand and product portfolio complexity

On the surface, Adaptive's products look like familiar dietary supplements: capsules, tablets, stick packs, and multi-packs in recognizable categories. Underneath, each SKU represents a web of decisions and constraints:

- **Multiple brands and markets.** A single formulation might have different label claims, counts, or packaging for US retail, DTC, Canada, Amazon channels, or specialty partners.
- **Clinical and marketing alignment.** Each product must balance clinical evidence, marketing claims, and regulatory guidance. Claims on the front of the label have to match what's in the FPSP, the supporting studies, and the underlying formulation.

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Without a central PLM hub, keeping these variants aligned and ensuring that downstream manufacturing and testing matched the intended spec was a constant source of overhead and risk.

SECTION 3.2

Manufacturing processes & network

Adaptive's manufacturing model combines a vertically integrated internal CM (Biovation) with additional third-party contract manufacturers for certain SKUs and brands. Across this network, operations include:

- Ingredient sourcing and qualification
- Formulation and pilot batches
- Blending, encapsulation, tableting, softgels, and stick-pack filling
- Bottling, blistering, and packaging into final formats
- In-house and third-party lab testing
- Distribution to retailers and DTC channels

This is a classic high-mix, regulated environment. Batch sizes vary, formulations differ by dosage form, and change requests are frequent. Every adjustment has implications across MMFs, FPSPs, test plans, and lot-release criteria.

When specs are scattered across legacy PLM and shared folders, lots are in another system, and quality events in yet another, even simple questions become difficult:

- "Did this lot follow the latest spec?"
- "Has this complaint pattern shown up before on this formula or this supplier?"
- "Can we safely rework this batch, or is it a total write-off?"

SECTION 3.3

Ingredients, testing, and supplier complexity

As a nutraceutical company, Adaptive depends on a broad network of raw material suppliers for botanical extracts, vitamins, minerals, probiotics, excipients, and packaging components. Like any nutritional supplement manufacturer operating under 21 CFR Part 111, Adaptive is required to maintain an Approved Supplier List (ASL) for every raw material, and to ensure that each supplier is properly qualified, audited, and re-audited on a defined cycle.

For every raw material, the quality team must:

- Qualify the supplier through questionnaires, quality agreements, and initial audits.
- Place that supplier on the ASL for specific raw materials only once they meet Adaptive's requirements.
- Re-evaluate and re-audit suppliers at defined intervals (based on risk and performance) to keep them on the ASL.

The raw materials themselves add another layer of complexity. Many of them:

- Have their own microbiological and chemical profiles (plate counts, yeast and mold, coliforms, pathogens, heavy metals, pesticides, residual solvents) with spec limits that differ by brand, product, and market.
- Require multiple CoAs and supporting documents – from raw material CoAs and identity tests to finished-product CoAs, plus Canada-specific analyses and special claim-related testing for Amazon or key retailers.
- Must be traced across RM lots, bulk blends, and finished-good lots, often through rework and quarantine pathways when something doesn't go as planned.

Before Unifize, verifying a single new raw material or raw-material lot could take about an hour. QA specialists had to pull documents from various shared folders, confirm specs in legacy PLM or PDFs, compare multiple CoAs, and check that everything matched the intended FPSP – usually managed via checklists in spreadsheets or personal notes. Small disconnects at this stage could ripple downstream into rejected lots, added testing, delays in release, or, worst-case, complaints in the field.

SECTION 3.4

Compliance & regulatory requirements

Adaptive's operational reality is shaped by multiple overlapping expectations:

- **21 CFR Part 111** for dietary supplements, covering manufacturing, quality control, and documentation.
- **NSF and third-party audits**, ensuring that both Adaptive and Biovation maintain GMP-compliant processes and facilities.
- **Retailer and marketplace requirements** (e.g., major retailers and Amazon) around label claims, testing, and response to issues.
- **International variants** like Canada-specific test panels and labeling rules, which affect how specs are written and how CoAs are generated.

Each of these adds documentation and traceability load:

- Specs and MMFs must show exactly how a product is intended to be made and tested.
- NCs, deviations, OOSs, and complaints must demonstrate investigation, risk assessment, and appropriate action.
- Audits require evidence on demand, not a scramble to assemble binders and spreadsheets in the week before a visit.

With specs, lots, and quality events fragmented across tools, Adaptive was spending too much time stitching together the story after the fact, and not enough time proactively managing quality.

SECTION 3.5

What the data revealed: recurring non-conformances and root causes

Once Adaptive and Biovation began analyzing their NC data more systematically, a clear pattern emerged: the issues weren't random; they clustered around a few repeatable failure modes with systemic root causes.

Typical non-conformances

Across brands, sites, and SKUs, most non-conformances fell into four main categories:



Lot number & traceability errors (most frequent)

- Incorrect lot numbers used during production
- Lot numbers changed after paperwork was initiated
- Product run under the wrong lot
- Mismatch between component lot and finished-good lot

This was the single most common NC theme and appeared in raw materials, WIP, and finished goods. It pointed to traceability and execution gaps in how lots were issued, recorded, and linked to specs and paperwork.



Labeling & packaging mismatches

- Label on box not matching product inside
- Incorrect packaging configuration
- Wrong product packed into the correct box (or vice versa)
- Packaging component issues tied to specific SKUs

These issues directly affect customer safety, regulatory compliance, and recall risk. The fact that they appeared across multiple SKUs showed they were process issues, not isolated product quirks.



Raw material / component issues

- Use of expired raw materials
- Incorrect ingredient issued to a batch
- Material identity issues (e.g., MCC, silica, rice flour)

Many NCs were literally named after specific ingredients, signaling failures upstream of manufacturing-in the warehouse, during issuing, or in material control-rather than just on the line.



Weight, fill, and specification deviations

- Low tablet weights
- Fill inconsistencies
- Product not meeting declared specification

These occurred less frequently than lot or labeling issues but carried higher product-quality and regulatory risk when they did appear.

Common root causes

When root-cause data was normalized (e.g., “Process failure” vs “Process Failure/Breakdown”), several drivers showed up again and again:



Expired materials (top root cause)

- FEFO not consistently enforced
- Weak expiry controls at issuance
- Limited system/physical checks before use

This was strongly correlated with raw-material NCs and repeated across different materials-clearly a systemic inventory and issuance control issue, not a single vendor problem.



Process failures / breakdowns

- Steps skipped or executed out of order
- Controls not embedded in workflows
- Reliance on human memory instead of enforced checks

Here, the process technically existed, but it wasn't robust against human error. The system design was contributing to mistakes.



Documentation & revision-control gaps

- Obsolete revisions in use
- Documentation errors or incomplete paperwork
- Operators working from outdated or ambiguous instructions

This reflected change-management and document-control weaknesses-exactly the sort of failures that fragmented PLM/EQMS and shared drives tend to produce.



Contamination-related causes

- Cross-contamination
- Handling or environmental control issues

These were less frequent but high severity, pointing to opportunities in segregation, cleaning validation, and handling SOPs.



Operator error (surprisingly less common)

Importantly, “operator error” appeared less often than process failure in the data. That distinction matters: it suggested that the system and workflows, not the people, were the main contributors to errors.

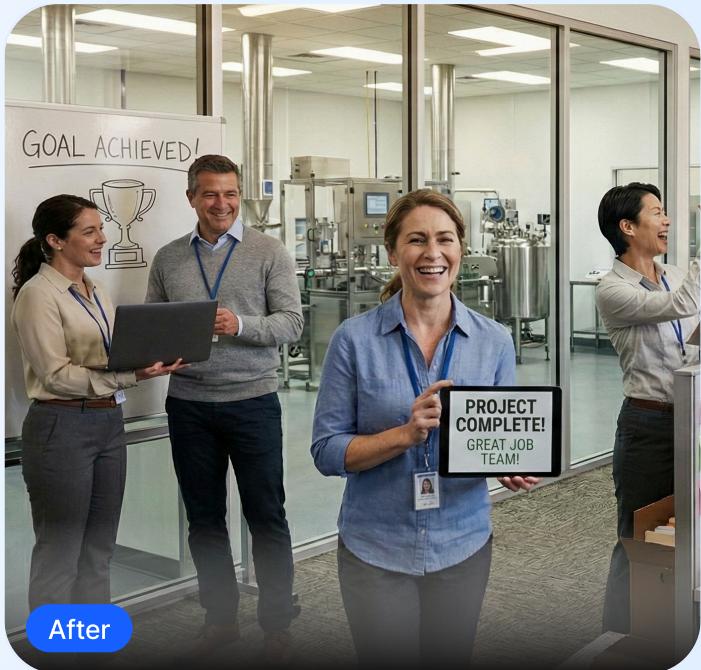
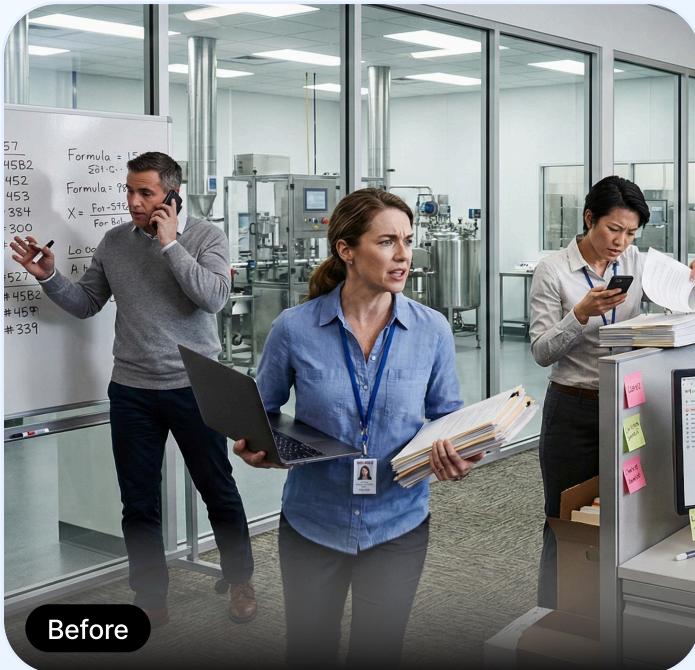
At a high level, the NC data told a consistent story:

- The most common issue type was lot number and traceability failures.
- The dominant root cause mix was expired materials plus weak process controls.
- System/process issues outweighed individual mistakes.
- Risk was concentrated in labeling, traceability, and material control.

In other words, Adaptive didn’t have a random quality problem. It had repeatable, process-driven issues that would never be fixed by retraining alone. They needed stronger lot enforcement and validation, expiry-aware issuance, embedded document-revision checks, and robust packaging/label verification gates-exactly the kinds of controls that a connected platform like Unifize could support.

SECTION 4

Challenges and solutions



Fragmented systems → One unified PLM + QMS backbone

Challenge (Before)

Adaptive was effectively operating in a maze of disconnected tools:

- Specs in a legacy PLM/EQMS (e.g., MasterControl) or in scattered documents.
- Lots and batch information in ERP and CM systems.
- Quality events (NCs, deviations, OOSs, complaints) tracked in separate EQMS tools, spreadsheets, or email.

Every part of the product lifecycle had its own “home,” but none of those homes talked to each other.

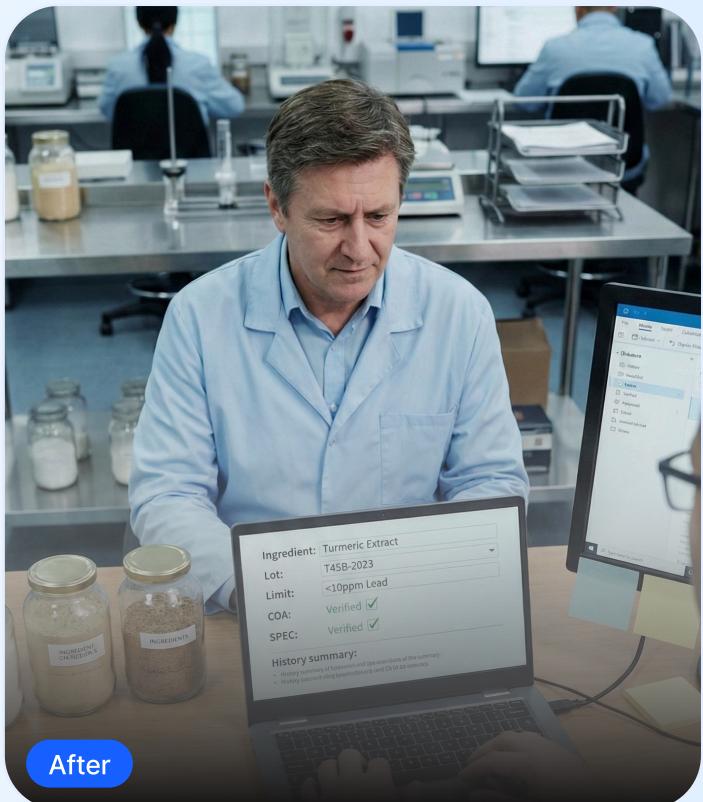
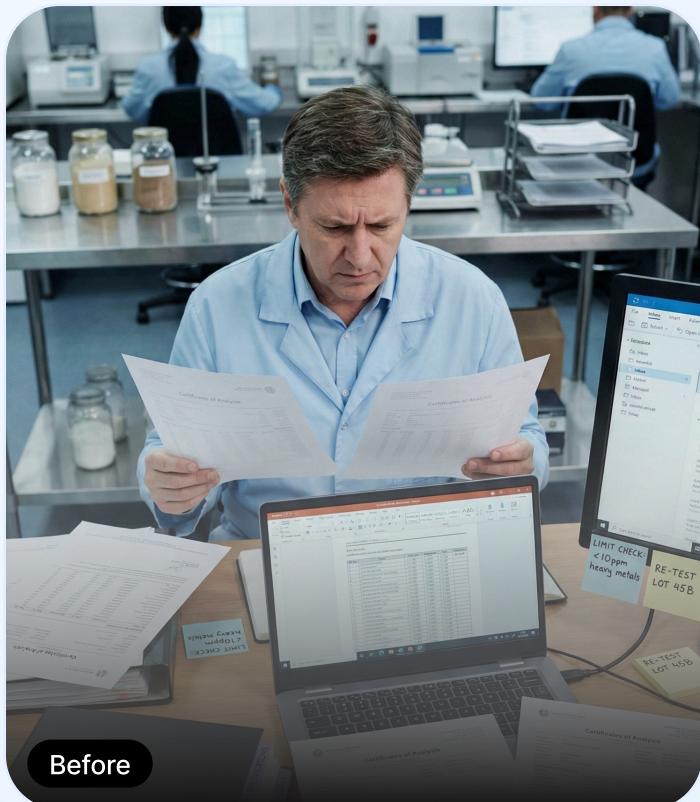
Someone investigating a lot issue might have to open half a dozen systems to answer basic questions about the spec, the ingredients, the CoAs, and any prior complaints.

Solution (After)

Unifize became the single connected platform spanning PLM, QMS, MES-adjacent lot tracking, supplier quality, and CMMS.

- FPSP records now hold the canonical finished-product spec and connect to MMFs, ingredients, packaging, artwork, and CoA outputs.
- NC, deviation, OOS, complaint, CAPA, audit, and supplier records all live in the same environment, linked directly to the products and lots they affect.
- RM, Bulk, FG, and packaging lots provide a unified genealogy from ingredient to finished bottle.

Instead of assembling the big picture manually, Adaptive can now see it on a single screen.



Slow ingredient verification → Checklist-driven single source of truth

Challenge (Before)

Ingredient verification was a heavy, repetitive task. QA specialists had to:

- Locate the right spec and limits (sometimes in PDFs, sometimes in legacy systems).
- Pull CoAs, micro/chemical panels, and supporting documents from different folders or emails.
- Cross-check everything manually to confirm that an ingredient or lot could be used.

Each verification could take around an hour, and the risk of overlooking a mismatch was real.

Solution (After)

In Unifize, ingredient verification became a structured, checklist-driven workflow:

- Ingredient and RM lot records are tied directly to FPSPs and active-ingredient analyses.
- QA sees the expected limits, required documents, and past history in one place.
- Verification steps are captured in a repeatable checklist, with required fields and attachments.

QA specialists report cutting ingredient verification time roughly in half - from about an hour to well under thirty minutes - while gaining more confidence that everything has been checked and documented properly.



Before



After



Lot-release delays and high testing costs → [Connected specs, lots, and testing](#)

Challenge (Before)

Lot release at the manufacturing site often required:

- Gathering test results from labs.
- Manually matching them to specs and acceptance criteria.
- Chasing approvals across email and meetings.

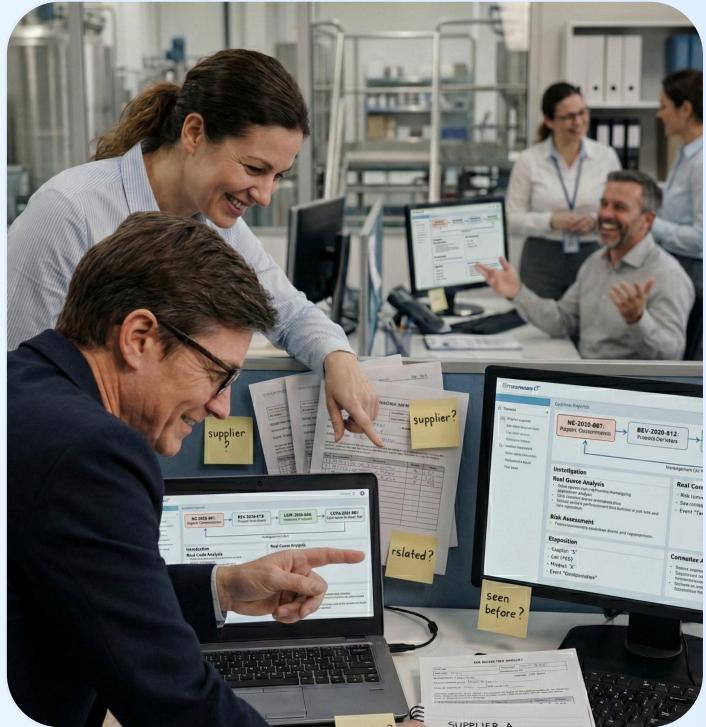
The process could stretch over days, which in turn drove up inventory carrying costs and led to more retesting “just to be sure”, contributing to monthly testing costs at Biovation of around \$146k.

Solution (After)

Unifize connected the dots between specs, lots, and test results:

- Each FG Lot or bulk lot is linked to its FPSP, MMF, and required tests.
- OOS records, NCs, and deviations link directly to the affected lots and tests.
- Lot-release approvals are routed through Unifize, with all data and documents visible in one place.

As a result, lot-release cycle time has fallen from days to minutes for many batches, and monthly testing costs have been reduced by around 50% (from roughly \$146k to \$65k) as redundant or low-value tests are eliminated.



Disconnected quality events → Closed-loop NC, deviation, OOS, complaint & CAPA

Challenge (Before)

NCs, deviations, OOSs, and complaints lived in different tools and formats. There was no simple way to see:

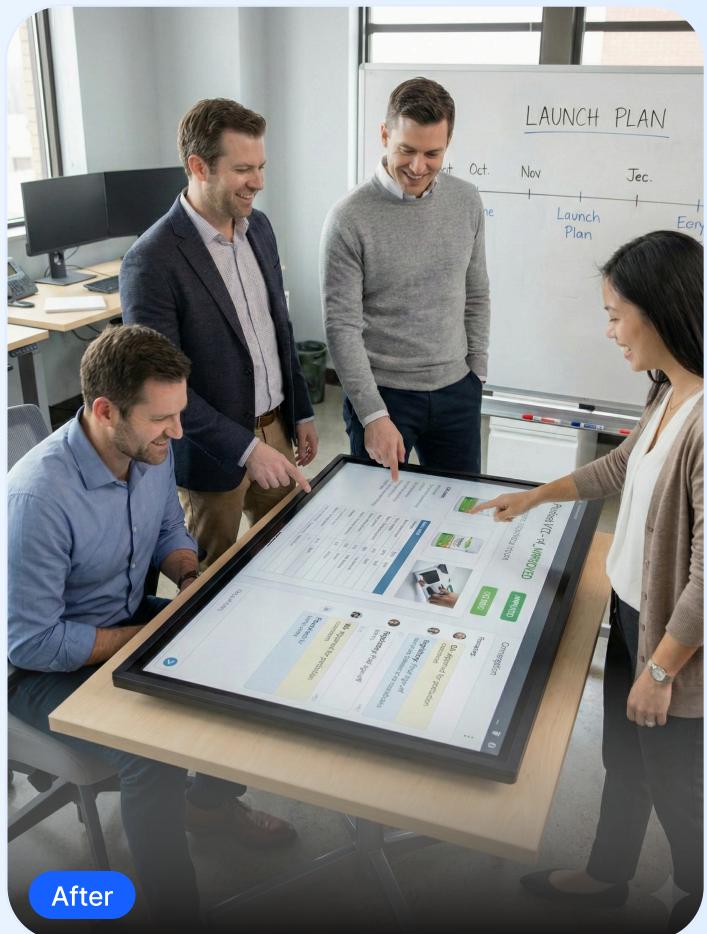
- Whether a complaint trend was connected to a specific supplier or batch behavior.
- Whether a recurring deviation should trigger a CAPA.
- How an ingredient issue at a supplier propagated into finished products.

Solution (After)

Unifize treats these events as part of a connected quality loop:

- NCs capture any out-of-expectation event, with structured sections for problem statement, investigation, root cause, risk assessment, disposition, and cost of poor quality.
- Deviations cover intentional departures from standard instructions (e.g., temporary process changes), tied back to MMFs, FPSPs, and lots.
- OOS manages analytical test failures, linked to RM, Bulk, FG lots and specs.
- Complaints consolidate consumer and retailer feedback by brand, SKU, and type.
- CAPAs can be spawned from any of these records and tracked through to completion, with links back to CoPQ and trends.

This creates a digital thread where a single complaint can be traced back to affected lots, underlying deviations, supplier issues, and, ultimately, improvements that prevent recurrence.



Email-driven collaboration → Conversation-first workflows

Challenge (Before)

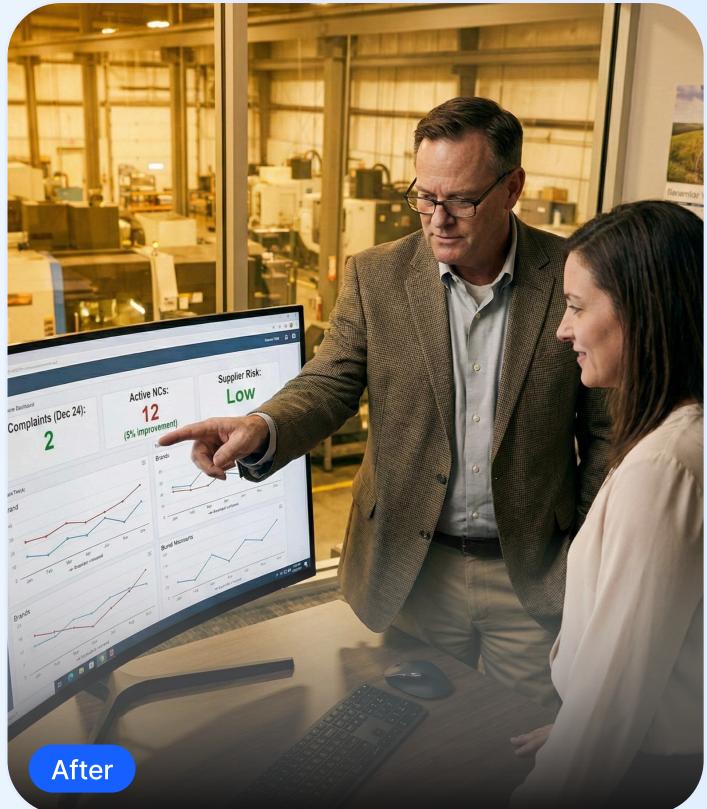
Product development and quality collaboration relied heavily on email, meetings, and manually maintained trackers. Every new product or issue kicked off long threads involving PD, QA, Legal, Marketing, retail account teams, and multiple CMs. Version control was fragile; it was easy for someone to be working off an outdated spec, slide deck, or label draft.

Solution (After)

Unifize became the shared workspace for each product, lot, and quality event:

- Each FPSP, NC, deviation, complaint, or CAPA has an associated conversation where stakeholders collaborate in real time.
- Approvals, decisions, and clarifications stay attached to the record they affect.
- New stakeholders (e.g., a retailer quality contact or external CM) can be looped in via email integration without leaving the system.

This shifts work from scattered inboxes into transparent, structured threads where ownership and next steps are clear.



Manual reporting & limited visibility → Live dashboards across brands and sites

Challenge (Before)

Leadership and QA had to rely on ad-hoc reporting to understand what was happening:

- Complaint rates by brand or SKU.
- Trends in deviations, NCs, or OOSs.
- Supplier performance and audit status.

Reports were built manually for QBRs or audits and quickly went out of date.

Solution (After)

Unifize provides role-specific dashboards for:

- Complaints by product, type, and status.
- Deviations and NCs by stage, owner, and monthly trend.
- Supplier audits and SCARs by owner and status.
- RM, Bulk, FG, and packaging lots by volume and release status.
- Preventive maintenance tasks and equipment status.

Rather than waiting for someone to "pull a report," leadership can open a dashboard and see how Adaptive and Biovation are performing, in near real time.

SECTION 5

Adaptive Health's connected quality workflows in Unifize

Once Adaptive Health consolidated their fragmented processes into Unifize, the real transformation was in how day-to-day work happens.



SECTION 5.1

FPSP-centric spec and product lifecycle

At the heart of the system is the Finished Product Specification Packet (FPSP), which acts as the PLM hub for each product.

Each FPSP captures:

- Product details: brand, SKUs, dosage form, regions, and customer/CM context.
- Full release spec: physical, dimensional, microbiological, and chemical criteria specific to the dosage form and market.
- Links to MMF/MMR, ingredient records, packaging BOMs, and artwork.
- Lot-code formats and traceability rules.

From each FPSP, Unifize can generate:

- Market-specific spec reports (e.g., US, Canada, GNC variants).
- CoA templates and final CoA PDFs tied to actual test results.

The FPSP workflow manages statuses from Draft to “FG Specs Approved” to Released, with a multi-site approval stack (Biovation QA, Adaptive QA, and other brand quality leads). Nothing moves forward until all required stakeholders have signed off – reducing the risk of misaligned expectations between brand and manufacturer.

Team	Status	Checklist	Deleted Fields	Privacy Settings	Advanced Process Settings	Reminders	Layout	Notification Settings
	1	Section	Basic Info					
	2	Linked Field	Customer(s)/Site(s)					
	3	Linked Field	Contract Manufacturer					
	4	Picklist	Is the product subcontracted?					
	5	Linked Field	Subcontractor (i.e., Blend/Stick Pack Manufacturer, Packager)					
	6	Linked Field	Product Name(s)					
	7	Text	Product SKU(s)/Code(s)					
	8	Picklist	Brand(s)					



SECTION 5.2

Managing NCs, deviations, OOS, and CAPAs

Unifize's QMS workflows give Adaptive a consistent, traceable way to manage quality events.

Non-Conformance (NC)

- Single record type for any out-of-expectation event affecting finished products, bulk, RM lots, packaging, specs, or artwork.
- Structured investigation sections capture the who/what/where/when, immediate actions, root cause analysis, risk assessment, and disposition.
- CoPQ fields record units scrapped and cost, giving leadership visibility into where quality issues are most expensive.
- Multi-level approvals ensure that both manufacturing and Adaptive QA sign off before closure.

Deviation

- Used for planned or unplanned departures from standard processes (e.g., alternate equipment, temporary formula adjustments, batch size changes).
- Links to FPSPs, MMFs, lots, and customers/brands, so the impact is clear.
- Routinely used, with hundreds of records in exports, indicating that deviations are managed as part of everyday control, not as rare exceptions.

OOS

- Tracks test failures or borderline results, linked to RM, Bulk, and FG Lots and their FPSP release criteria.
- Integrates tightly with NC and Deviation via "Related OOS" and "Related NCs" fields.

BASIC INFO

PRODUCT/COMPONENT DETAILS

Product

#389: NV - Super Beta Prostate (NV-SBP)

+ Add Product

Bulk Lot

#1466: NV-SBP Bulk Lot #BIO3021, BIO3020

#1827: NV-SBP Bulk Lot #BIO4249, BIO4250

#1994: NV-SBP Bulk Lot #BIO4979, BIO4980

+ Add Bulk Lot

FG Lot

#4907: NV - Super Beta Prostate 60ct Amazon - 24ct/3pk Ma...

+ Add FG Lot

NON-CONFORMANCE DETAILS

INVESTIGATION

ROOT CAUSE

INITIAL ASSESSMENT OF PRODUCT IMPACT

RISK ASSESSMENT

DISPOSITION

INITIATE REWORK

CAPA(S)

APPROVAL(S)

GENERATE PDF REPORT

RELATED TASK(S)

RELATED RECORD(S)

Complaints & CAPA

- Complaints are logged by brand/SKU and type, e.g., packaging damage, count discrepancies, odor issues. Dashboards show trends and completion metrics over time.
- CAPAs consolidate systemic fixes for recurring formulation, packaging, or process issues, and can be initiated from NCs, deviations, OOSs, Complaints, or audits.

Together, these workflows create a tight loop where every event is investigated consistently, linked to the right specs and lots, and, when necessary, tied into a CAPA that drives lasting change.



SECTION 5.3

Lot genealogy, supplier quality, and preventive maintenance

Unifize also acts as a lightweight MES and supplier-quality system:

- RM, Bulk, FG, and Packaging Lots capture the flow of material from raw ingredients through bulk blends, finished goods, and packaging runs, including rework, quarantine, and inventory adjustments where needed.
- Lots are directly linked into NC, OOS, Deviation, Complaint, FPSP, and MMF records, creating a complete genealogy for each finished bottle on a shelf.
- Supplier and Supplier Lot records bring in vendor performance, audits, and SCARs, tying supplier behavior directly to ingredient and product quality.
- Preventive Maintenance, Equipment, and Machinery modules track planned maintenance tasks and asset status, with dashboards showing tasks completed by month and pending work by technician, supporting reliable operation of blending, encapsulation, tablet presses, and packaging equipment.

This means that a trend in a particular failure mode can be explored from multiple angles, supplier lot, equipment performance, process deviations, within the same system.

Team	Status	Checklist	Deleted Fields	Privacy Settings	Advanced Process Settings	Reminders	Layout	Notification Settings
	29	Section	Batch Record(s)					
	30	File Upload	Blending Batch Record					
	31	File Upload	Encap/Tab Batch Record					
	32	Section	Planned FG Lot(s)					
	33	Child Conversation	Planned FG Lot(s)					
	34	Section	COA					
	35	File Upload	Bulk Lot COA					

[+ Add Fields](#)



SECTION 5.4

Dashboards & real-time visibility

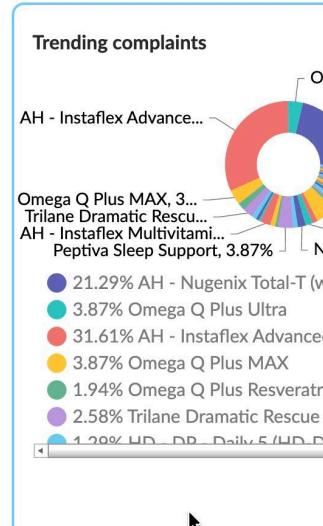
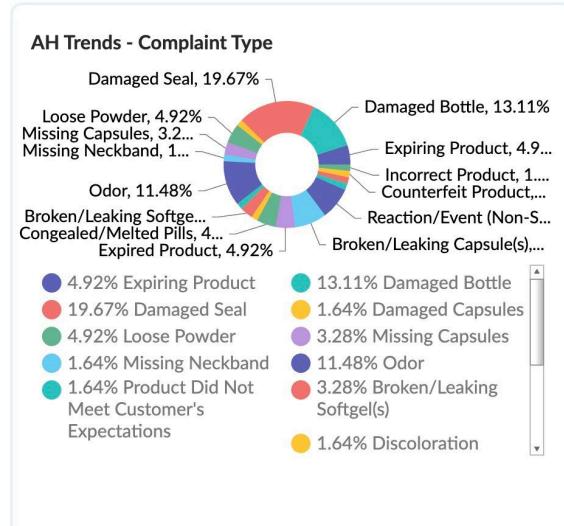
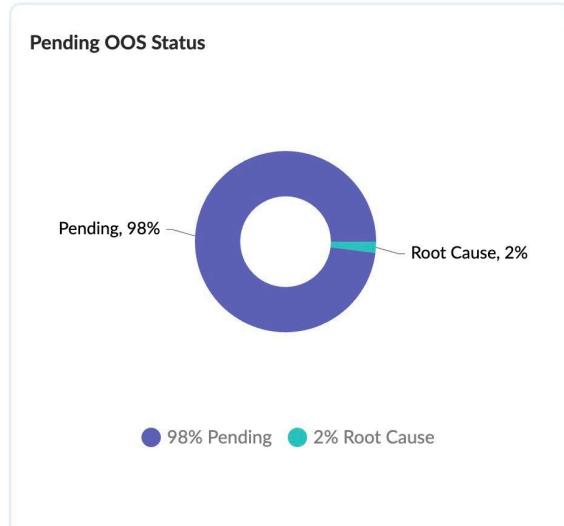
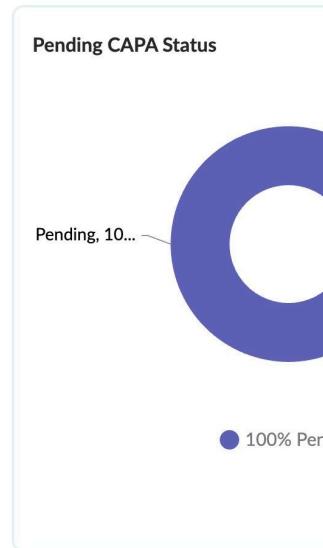
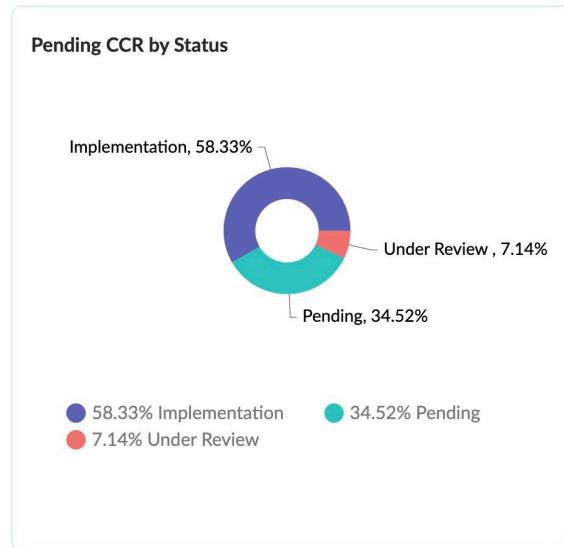
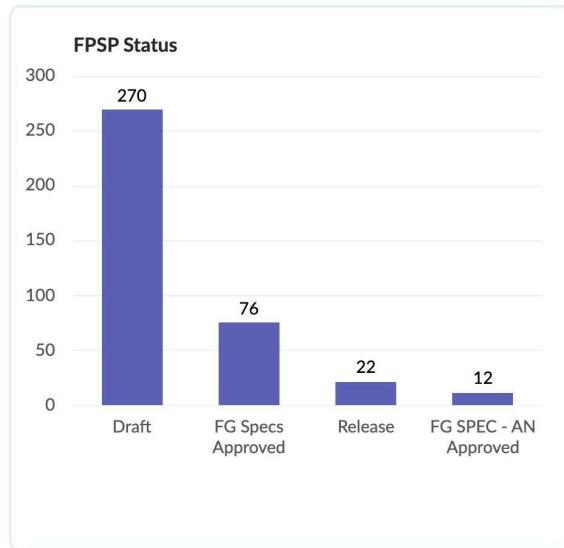
Finally, Unifize's dashboards give Adaptive a real-time operational view:

- **Complaint dashboards** show counts by brand, type, and status, plus completeness metrics.
- **Quality event dashboards** track NCs, deviations, OOSs, MMFs, CAPAs, and trends across months.
- **Supplier dashboards** highlight audits, SCARs, and ingredient volumes.
- **Lot dashboards** show the pace of RM, Bulk, FG, and Packaging lot creation and release.
- **PM dashboards** summarize maintenance activity and upcoming tasks.

For Adaptive, this has shifted leadership conversations from “Can someone pull these numbers?” to “What are this month’s trends telling us, and what should we change?”

Adaptive Health Dashboard

Created by: Mikala Hukka



SECTION 6

Implementation journey

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



Mapped processes across brand and manufacturing teams

The project began by mapping how specs, lots, quality events, and complaints actually flowed across Adaptive, Biovation, and other CMs. This surfaced where steps were duplicated, where information dropped between systems, and which processes created the most friction.



Stood up FPSP and core spec control

FPSPs, MMFs, and ingredient specs were configured as the backbone of the PLM layer. Initial work focused on flagship brands like Nugenix and Instaflex, ensuring that each had a clean, connected spec with the right tests, limits, and outputs.



Migrated existing specs and key historical lots

Legacy specs and active SKUs were imported into Unifize, along with enough lot history to support traceability and trend analysis. This gave teams immediate value in investigations without waiting for "only new data" to accumulate.



Implemented NC, Deviation, OOS, and Complaint workflows

The core QMS workflows were stood up and tuned to match Adaptive's investigation styles, risk assessments, and approval chains. Dashboards for NCs and complaints provided early visibility for QA leadership.



Extended coverage to lots and supplier quality

RM, Bulk, FG, and Packaging Lots, plus Supplier and Supplier Lot records, were added to create end-to-end genealogy and supplier traceability. Supplier audits and SCARs were tied directly into NCs and OOS records.



Rolled out Preventive Maintenance and CMMS

Preventive Maintenance, Machinery/Asset, and related dashboards were brought online for critical equipment, ensuring that mechanical reliability could be managed in the same platform as quality and specs.



Onboarded cross-functional teams

Product Development, QA, manufacturing QA, Regulatory/Legal, Marketing, and supplier quality teams were trained on Unifize, with each role using a tailored set of processes and dashboards. Over time, these became the default place where work happens rather than an “extra system” to update.



Scaled to broader portfolio and deeper MES-adjacent use

Once core brands were stable, additional brands (Peptiva, Super Beta Prostate, Dr. Sinatra, etc.) were brought onto the platform. Lot tracking expanded to cover more SKUs, including rework and quarantine pathways, so that investigations could rely on complete genealogy.



Standardized templates and PDF outputs across brands

FPSP templates, spec PDFs, and CoA outputs were harmonized across brands and markets, reducing redundant work and ensuring a consistent standard of documentation.



Embedded CoPQ and CI practices

NCs began capturing CoPQ data more systematically, and CAPAs were prioritized based on cost and risk impact. Unifize’s dashboards and CoPQ fields laid the groundwork for a more formal continuous improvement program.



Shifted to a continuous improvement mindset

With processes stabilized and data flowing, Adaptive Health moved to using Unifize as a platform for ongoing improvement, refining templates, adding new dashboards, and exploring deeper analytics rather than just “keeping the lights on.”

SECTION 7

Results achieved

Across the Adaptive–Biovation ecosystem, Unifize has driven large, quantifiable improvements in core quality workflows:

Outcome / Workflow	Before Unifize	After Unifize	Impact
Overall quality process cycle times	 Many quality workflows (NCs, change requests, approvals, lot review) could stretch over days or weeks, with work scattered across email, shared drives, and multiple systems.	 Turnaround time on most quality processes reduced by ~25–75%, depending on the workflow.	Faster decisions and fewer bottlenecks across the board.
Finished-good lot release	 Finished-good lots often took half a day to work through release checks, documentation and approvals.	 Finished-good lot review and release now typically takes around 10 minutes once test data are in.	From ~4 hours to ~10 minutes for a standard FG lot.
Quality headcount capacity	 Multiple QA personnel were tied up moving paperwork, chasing approvals, and reconciling data between systems.	 The efficiency gain from Unifize has effectively freed up the equivalent of 2–4 QA FTEs worth of capacity.	Same team, significantly more throughput.
Non-conformance resolution	 NCs could take days to weeks to fully document, investigate, and close, especially when root causes crossed sites or suppliers.	 Typical NCs now move from initiation to closure in hours, with all links (raw materials, BoMs, proofs, lots) in a single record.	From days/weeks to hours for most NCs.

Outcome / Workflow	Before Unifize	After Unifize	Impact
Quarantine time for quality issues	👎 Product involved in OOS or NC events might sit in quarantine for a month, tying up inventory and delaying shipments.	👍 With linked NC/OOS workflows and faster investigations, many of these holds are cleared in hours, avoiding backorders.	Quarantine reduced from ~1 month to hours in typical cases.
Documentation & raw material verification	👎 Reviewing documents for a single new raw material (CoAs, specs, supporting docs) could take about an hour, hunting through multiple folders and systems.	👍 Tailored, checklist-like workflows in Unifize have cut that time by half or more for the same level of diligence.	~50%+ faster document and raw material review.
Testing cost at Biovation	👎 Biovation's monthly testing spend sat at roughly \$146k/month, driven partly by over-testing and manual decisions.	👍 Using Unifize data to tighten test strategies and release logic helped reduce that to around \$65k/month in two months.	~50% reduction in monthly testing cost.

SECTION 7.2

How the team actually works differently now

Beyond raw numbers, Unifize has changed what a “normal day” looks like for the Adaptive–Biovation quality and product teams.



Unifize as the primary workspace for quality and PD

For leaders like Mikala, Unifize has effectively become the home base for her job. Roughly 80% of her day now runs inside Unifize – reviewing NCs, approving change requests, signing off on updated packaging specs, SOPs, and billing records, all from one place. Email, Slack, and Teams are still there, but they’re supporting tools, not the system of record.

That shift pulls decision-making out of inboxes and into traceable workflows that can be audited.



Faster, more reliable approvals and prioritization

Approvals no longer depend on “Did you happen to see that email?”:

- Approvers see their outstanding tasks directly in Unifize, not buried under unrelated messages.
- Urgent requests (like a finished-good lot needed for an urgent shipment) can be flagged and turned around in ~15 minutes, as long as the supporting data are in place.
- Because approvals happen next to the data (specs, lots, documents), there's less room for “I didn't realize what I was approving” and fewer missed steps.

In practical terms, that means less firefighting and fewer late surprises for the fulfillment center and retail partners.



Accountability and compliance embedded in the system

Requests for quote, commercialization quotes, spec changes, and document revisions used to live in one-off emails. If the key person was out or left the company, context went with them.

Now, all of that is captured as tickets and workflows in Unifize:

- RFQ and commercialization decisions are visible to all relevant parties with access.
- If something in a quote is incorrect, the change is made in the system, with a revision history, not buried in a reply-all thread.
- Access is controlled by user role, and every change has an audit trail.

This brings accountability and compliance into the fabric of the system itself rather than relying on tribal knowledge.

SECTION 7.3

Recall readiness & mock recalls

As the Adaptive–Biovation team matured its quality system, mock recalls became a key way to test whether all this data and process rigor would actually stand up under pressure. Those drills revealed that Unifize wasn't just helping with day-to-day tasks; it was materially improving recall readiness.



Lot-based product traceability recalls

Most mock recalls focus on finished-good, lot-level traceability – the same way a real recall would start.

Typical scenario:

- Start from a specific finished-good lot.
- Use Unifize to trace back to:
 - The precise FG lot number and all associated records
 - The bulk / WIP lots that fed it
 - The raw material or packaging lots involved
- Then trace forward to:
 - Production records (who made it, when, under which instructions)
 - Distribution records (which customers/channels received it)
 - Quantity reconciliation (how much was made, how much shipped, how much remains on hand)

Because NCs, OOSs, deviations, and mock recalls are all linked to RM, bulk, and FG lots inside Unifize, these exercises mirror the actual non-conformance profile the data had already shown: lot number issues, traceability gaps, and documentation inconsistencies.

The positive signal: mock recalls are designed around real risk areas, not artificial “textbook” scenarios.



Raw material → finished product trace exercises

Another common drill flips the problem: start at the raw material and work forward.

Typical scenario:

- Pick a raw material or component (often one with a history of NCs or a critical supplier).
- Ask: for this specific RM lot:
 - Which bulk lots did it feed?
 - Which finished-good lots did those bulks become?
 - Where were those finished goods distributed?

This puts real pressure on:

- The Approved Supplier List (ASL) and supplier records
- Raw-material receiving, lot assignment, and expiration controls
- Lot genealogy across RM → bulk → FG

The pattern across these drills: Adaptive is very aware that supplier or raw-material issues are a primary recall risk, and they practice exactly those traceability questions Unifize is built to answer.



Documentation-driven recall execution

Finally, mock recalls have highlighted how heavily the organization depends on documentation quality and accessibility:

- Batch records
- Lot genealogy and NC/OOS records
- Distribution logs and customer/channel mapping

In earlier days, success or failure in a mock recall hinged on how quickly people could hunt through paper, shared drives, and emails. Now, those same records are being pulled from Unifize:

- NCs and deviations are already linked to lots.
- CoAs, specs, and approvals sit on the relevant product/lot records.
- Distribution information can be filtered and exported directly from the same environment that holds the quality story.

The drills still rely on documentation – as they should – but they no longer depend on heroics and ad-hoc searches. Instead, they validate that the systematic links between specs, raw materials, batches, NCs, and customers are working as intended.

SECTION 8

Moving forward

Adaptive Health's work with Unifize is still evolving. They now have a robust, connected platform that ties together PLM, QMS, MES-adjacent lot tracking, supplier quality, and CMMS, but there is further upside.

1

Deeper MES and eBatch adoption

Extending beyond lot records into electronic batch records, travellers, and in-process checks for critical SKUs to further reduce paper and manual transcription.

2

Training automation

More tightly linking SOP revisions to training events, so that when specs or procedures change, affected users automatically receive and complete updated training in Unifize.

3

Supplier-quality deep dives

Building richer supplier scorecards, automating parts of incoming inspection, and exploring a vendor portal for more collaborative NC and SCAR management.

4

Continuous-improvement and CoPQ analytics

Using the CI module and CoPQ data to prioritize improvement projects, track ROI, and standardize how CAPAs are evaluated for impact.

5

Optional EHS and integration expansion

Bringing safety incidents and hazards into the same platform, and exploring integrations with ERP or DTC/CRM systems to further automate data flows.

Most importantly, the relationship between Adaptive, Biovation, and Unifize has shifted from "software project" to ongoing partnership. Unifize is no longer just the place where specs and records live; it's the operating system for how Adaptive brings products to market, manages risk, and continuously improves.

As Adaptive's portfolio and channels continue to grow, that connected foundation ensures that quality and compliance can keep pace - not as a drag on innovation, but as an enabler of faster, safer, and more confident product development.