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Scaling with Unifize

How RF Health Built A Scalable QMS And Freed 120+ Hours Annually

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> *"We needed a system that could grow with us. Unifize wasn't just a software switch; it was a strategic shift that gave us the operational maturity to go from an ambitious startup to a trusted VA supplier. It unified our processes and our people."*
>
> Jarod Markley
> Director of Quality & Regulatory Affairs, Recovery Force Health

EXECUTIVE SUMMARY

The Core Narrative

In the second quarter of 2024, Recovery Force (RF) Health, an innovator in therapeutic medical devices, achieved a landmark milestone: securing a near-$1 million contract with the Houston VA medical center. This commercial success highlighted not only the strength of their product portfolio but also their ability to meet the rigorous operational and regulatory expectations of large healthcare institutions.

Behind this achievement was a quiet but critical transformation. RF Health had state-of-the-art products, but their growth was being constrained by a fragmented and rigid quality management system (QMS). By replacing their siloed quality system with Unifize's unified platform, RF Health didn't just improve efficiency, they built the scalable, audit-proof foundation necessary to serve customers across both the private and government healthcare sectors.

The Key Pillars Of Transformation

- **Unified a "Franken-system"** of Greenlight Guru and Excel (RF Health's quality system was split between them) into a single source of truth for all quality and operational data.
- **Automated critical processes,** including calibration, maintenance, and training, eliminating manual tracking and reducing compliance risk.
- **Gained real-time visibility,** saving the Quality team an estimated 120+ hours annually by empowering field staff to log quality events directly.
- **Established an audit-ready,** scalable foundation that proved instrumental in securing a major government contract.

COMPANY BACKGROUND

Recovery Force Health

Based in Fishers, Indiana, Recovery Force Health is more than a medical device manufacturer; it's a company born from a personal mission to improve patient outcomes. The company's genesis traces back to 2013, when founder Matt Wyatt witnessed his father struggling with compliance issues related to the bulky, cumbersome pneumatic compression devices prescribed after bilateral knee surgery. This firsthand experience sparked a vision: to create a new generation of therapeutic technology that was not only effective but also patient-centric and data-driven.

The result was the MAC (Movement and Compression) System, a flagship product designed for the prevention of deep vein thrombosis (DVT). Unlike the decades-old predicate devices that cover a patient's entire lower leg, the MAC system offers a compact, modern design that promotes both mobility and compliance.

However, RF Health faced a significant market challenge: convincing a risk-averse healthcare industry to adopt new technology. To overcome this, they needed more than an innovative product; they needed to demonstrate unimpeachable operational excellence and a rock-solid quality system.

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OPERATIONAL REALITY

The Need for a Unified System

Before Unifize, RF Health's quality management was defined by fragmentation. The company operated a "Franken-system" where design controls lived in Greenlight Guru, while nearly every other critical process - quality events, complaints, calibration, maintenance, and supplier quality - was managed in a patchwork of Excel spreadsheets.

This Siloed Setup Created Constant Friction:

Manual hand-offs required re-entering data across tools, raising the risk of errors.

"Telephone-game" delays meant product issues from the field were filtered through multiple people before being logged.

Lack of visibility left leadership without a real-time, holistic view of quality and operational performance.

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At the same time, RF Health operated in one of the most demanding regulatory environments in healthcare. As a medical device innovator, it had to comply with:

- **FDA 510(k)** clearance pathways
- **ISO 13485** quality management standards
- **ISO 13485** quality management standards
- **HIPAA** safeguards for data management

For a small but fast-growing OEM, this combination of disconnected tools and stringent compliance obligations created a ceiling on growth. RF Health needed a system that could unify its operations, scale with its business, and provide the audit-ready foundation to earn the trust of hospitals and government healthcare providers alike.

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Key Challenges with Fragmented Systems

Despite having innovative products and a dedicated team, RF Health's operations were constrained by outdated, disconnected, and overly rigid systems. Several core challenges stood out:

Scalability Constraints

- Time that could have been spent on innovation was consumed by administrative rework.
- Disconnected tools made it difficult to scale operations and compliance in step with the company's growth ambitions.

Limited Participation Across Teams

- Only a small group of people could actively create or manage records. Field staff and sales reps (the ones closest to customers and product issues) had no direct way to log feedback, slowing down communication and responsiveness.

Heavy Administrative Burden

- Training required manual record creation, distribution, and tracking, often demanding the equivalent of a dedicated coordinator.
- Calibration, preventive maintenance, and supplier certifications were tracked through spreadsheets, Outlook reminders, or static file dumps, leaving little visibility or traceability.

Rigid, Inflexible Workflows

- Processes couldn't be adapted to fit the company's needs. Instead, teams had to adjust their ways of working to fit whatever the software allowed.
- Important context and metadata often had no place to live in the system, creating gaps and forcing manual workarounds.

Audit and Compliance Risks

- Critical records were scattered across different tools, making retrieval slow and unreliable during audits.
- Document updates weren't automatically linked to operational processes like inspections, increasing the risk of outdated information being used.

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CHOOSING UNIFIZE

A Strategic Shift

Recognizing that their current tools were limiting their potential, RF Health began the search for a new QMS. This was a strategic shift in their philosophy toward quality management, moving from a siloed function to an integrated, company-wide discipline.

Feature	Before: Greenlight Guru + Excel	After: Unifize Platform
User Access	Limited, seat-based licenses	Unlimited users for one price
Data Flow	Manual, fragmented, high risk of error	Unified, real-time, single source of truth
Process Scope	Primarily Design Control	End-to-end (QMS, DMS, CMMS)
Collaboration	Constrained to QA department	Extended to Ops, Field Reps, & Suppliers
Agility	Rigid, difficult to configure	Flexible, configurable by users

Unifize emerged as the clear choice for several key reasons:

1. **Collaboration Over Control:** The "unlimited users" model was a game-changer. It allowed RF Health to extend the QMS beyond the core quality team to operations staff and, crucially, to field representatives, without punitive licensing costs. This was a cultural enabler, not just a pricing benefit.

2. **Agility Over Rigidity:** In a bold move that demonstrated both their confidence and Unifize's flexibility, RF Health opted to "start in production" for their implementation. This allowed for faster feedback and real-world validation, a stark contrast to the rigid, lengthy rollouts typical of legacy systems.

3. **A True Partnership:** Unifize's 12-week implementation plan, which included unlimited support, positioned them as a partner invested in RF Health's success, not just a vendor selling a product.

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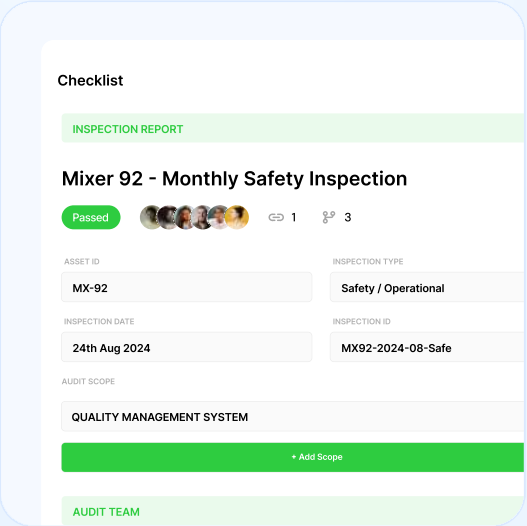
SOLUTIONS

Integrating Quality into Operations

With Unifize, RF Health systematically dismantled its operational silos and wove quality into the fabric of its daily work.

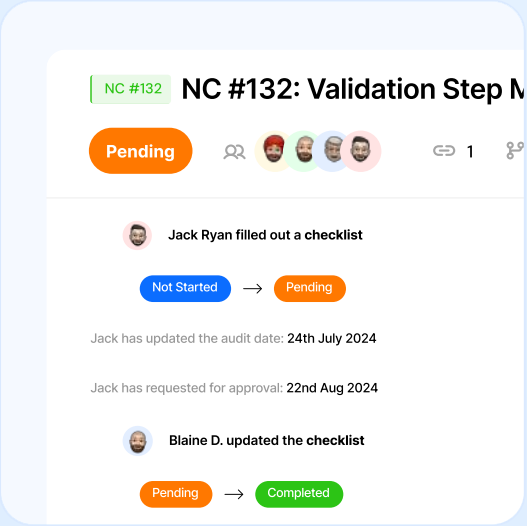


From Reactive Lists to Proactive Intelligence (Calibration & Maintenance):

The static Excel checklist for equipment management was replaced with a dynamic, living system. Every asset in Unifize now has a digital twin with its complete history, status, and linked certificates. Automation now auto-spawns preventive maintenance tasks from events like firmware changes, eliminating manual scheduling and ensuring constant compliance.

From Information Gatekeepers to Knowledge Enablers (Document Control & Training):

The QA team transformed from a bottleneck into an enabler. By integrating Unifize's version control with SharePoint's co-authoring capabilities, document collaboration became seamless. Crucially, automated training modules now push quizzes and refreshers with each document revision, creating a closed-loop system that ensures and documents competency across the organization.



From Lagging Data to Real-Time Feedback (Quality Events & Complaint Handling):

Perhaps the most significant transformation was closing the gap between the field and the factory. Field representatives are now empowered to raise non-conformances and complaints directly in Unifize from any device. This transforms quality from a backward-looking report into a real-time, forward-looking business intelligence stream, enabling faster resolutions and proactive improvements.

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Implementation Journey

RF Health's implementation was as agile as the system they chose. Foregoing a traditional sandbox approach, they opted to build directly in production, allowing for iterative design and rapid real-world testing. This bold strategy paid off, accelerating adoption and ensuring the final configuration was perfectly tuned to their needs.

Modules Implemented: Unifize became the central nervous system for virtually all GxP processes, including:

Live

- Quality Events (NCs, Deviations)
- CAPAs & Complaints
- Document Control & Training

Implementation

- Calibration & Maintenance
- Audits & Supplier Quality

Roadmap

- Incoming Inspections
- Design Controls

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Implementation Snapshot

Stage / Area	What Happens Today	Unifize Touch-points & 2025 Plan
Site & Routing	All production is carried out at a single plant located in Fishers, Indiana. Work orders follow a stepwise router process moving through stations numbered 10 to 90, covering build, test, final inspection, and pack-out.	The plan is to pull ERP-generated router data directly into Unifize. This will eliminate double entry and give the Quality team live visibility into each operation.
Material Flow & Incoming Checks	Raw materials such as textiles, foams, and PCBs arrive from approved vendors. Incoming inspection forms are filled out manually, scanned, and stored, with criteria varying by part number.	The manual Incoming Data Record (IDR) will be replaced with an electronic Incoming Inspection app within Unifize. This will automatically pull specifications and sample sizes, and automatically raise non-conformance reports when parts are out of tolerance.
Assembly & Calibration	Controllers are calibrated on a dedicated stand, and each unit generates approximately 24 calibration records before sleeve mating and packaging.	Calibration records are already stored in Unifize. The next step is to automatically link each record to its corresponding work order and asset to enable out-of-tolerance impact analysis.
Final Release & DHR	During pack-out, lot and serial numbers are created. The Device History Record (DHR) is manually compiled by combining labels, calibration certificates, router files, and inspection PDFs.	The 2025 objective is to automatically generate the DHR directly within Unifize, using data that is already captured in the system (such as router steps, test results, and labels).
Traceability & Maintenance	Finished-good lots and serial numbers, along with component and supplier lots, are stored in Unifize. Preventive maintenance tasks are automatically generated from the Equipment module.	The plan is to expand traceability by including router operations and incoming inspection lots, while also strengthening analytics for preventive maintenance.

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Outcomes & Measurable Impact

The shift to Unifize delivered immediate and measurable results, providing the credibility and operational proof needed to win major contracts.

Efficiency Gains

- The QA team is reclaiming ~30 hours per quarter by eliminating manual data entry and follow-ups.
- They’re also projecting a 75% reduction in time for handling field records, from 40 hours down to just 10.

Audit Readiness

- During a recent Intertek audit, the auditor praised the system's efficiency, noting the ability to retrieve any requested document instantly. What used to take hours of preparation now happens in real-time.

Adoption & Scalability

- With over 13,500 serial numbers tracked, Unifize is the system of record for production.
- Every employee is engaged in the platform, validating the power of the unlimited-user model.

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Deep Dive on Key Use Cases

Use Case	What Changed with Unifize	Impact
Calibration & Preventive Maintenance	Equipment records centralized with one-click access to full history, certificates, and upcoming tasks. Preventive maintenance auto-scheduled based on triggers like firmware updates.	Eliminated manual tracking, improved reliability, and ensured nothing slips through the cracks.
Document Management & Training	Document revisions auto-trigger training tasks and quizzes, with results auto-graded and stored in a permanent record.	Reduced administrative overhead, accelerated training compliance, and strengthened audit readiness.
Customer Feedback & Field Reporting	Sales reps can log complaints directly in the field via mobile, instantly notifying the quality team and linking to CAPAs or NCs.	Faster investigations, quicker resolution cycles, and stronger customer responsiveness.
Automated Device History Record (DHR)	All serial numbers, lot records, inspections, and quality events unified in one system, laying the foundation for automated DHRs.	Dramatically simplified compliance reporting and set the stage for fully automated DHR generation.

The Road Ahead

RF Health's journey with Unifize is ongoing, with a future roadmap focused on deeper integration and intelligence. The company plans to create seamless data flows with their ERP (Global Shop) and CRM (HubSpot) to achieve a truly unified enterprise data model. They will also expand the use of supplier quality data and shop-floor metrics to drive continuous improvement. Looking further ahead, RF Health is exploring future-facing technologies like AI/LLM for predictive trend detection, recommending CAPA actions, and even auto-generating training questions.

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Key Takeaways for Medical Device Innovators

Configurable Beats Turnkey

Manual hand-offs required re-entering data across tools, raising the risk of errors.

Unlimited Access is Non-Negotiable

A culture of quality is impossible when your software license model forces you to exclude most of your team.

Technology Should Drive Credibility

The goal is not just to be compliant, but to be audit-ready at all times. This builds the trust needed to win enterprise and government contracts.

Conclusion

Recovery Force Health's transformation is a powerful testament to the fact that the right technology can be a force multiplier for growth. By moving from a manual, rigid system to a connected and continuous one, they didn't just buy a QMS, they invested in a new operational paradigm. Unifize has become the enabler of their regulatory confidence, their operational excellence, and their ambitious future. Their story leaves the industry with a critical question:

"Imagine what your teams could achieve if everyone had access to quality."

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About Unifize

Unifize helps ISO and FDA-compliant companies manage risk, drive operational efficiency, and accelerate innovation by bringing quality, operations, and product development teams into a single source of truth that's easy to implement and adapt as business needs change.

We integrate the entire process lifecycle, unifying these teams and their conversations, documents, data and workflows into one, collaborative, cloud-based platform, which enables unprecedented visibility, traceability, accountability and process efficiency.

Want To See How Unifize Can Help Your Team Move Faster — And Stay Compliant? Let's Talk.

Book a Demo