

# **CASE STUDY**

# How a Global Pharma Leader Upgraded Its QMS in One Weekend



# **Table of Contents**

Introduction	3
The Starting Point: Fragmented Systems and Mounting Risks	4
Choosing the Right Partner: Why Quality Forward Was Selected	5
The Roadmap to Transformation: How We Rebuilt The Quality System	6
Results: A Seamless Transition With Real Business Impact	7
The Shift: How We Built a Culture of Quality	9
Leaders Set the Tone	10
Lessons Other Life Sciences Companies Can Learn From This Journey	12
Quality as a Growth Engine, Not a Checkbox	
About Quality Forward	14
Why Pharma Companies Choose Quality Forward	14
References	15

# Introduction

Life sciences companies are under more scrutiny than ever. Regulators, partners, and customers want proof that quality processes are not just in place but working properly. Teams must be able to show how decisions are made, how different departments stay aligned, and how they respond when something unexpected happens. One global pharmaceutical manufacturer with operations across Europe faced exactly this challenge.

For over a decade, the company had relied on a legacy, on-premise eQMS to manage critical quality processes across more than 30 sites. Initially, the system supported the company's needs. However, as the business expanded and regulatory expectations became more complex, cracks began to appear. The limitations of their ageing platform included an outdated user experience, difficult reporting, costly upgrades, and poor real-time visibility, all of which started to create operational risks.

Senior leadership recognised that their existing system could not support the company's next stage of growth. Upgrades were becoming more expensive and disruptive. Teams struggled to collaborate across sites. Configuration migrations required downtime. Quality operations were under strain, and preparing for inspections was growing harder, not easier.

To protect their reputation, regulatory standing, and future expansion plans, leadership made the decision to replace their legacy eQMS with a modern, cloud-based solution that could meet today's demands and prepare the company for tomorrow. They chose to partner with Quality Forward to make that transition happen, while preserving the critical data, workflows, and validated procedures they had spent years building.



## The Starting Point: Fragmented Systems and Mounting Risks

Before embarking on their transformation journey, the company's quality operations were managed through an onpremise eQMS that had been in place for more than a decade. The system was used across 30 sites to handle CAPAs, change controls, audits, complaints, supplier quality and other quality processes. While it had served its purpose in the early years, the system had become increasingly difficult to manage as the company grew.

The challenges were clear. The technology was outdated, making it difficult to create reports or support real-time collaboration between end users and developers. Migrations required scheduled downtime, which disrupted operations and created added pressure during critical periods. Upgrades were not only costly but also time consuming, requiring new servers to be installed and full system revalidation every two to three years.

68% of pharma companies say outdated systems slow down quality processes.<sup>1</sup>

On top of that, support fees were rising steadily. The cost of maintaining the system was no longer justifiable, and the value it delivered had started to decline. More importantly, teams were losing visibility into their quality operations. Investigations took longer to close, and reports became harder to produce.

Leadership recognised that the risks were no longer theoretical. If the company continued with its legacy system, the consequences could include slower product launches, missed inspection deadlines, and weakened supplier oversight with increasing eQMS IT costs...

At the same time, they were not looking to reinvent everything from scratch. Their existing workflows had been carefully built and validated to meet regulatory expectations. What they needed was a partner who could migrate their entire system into a modern, cloud-based eQMS without forcing widespread changes to their approved ways of working.

The vision was clear. A one-to-one migration that would protect what was already working while removing the friction, delays, and increasing costs of their legacy platform.

	Before (Legacy QMS)	After (Quality Forward QMS)
Reporting	Manual, slow, hard to customize	Real-time, visual dashboards
Upgrades	Costly, every 2–3 years	Automatic, cloud-native
Collaboration	Siloed, site-specific	Connected, cross-site in real time
Downtime	Required for migrations	None
Support Costs	Rising annually	60%+ lower with SaaS





## Choosing the Right Partner: Why Quality Forward Was Selected

The search for an eQMS partner was deliberate and carefully planned. The company needed more than a software provider. They needed a team that understood the realities of running quality operations inside a regulated pharmaceutical environment.

#### Several factors guided their selection:

#### Life sciences expertise

They needed a partner who already understood GMP expectations, regulatory compliance frameworks, and the practical challenges faced during inspections. They did not want to invest time teaching a vendor about industry standards. They were looking for someone who could immediately engage with their needs.

#### Ability to replicate existing workflows

With more than 30 validated workflows in use, the goal was not to redesign everything from scratch. They were determined to avoid massive changes that would disrupt daily operations. The new system had to replicate their existing processes closely, with only light adjustments where needed.

#### Data migration without compromise

Maintaining access to legacy data was a top priority. The company did not want their historical records archived in a separate, hard-to-reach location. They needed a solution that would bring all closed and open records into the new platform without losing visibility or creating unnecessary complexity.

#### User experience and training

The transition had to be as smooth as possible for end users. They understood that the less disruption to the user interface and business processes, the faster their teams would adapt. A familiar layout and intuitive navigation were important to keep momentum after the system went live.

#### Cost and time efficiency

They had no interest in a long, drawn-out project. They wanted a clear, efficient plan to complete the migration, validation, and go-live with minimal disruption to daily operations. Delays or complex customizations were not acceptable.

Quality Forward met these needs directly. Built on the ServiceNow platform, it combined modern technology, powerful configuration options, and a deep understanding of life sciences quality management. The team proposed a practical, phased approach that focused on preserving the client's validated state, ensuring real-time access to migrated records, and providing a seamless experience for users across all sites.

It was not just about replacing old software. They saw Quality Forward as the partner that could help them protect the guality standards they had built over decades, while making their systems stronger and easier to manage for the years ahead.





# The Roadmap to Transformation: How We Rebuilt The Quality System

The project was built around a simple principle: replicate the working procedures exactly, migrate all legacy data, and move onto a modern platform without causing disruption.

#### Together, we followed a clear, structured path to make that happen.

#### 1. Scoping and System Mapping

The first step was a full review of the existing eQMS setup. The project team mapped out over 30 workflows, covering CAPAs, change controls, audits, complaints, and supplier management. The goal was not to change processes but to make sure that each workflow could be mirrored inside the new system without needing major updates to validated procedures.

#### 2. Configuration and Validation

Quality Forward provided an out-of-the-box SaaS solution built on ServiceNow. Using no-code configuration tools, the platform was adjusted to match the exact working methods. Every adjustment was documented and validated in line with GxP best practices, providing a smooth and compliant transition from the on-premise system to the cloud-based eQMS.

#### 3. Closed Records Migration

The project prioritized closed records first. Because these records made up the bulk of their historical data, migrating them early reduced time pressure during the final cutover. Data mapping was carefully reviewed and corrected where needed. Validation activities were performed to check the accuracy and completeness of migrated information.

#### 4. Cutover Planning for Open Records

Open records, recently closed records, and any reopened records were scheduled for migration during the final cutover weekend. Separating this phase meant that the project minimized disruption to daily operations. Validation planning was adjusted accordingly: because closed record migration had already been validated thoroughly, a smaller sample size was required for the open record phase.

#### 5. Cutover Execution

Cutover was scheduled over a single long weekend.

- The old system was locked down on Friday afternoon.
- Open records and recently closed records were migrated immediately afterward.
- Validation checks, including quantity and quality reviews, were completed before users were given access to the new platform.
- User accounts and permissions were migrated just before the cutover to guarantee accuracy.

By Monday, core migration tasks were complete. By Tuesday noon, all users had full access to the new system.



#### 6. Training and Support

Training focused on practical skills. Because workflows stayed almost identical, users only needed to learn the new system's interface. Familiarity with processes made the learning curve much faster. Site champions were identified to support teams during the early days post-launch.

#### 7. Post-Go-Live Monitoring

After launch, both parties kept a close eye on system performance. Any small configuration updates were addressed quickly. Continuous monitoring helped to confirm that migrated records, audit trails, and attached files behaved as expected across all user groups.



### **Results: A Seamless Transition With Real Business Impact**

The migration to Quality Forward was a success across every major measure of quality, compliance, and operational continuity. Instead of disruption, the company achieved a smooth transition that protected the integrity of its historical data and strengthened its long-term compliance position. Some of the most important outcomes included:



#### 8

#### 1. Complete Data Migration With Integrity

All historical records, including over 400,000 quality records, 8 million audit trail records, and approximately 500,000 file attachments, were successfully migrated to the new SaaS-based system. No critical information was lost or degraded during the process. Past records remained easily accessible for daily operations and audits.

#### 2. No Changes to Workflows or System Configuration

The company was able to maintain its existing quality procedures without the need for major updates or revalidation. The familiar workflows, approval processes, and documentation structures were mirrored exactly in the new system, minimizing disruption to teams across all 30 sites.

#### 3. Zero Downtime to Core Quality Operations

The final cutover was completed over a three-day weekend, meaning only a single working day was affected. When the new system went live on Tuesday afternoon, more than 1,000 users were able to access and work within the system immediately, with only minor transition issues reported.

#### 4. Modern Cloud Technology

Having the QMS running on a modern cloud platform such as ServiceNow enables access to the latest technology advancements such as AI (Machine Learning, Generative AI, Agentic AI) & Process Mining. Also all automations are done immediately (with no need to wait 10-15 minutes as in on prem solutions). Cloud also enables better collaboration: Users can work in parallel in the same record and teams can make configuration changes in parallel to different business processes with no need for Team B to wait for Team A. User experience was improved e.g. users enjoy full visual display of all their business processes and where they are currently within the process.

#### 5. Fully Validated System for Regulatory Compliance

Every step of the migration, configuration, and cutover process was validated to meet stringent regulatory requirements, including GxP, FDA 21 CFR Part 11, and ISO standards. The Quality Forward system now provides the client with full traceability, audit readiness, and documentation control to support ongoing compliance across all global operations.

The migration was not just a technical project. It created a stronger, more resilient quality environment that protects their data, improves operational efficiency, and positions the company to adapt and grow without major system disruptions.

#### 6. Significant Cost Savings

Moving from a costly on-premise system to Quality Forward's SaaS model reduced the IT and maintenance costs by approximately 60%. In addition to lower operational costs, the company no longer faces expensive server upgrades, downtime for system migrations, or rising annual support fees. Cloud-based QMS platforms reduce total cost of ownership by 35–60% compared to on-premise systems<sup>2</sup>



### The Shift: How We Built a Culture of Quality

Improving systems is important. But the most meaningful and lasting change happens when quality becomes part of how people think, work, and solve problems together. For the client, adopting Quality Forward was not just a technical upgrade. It was the catalyst for building a stronger, more consistent culture of quality across the entire organisation.

# Quality Became Everyone's Responsibility

In the early stages of implementation, one of the biggest challenges was mindset. Historically, quality had been viewed as the responsibility of the QA department. Operators, engineers, and even supervisors often saw it as something external to



their day-to-day roles. It was common to hear phrases like "Quality will handle it" or "Let's wait for QA to review."

Moving to a connected, transparent eQMS changed that dynamic. For the first time, teams could see their actions linked directly to quality outcomes:

- When quality records were updated, the process owner, not just QA, was part of the investigation.
- When a supplier issue was flagged, purchasing and quality worked together to address it.
- When procedures were updated, operational teams had visibility into the changes and participated in retraining planning.

This visibility created ownership. People understood that their actions, small and large, contributed directly to audit readiness, product safety, and regulatory compliance. Quality was no longer something that happened after the work. It became part of how the work was done.

70% of successful digital quality transformations are directly linked to active executive involvement.<sup>3</sup>



## Leaders Set the Tone

Cultural change does not happen without leadership. From the beginning, the leadership team was actively involved in the rollout and adoption of Quality Forward. They did not just sponsor the project in name. They attended training sessions, participated in Management Review meetings, and reinforced the message that quality was a business priority, not a compliance burden.

#### Specific leadership actions made a measurable difference:

- Site directors requested regular updates on CAPA metrics and training completion rates, showing that these KPIs mattered at the highest levels.
- Department heads set the expectation that team members would engage fully with the system, not treat it as extra paperwork.
- Quality managers were empowered to raise issues proactively, and leadership responded with resources and support rather than delay or resistance.

These actions sent a clear message: using the system was not optional. It was part of working at the company.

#### Small Wins Created Momentum

One key lesson from the project was the importance of celebrating early wins. During the first three months after golive, they focused on achievable goals that would build trust and show the value of the system:

- A targeted effort to close open CAPAs faster than before, using the new system's streamlined workflows.
- A site-wide training update project that showed the benefits of automated assignments and tracking.
- A successful supplier audit where the team demonstrated real-time access to qualification records, impressing the auditor

Each of these wins was shared internally, at town halls, in newsletters, and during team meetings. Recognition was given not just to the quality team, but to cross-functional contributors who showed ownership of the process. These moments built pride and helped overcome early resistance.

#### **Communication Was Relentless and Practical**

Another important factor in shaping the culture was how communication was handled. Project leaders made a deliberate decision: no jargon, no vague slogans, and no top-down mandates without explanation.

#### Instead, communication focused on real, practical examples:

- How using the system properly would make inspections less stressful.
- How linking CAPAs to risks would make it easier to prioritise actions. ٠
- How completing tasks on time would reduce last-minute panic and audit findings.



11

Workshops were organised to walk teams through real-life scenarios. Short videos showed how to complete key tasks inside the system. Leaders consistently tied the benefits back to everyday work: fewer surprises, clearer responsibilities, better outcomes. Because communication stayed grounded and relevant, adoption grew steadily, and resistance shrank.

#### Accountability Without Blame

Perhaps the most powerful cultural change was how mistakes and gaps were handled. In the past, audit findings or missed deadlines sometimes triggered finger-pointing or defensive reactions. The focus was often on assigning blame rather than fixing the process.

With Quality Forward in place, they shifted toward a model of accountability without blame. The system made it easier to see where processes were breaking down:

- Were deviations logged but left open too long?
- Were document updates getting bottlenecked at approval stages?
- Were training assignments slipping through the cracks for certain teams?

When issues were identified, the conversation became about solving the problem, not blaming individuals. Root cause analysis was treated as a learning opportunity, not a punishment. Teams saw that quality gaps were viewed as system issues first, not personal failures.

This approach built trust. People felt safer raising concerns early, which meant problems were addressed faster, before they grew into audit findings or operational risks.

#### **Quality Became a Competitive Advantage**

#### As these cultural shifts took root, they began to notice secondary benefits that went beyond compliance:

- New product launches moved faster because quality processes were built into early project stages, not bolted on at the end.
- Supplier relationships improved, as they could demonstrate a stronger oversight process and clearer expectations.
- Recruitment and retention improved for quality roles, because new employees saw that quality was taken seriously, supported by real systems and leadership commitment.

In short, quality became part of the brand, internally and externally. Instead of being seen as a department or a cost centre, quality became an asset that supported business goals.



# Lessons Other Life Sciences Companies Can Learn From This Journey

The experience with Quality Forward was not unique because of their size or resources. It succeeded because of how they approached the change. Their journey offers important lessons for any life sciences company looking to strengthen their quality systems and culture.

Only about 20% of pharma and medtech companies have successfully transitioned from 'doing digital' to truly 'being digital.<sup>4</sup>

#### 1. System Changes Alone Are Not Enough

Installing a new system is relatively easy. Building new habits around that system is the real work. The client did not treat their eQMS launch as an IT project. From day one, it was positioned as a business improvement initiative. The conversation was not about learning new software, it was about building better ways of working. Companies that treat system changes as technical upgrades often miss this step. They focus on getting the platform live but fail to support the people using it. The lesson is clear: success comes when the system is woven into everyday routines, not layered on top of them.

#### 2. Leadership Visibility Changes Everything

At the company, quality leaders and senior executives did not disappear after the kickoff meetings. They stayed visible. They referenced the system in operational reviews. They asked for CAPA metrics. They requested training updates based on system data. Their constant attention sent a message that using Quality Forward properly was not optional, and it was not just a "QA thing." It was part of business performance.

Other companies can learn from this. Real culture change does not come from posters, slogans, or policy updates. It comes when senior leaders ask about quality in the same breath as revenue, production, or customer satisfaction.

#### 3. Small Early Wins Matter More Than Perfect Plans

The company did not wait for every module to be optimised before celebrating progress. They picked high-impact, achievable goals early on, closing CAPAs faster, updating training records more efficiently, demonstrating supplier oversight in an audit. These wins built belief in the system.

Perfection can be the enemy of momentum. Companies should look for areas where quick, visible improvements are possible. Each small win creates confidence. Each success story quiets resistance. Over time, those wins compound into real change.

#### 4. Practical Communication Beats Theoretical Messaging

Communication was grounded in real scenarios. No corporate jargon. No vague promises about "transformation." Instead, project leaders showed how using the system would solve everyday frustrations: fewer training headaches, faster investigations, easier audits.





#### 5. Accountability Must Be Paired with Psychological Safety

One of the boldest choices that was made was shifting how they handled mistakes. The goal was not to eliminate errors through fear. It was to surface them quickly so they could be fixed at the process level. Blame was removed from the equation.

This change encouraged openness. It made audits less stressful. It helped teams feel comfortable raising concerns without fear of being punished. Any company trying to strengthen quality culture must build this kind of environment, one where accountability is real, but psychological safety is stronger.

#### 6. Quality Is Not a Department, It Is a Business Strategy

This company showed that true quality is not a side function. It is a strategic advantage. Better quality systems reduced their time-to-market for new products. Improved supplier management strengthened their resilience against supply chain disruptions. Stronger training processes built a more skilled workforce.

When quality is embedded in every function, not just QA, business performance improves across the board. That lesson applies whether a company is small or global, new or established.

## Quality as a Growth Engine, Not a Checkbox

The migration to Quality Forward strengthened both their quality systems and their organisational culture, helping them operate with more structure, collaboration, and confidence.

They showed that real quality is about more than passing inspections or avoiding nonconformances. It is about building systems and habits that support stronger business outcomes over time. It is about creating an environment where doing the right thing is the easy thing.

Today, the teams are not preparing for audits at the last minute. They are inspection-ready every day. They are not rushing to track training or CAPAs across spreadsheets. They have realtime visibility into the health of their quality system. They are not reacting to issues after they explode. They are spotting risks early and addressing them proactively.

Only 23% of life sciences companies believe their QMS helps drive business performance.<sup>5</sup>

Most importantly, quality is not seen as extra work. It is seen as smart work. It is viewed as a tool to enable faster launches, safer products, and more efficient operations.

Quality Forward helped to unlock a new level of performance and confidence. That is the kind of transformation every life sciences company can aspire to and achieve with the right system, strong leadership, and a clear mindset.



# **About Quality Forward**

Quality Forward is a modern eQMS built specifically for regulated industries like pharmaceuticals, biotech, and medical devices. Unlike legacy systems that rely on outdated architecture and require constant IT upkeep, Quality Forward leverages the power of the ServiceNow platform to deliver a cloud-native, scalable, and easily configurable solution. Designed with the realities of GxP compliance, inspection readiness, and cross-functional collaboration in mind, Quality Forward enables quality teams to manage CAPAs, change controls, audits, complaints, training, supplier qualifications, and more—all within a unified, validated environment.

# Why Pharma Companies Choose Quality Forward

- No-Code Configuration: Maintain validated processes without starting from scratch. Make updates without developers or downtime.
- Fully Validated SaaS: Built to meet FDA 21 CFR Part 11, ISO 13485, and EU Annex 11 compliance requirements.
- Cost-Effective Deployment: Reduce total cost of ownership by up to 60% vs. legacy on-premise systems—no hidden fees, infrastructure, or drawn-out upgrades.
- Trusted by Regulated Industries: Chosen by pharmaceutical, biotech, and medtech companies who need proven compliance, not just software.
- True Cloud Benefits: Automatic updates, no server maintenance, and real-time collaboration across global teams.
- Migration Without Disruption: Preserve existing data and workflows with zero loss and minimal retraining.
- Inspection-Ready Every Day: Real-time dashboards, audit trails, and integrated document control keep you always prepared.

With Quality Forward, life sciences organizations don't just digitize their quality processes - they future-proof them. The platform transforms quality from a compliance function into a strategic business advantage.



Quality Forward, built on ServiceNow, combines powerful digital workflows with a purpose-built eQMS for regulated industries.



Quality Forward is proud to be backed by Yokogawa, a global leader in industrial automation and digital transformation.

Founded in 2017, Quality Forward was established to solve a critical challenge in life sciences: enabling organizations to migrate from outdated, on-premise quality systems to a secure, cloud-native eQMS; without disrupting existing workflows or losing historical data. The solution combines a best-in-class digital experience with AI-driven insights, automated validation, and real-time reporting. Built on the ServiceNow platform, it empowers quality teams to digitize, integrate, and manage critical quality processes; deviations, CAPAs, audits, training, document control, risk, and more, with traceability and ease.

© 2025 Quality Forward Ltd. | www.qualityfwd.com

Learn more about how Quality Forward can help your business grow.

**Request a Free Trial** 



#### 15

### References

- 1 https://pharmamachines.com/factories-of-the-future/
- 2 <u>https://blog.qooling.com/cloud-based-qms-vs-on-premise-qms/</u>
- 3 https://www.bcg.com/publications/2020/increasing-odds-of-success-in-digital-transformation
- 4 <u>https://whatfix.com/blog/digital-transformation-life-sciences/</u>
- 5 https://www.pwc.com/us/en/industries/pharma-life-sciences/next-in-pharma-trends.html