Case Study

Aerogen® Pharma

Our Client

Daniel Burgess
Strategic Quality Leader

Profile

Location: Ireland / USA
Size: SMB
Sector: Healthcare

Focus Areas

Policy Management
Regulatory Compliance
Quality & Document Control

Technology

Azure AI
Policy Express

> "...the cost and complexity of traditional electronic QMS solutions made digital transformation seem out of reach."

Policy Express delivers compliance in 90 days

Policy Express helps organisations like Aerogen Pharma in life sciences build compliant, inspection-ready quality systems within Microsoft 365 – without the enterprise price tag.

Aerogen Pharma, a nimble biopharmaceutical company, revolutionised its QMS (Quality Management System) by replacing its cumbersome paper-based processes with Policy Express, a SharePoint-based policy management and document control solution.

The result was a rapid increase in compliance, enhanced collaboration, and significant cost savings, all while ensuring the highest standards of data integrity required for regulatory approval.

Full deployment & rollout in under 90 days

100% training compliance within 2 months

Reduced costs vs enterprise QMS

Improved collaboration and audit readiness

Meet the Client

Aerogen Pharma is a small biopharmaceutical company dedicated to developing inhaled treatments, with a core mission of caring for patients, particularly babies with respiratory distress syndrome. As a small but growing company in a highly regulated industry, maintaining a robust and compliant quality management system is critical to their success.

The Challenge

Like many small pharmaceutical companies, Aerogen Pharma relied on paper-based approvals with wet signatures, an inefficient process with potential difficulty in version control. However, the cost and complexity of traditional electronic QMS solutions made digital transformation seem out of reach.

The market for electronic document management systems presented its own hurdles. "There are a few companies offering complex quality management systems for our industry, but they're expensive – built for a specialist market," Burgess explained. "And when every dollar counts, especially in early development, they're just not a viable option."

This created a significant barrier. The company needed a reliable system to look after their records from day one to be prepared for regulatory inspections, but the available solutions were costly and complex.

The Solution

Aerogen Pharma discovered a powerful and practical alternative in Policy Express. The solution extends Microsoft SharePoint, a service the company was already using and paying for, into an Electronic Quality Documentation System (eQDS) platform for controlled document management.
Aerogen Pharma was immediately impressed by several key factors:

Cost-Effectiveness: It leveraged their existing Microsoft investment, eliminating the need for a large and new expenditure.

Regulatory Compliance: The system provided the necessary tools to maintain data integrity and create a full audit trail, addressing old arguments that SharePoint wasn't suitable for regulated environments. "You can definitely validate the system," Burgess confirmed. "I can't do anything in SharePoint now without being tracked."

Innovative Collaboration: A standout feature was the ability for users to communicate directly with the author of a procedure within the system. "I have not seen that in any other eQDS where you can directly communicate with the author... That's a huge part," he emphasised. This feature was key to fostering their culture of continuous improvement.

The Implementation

The transition from paper to the new electronic system was remarkably swift. The entire process, from initial setup to full operation, was completed within 90 days.

Phase	Duration	Key Activities
Setup	2 weeks	Installation and configuration
Validation	6 weeks	Internal testing under US & EU regulations
Rollout	7 weeks	Procedures uploaded, training and user adoption

System Setup : The system itself was installed in just a couple of days, with configuration taking only a week or two.

Validation: The majority of the timeline, about six weeks, was dedicated to Aerogen Pharma's rigorous internal validation process to ensure the system was "perfectly fit for purpose under our regulatory infrastructure," meeting both US and European regulations.

Launch: The system was populated with procedures in parallel to validation, leading to a smooth launch.

"I like to say we review our procedures every time we use them, and if you see something that could be improved, being able to comment back to the author is really important to maintain that continuous improvement process."
Dan Burgess, Senior Director of Quality Assurance

"The amount of saving that it creates and that assurance of the integrity of the documentation from day one is huge. I would say this to any company... Don't even think about doing it on paper."

The Outcome

The impact of Policy Express was immediate and significant.

Rapid User Adoption and Compliance: The platform's intuitive nature led to high user adoption. "Two weeks after launch... 91% of people have confirmed that they have done the training," Burgess reported. At the time of the interview, that number had already reached 100% compliance.

Enhanced Efficiency and Data Integrity: With a built-in automated publishing process, accessing old versions is no longer a concern. Employees can trust they are always accessing the correct and current procedures, which Burgess calls a "massive plus."

Empowered Team and Expanded Capabilities: An unexpected benefit was how the solution "opened our eyes to the possibilities of SharePoint." The team received valuable training and began leveraging SharePoint for other quality system tasks, such as managing their approved supplier list, further boosting efficiency.

Significant Cost Savings: By choosing Policy Express, Aerogen Pharma avoided the immense cost of traditional enterprise QMS solutions, allowing them to allocate funds to their primary mission of helping patients.

Key Takeaways

For Aerogen Pharma, Policy Express provided the perfect blend of affordability, compliance, and innovation. The solution empowered them to leave their inefficient paper-based system behind and embrace a modern, electronic QMS that supports their culture of quality and continuous improvement.

The partnership not only solved their immediate document management challenges but also unlocked new efficiencies within their existing technology stack, proving that a robust, inspection-ready quality system is achievable.