

Maly IT Solutions

Case Study – Pharmaceutical Sector

A 16-year bespoke software partnership with a leading global pharmaceutical and aesthetics manufacturer — spanning two parent companies, 500 global users, and over 100,000 records processed across critical compliance systems.

Trusted for 16 Years by a Global Pharmaceutical Manufacturer

How a long-term bespoke software relationship grew with a global pharmaceutical business — and survived an acquisition

AT A GLANCE

CLIENT	A leading global pharmaceutical and aesthetics manufacturer
RELATIONSHIP	16+ years (2009 – present)
USERS	500 globally across 3 core departments
SECTOR	Pharmaceutical / Life Sciences
ENVIRONMENT	GxP Validated (Good Practice — the regulatory framework governing pharmaceutical manufacturing and data integrity)
RELEASES	2–3 validated releases per year
TECHNOLOGY	ASP.NET Core (evolved from Silverlight)
SERVICES	Design, Build, Deploy, Integrate, Support

38,000+

Regulatory Affairs
Forms Processed

13,000+

Artwork Projects
Managed

28,000+

Workflow Instances
Completed

25,000+

Temperature Monitoring
Records

Cumulative records processed across all systems as of 2025 — each one a real business process handled reliably, in a regulated pharmaceutical environment.

The Challenge

The story begins with a global pharmaceutical and aesthetics business — a company whose products are sold in markets worldwide, and whose labelling, regulatory documentation, and supply chain processes must meet the compliance standards of every one of those markets. Over a sixteen-year period, that business was acquired by one of the world’s largest pharmaceutical corporations, which brought its own processes, standards, and scale. Throughout both chapters of that story, Maly remained the trusted software partner.

When the relationship began, the client had inherited a SharePoint-based system from a previous supplier. It was unreliable, its data couldn’t be trusted, and it was the wrong tool for the job. But SharePoint was just one part of the picture. Alongside it, teams were managing an array of compliance-critical processes through spreadsheets, email chains, and regular catch-up calls — with no single system joining them up. As the business grew, these ad hoc approaches brought their own risks into the fold.

In pharmaceutical manufacturing, the consequences of process failures are not abstract. An artwork — the label, leaflet, foil, or box that accompanies every medicine — must meet the precise regulatory requirements of every market it is sold into. Get it wrong, and the drug cannot legally be sold there. Get it wrong at scale, and the consequences extend to product recalls, regulatory sanction, and reputational damage. Incorrect labelling is consistently among the top causes of drug recalls — and clinically significant recalls are not rare events.

A temperature excursion tells a similar story: when drugs are shipped, their temperature is monitored throughout transit. If a medicine — particularly one like a vaccine that requires strict cold chain conditions — is exposed to temperatures outside its safe range for too long, it may no longer work as intended. In those circumstances, releasing it to patients is not an option. The tools in use at the start of this relationship were not equal to those stakes.

“From the first day to now this has been an outstanding experience. I could not recommend them highly enough.”

Senior Regulatory Affairs Leader, Global Pharmaceutical Manufacturer

The Approach

Rather than patching the inherited system, Maly's first act was to diagnose the real problem. SharePoint was not the right foundation for data with the integrity requirements of a regulated pharmaceutical environment. The recommendation was to start again on the right foundation — rebuilding the system as a proper database, so that data was accurate, consistent, and could actually be relied upon. That willingness to tell the client what they needed to hear, rather than what was easiest to deliver, set the tone for the relationship that followed.

The SharePoint system was replaced with a properly architected database, and from that foundation, Maly began building the tools the business actually needed — configured to the client's own processes, not the other way around. Over the years, this has included:

- A structured RA-to-Artworks workflow system replacing ad hoc email and spreadsheet communication between Regulatory Affairs and the Artworks team — enabling changes to be logged, queried, routed, and tracked through to completion with full audit trails and business metrics.
- A temperature excursion monitoring system that parses data emailed from third-party tracking devices and routes it into a compliance workflow, enabling the internal team to assess and investigate anomalies before product release.
- A Regulatory Forms tracker grouping forms by country and stage — giving the business visibility it previously had to manually compile.
- A SAP data preparation tracker eliminating manual data compilation ahead of system entry.

All systems are built and maintained within a GxP-validated environment — meaning every release follows the formal change control and documentation standards required by pharmaceutical regulators. With 2–3 releases per year, each one goes through a structured validation process before it reaches users, meeting both industry regulatory standards and the client's own internal security requirements.

Surviving the Acquisition

In 2019, the client was acquired by one of the world's largest pharmaceutical companies — a multi-billion dollar transaction that typically brings sweeping changes to supplier relationships. For many incumbent vendors, an acquisition of this scale means being replaced.

Maly was not replaced.

The acquiring business recognised the value of what had been built and the quality of the relationship. Over the subsequent years, Maly worked with the new parent organisation to rebuild and adapt the systems to their own processes, compliance frameworks, and technical standards — effectively re-earning the partnership from scratch within a larger, more demanding corporate environment.

Today, the systems continue to evolve. The technology stack has been modernised twice over — from Silverlight to ASP.NET, and from ASP.NET to ASP.NET Core — ensuring the client carries no technical debt from a 16-year-old codebase.

What Makes It Work

Sixteen years is a long time in software. Technologies change, businesses change, and people change. The question worth asking is: what has kept this relationship intact?

The answer is not simply competence — though the technical delivery has been consistently strong. It is trust. In a GxP-validated environment, every release carries formal compliance obligations. Stakeholders on both sides need to be confident in what is being built and why. That confidence is built over time, through transparency, through adaptability, and through a genuine understanding of the client's world — not just their software requirements.

When projects are difficult — and in any long relationship, some will be — both sides work through it together. That is what a real partnership looks like.

Timeline

2009	First engagement — fixing and then replacing an inherited SharePoint system with a properly architected database solution.
2013–18	RA-to-Artworks workflow system built and expanded — replacing spreadsheets and email with a structured, auditable digital process.
ONGOING	Temperature excursion monitoring system deployed — parsing third-party data feeds into a compliance-ready workflow.
ONGOING	SAP data preparation tracker and Regulatory Forms tracker delivered — eliminating manual compilation across departments.
2019	Following acquisition by a larger parent corporation, Maly was retained as trusted partner; systems rebuilt to the new organisation's processes and compliance standards.
TODAY	500 global users. 2–3 GxP-validated releases per year. Platform evolved from Silverlight through ASP.NET to ASP.NET Core.

Results

The outcomes of this partnership go beyond the numbers, though the numbers are significant:

- 38,000+ regulatory affairs forms processed through structured, auditable digital workflows.
- 13,000+ artwork projects managed end-to-end, reducing the risk of non-compliant labels reaching market.
- 28,000+ workflow instances completed across all systems, each one a business process that no longer depends on email or spreadsheets.
- 25,000+ temperature monitoring records handled systematically, supporting patient safety decisions.
- A technology platform that has been modernised twice without operational disruption.

A supplier relationship that survived a major corporate acquisition and grew stronger for it.

Perhaps most tellingly: the systems today are used by 500 people across a global pharmaceutical business. They were built by a team based in Suffolk.

Could we do this for your business?

We offer a free 30-minute exploratory call — no sales pressure, just practical advice.

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