



storm
a littlefish company

CASE STUDY

SteriPack

Elevating Global Quality Excellence



SteriPack

SteriPack Elevates Global Quality Excellence Through App Modernisation and Azure Cloud Adoption

With global operations spanning Ireland, Poland, Malaysia and the US, SteriPack is the partner-of-choice for the world's leading medical device, pharmaceutical and allied industries, offering contract manufacturing services from initial concept through to finished design. For over 20 years, the organisation has remained committed to maximising benefit for their customers through the delivery of product quality excellence and the elimination of waste in the production process.

Embarking on an ambitious digital transformation strategy, SteriPack sought to modernise their existing technology infrastructure, to consolidate systems across the globe. To realise customer and service gains through the optimisation of people, processes and technology. An initiative that would transform not only how they operate but the working lives of the SteriPack team, all while adhering to ISO 13485 and FDA quality standards.

Achieving System Integration with Global Reach

Operating within a highly regulated industry, the modernisation of the existing Quality Management System (QMS) would prove an essential milestone on SteriPack's digital transformation journey. While the legacy system proved effective for the management and adherence to quality standards, SteriPack sought to further enhance integration with all other operating systems to support the organisations growth ambition. Comptability with core systems such as the Manufacturing Execution System (MES), Enterprise Resource Planning (ERP) and Project Management software was required to eliminate an over-reliance on manual reporting and paper-based processes.

Taking a cloud first approach to digital transformation, the project required moving from an on-premises solution to a global-ready cloud environment. Speaking on the decision to adopt Azure, Joe Tallon,

Director, Global IT at SteriPack stated; "with 95% of our systems currently on the Microsoft Technology stack we were keen to explore how Azure could accelerate our digital transformation journey. As this was our first foray into Azure, we reached out to Microsoft solutions specialist, Storm Technology, to understand if Azure would be the right fit for our business needs.

Storm's expertise and deep understanding of the importance in driving business transparency through systems integration, gave us the confidence to proceed with our move to the cloud. Smart cloud-based integrations ensured the new QMS would leverage existing technologies for maximum impact, including Single Sign On with Azure Active Directory, document control via M365 and the use of Power BI and Azure Data Services to facilitate process optimisation."

Adopting a People Focused Approach to Change

Conscious of the potential impact of change resistance, SteriPack were aware they would need to take a measured approach to system design and implementation, addressing user engagement and adoption up front. "While the global sites operated under one regulatory standard, different cultures and backgrounds create differing views and opinions. Any new system would need to provide the flexibility to account for these variances yet rigid enough to provide our customers and management team with confidence that key processes were being followed.

We learnt a lot about Change Management and Adoption from the team at Storm. By investing time in Change Management and Business Analysis we were able to get all quality managers actively involved in project sign off, resulting in increased levels of user confidence and easier buy-in across all sites. The success of this approach has brought senior leaders into the fold of Change Management and Adoption with change management practices now implemented on every digital transformation project" explained Tallon.

A Module Solution Designed for Success

Designed to align with existing operations and future growth through acquisition, the QMS was designed as a modular

“...the solution leverages Azure Data Platform and Power BI to deliver greater business insight and streamline operations from a training management perspective...integration of Power BI and fronting of these reporting dashboards through Teams has driven up system adoption and provides the leadership team with real-time data at both a global and individual site level.

Joe Tallon
Director, Global IT
SteriPack

AT A GLANCE

Client:
SteriPack

Industry:
Pharmaceutical

of Employees:
501 - 1000

Business Challenge:

- ▶ Fragmented business systems with limitations surrounding system integration and data flow.
- ▶ Over-reliance on manual reporting and paper-based processes.
- ▶ Migration of on-premise systems to cloud in line with cloud-first global IT approach.

Services / Solution Overview

- ▶ **Technology:**
Azure Data Platform
Power BI
- ▶ Change Management & Adoption

Benefits Realised

- ▶ Global re-enforcement of regulatory and quality standards.
- ▶ Efficiency gains with digitalisation of paper-based processes.
- ▶ Systems integration and visual dashboards ensure real-time access to quality business data.

storm
a littlefish company

Supplier Corrective Action Request (SCAR), Audits, Issues and Compliance, Non-Conformance with Corrective and Preventative Actions (CAPA) and Complaints management, with additional modules planned for development and roll out in 2022.

Training and Document Control

With each customer engagement bespoke and services spanning all stages of the production cycle from concept to realisation, prototyping to production, maintaining highest levels of training and documentation control is key to ensuring customer excellence and regulatory compliance.

"Operating at global scale with some 2000+ courses and 160,000+ trainings events completed in 2021 alone, managing the audit trail for all completed and outstanding training globally proved a challenge with the legacy software. The solution built by Storm has completely transformed the training experience. Providing employees with access to a modern, user-friendly training portal, empowering them to take control of their individual training."

In addition to transforming the employee experience, the solution leverages Azure Data Platform and Power BI to deliver greater business insight and streamline operations from a training anagement perspective. The course management module enables trainers to view, manage and share courses, while training administrators can run reports and investigate training issues via the GAP analysis tab. This real-time insight has generated efficiency gains, allowing the business to concentrate training resources where they are needed most. The integration of Power BI and fronting of these reporting dashboards through Teams has driven up system adoption and provides the leadership team with real-time data at both a global and individual site level" explained Tallon

Integrated with SharePoint for document control the solution automates the document approvals and subsequent training process. These fully automated workflows and approval processes ensure full compliance with 21 CFR Part 11.

Designed to re-enforce quality controls the QMS integrates with the Manufacturing Execution System and Standard Operating Procedures (SOP) associated with a production line, the operator's training status is then fact-checked against this SOP automatically blocking any operators with outstanding training requirements for that line item from engaging in item production.

Having successfully transformed training and document management, SteriPack sought to digitise the Quality Assurance processes, to transform the traditionally paper and excel based processes associated with audit management.



Application Modernisation using Azure has enabled us to digitise paper-based processes within the business. This has in turn resulted in efficiency gains, reducing the reliance on manual, paper-based processes. The most significant impact of the solution on our business had been the gains realised in terms of business insight. Integration with critical operational systems allows our leadership team live access to quality data across the globe, enabling us to quickly see emerging trends, risks and opportunities.

Joe Tallon
Director, Global IT
SteriPack

Audit, SCARs, Issues & Compliance

Acting as a central repository for Customer, Supplier, Internal and Regulatory reports and data, the Audits module spans the entire audit process. All processes are managed with supporting documentation catalogued to allow rapid retrieval for further analysis. Smart document control protocols ensure any controlled documents maintain the revision as at the time of linking for improved visibility, while integration with Power BI provides site managers and business leaders with an instant view into outstanding and actioned conformance issues.

With accountability critical for quality management and FDA compliance the digitisation of the SCAR module extends the CAPA compliance process to suppliers, reducing audit times and enhancing regulatory compliance. Integrating with critical data systems such as the ERP, to support vendor performance monitoring, this module creates a digital repository for all SCARs related documentation and information tracking progress from creation throug to effectiveness monitoring and closure. Non-supplier related issues or complaints are logged in a similar manner and tracked through the Issues & Complaints module management.

Empowering Quality Excellence Through Cloud Adoption

Speaking on the impact of the QMS, Tallon stated; *"Since go-live the solution has transformed our quality management process. Application Modernisation using Azure has enabled us to digitise paper-based processes within the business. This has in turn resulted in efficiency gains, reducing the reliance on manual paper-based processes. The most significant impact of the solution on our business has been the gains realised in terms of business insight. Integration with critical operational systems allows our leadership team live access to quality data across the globe, enabling us to quickly see emerging trends, risks and opportunities. Armed with the data we can make informed decisions in real time, critical for the fast-moving marketplace in which we operate."*

The adoption of cloud technologies enabled us to navigate the challenges presented by Covid-19 from remote working to the increased demand for training and documentation. This ability to rapidly respond to market shifts has allowed us to expand our production line and harness opportunities for growth with the introduction of sterile nasal swabs, swabs used for sample collection in the fight against Covid" concluded Tallon

Building on the success of the project, SteriPack have moved to the next phase of their Digital Transformation journey, with the design and build of an Inspection Management solution in collaboration with Storm.

Looking to harness the power of cloud first solutions and application modernisation? [Click here](#) to request a call from our Application Modernisation solution specialists.



Contact Us

Dublin

The Capel Building,
Mary's Abbey,
Dublin 7
D07 FK22

Galway

15 Market Street,
Galway,
H91 TCX3

Belfast

18 Ormeau Avenue,
Belfast,
BT2 8HS

Nottingham

Price House, .
Stoney St
Nottingham
NG1 1LS

T: +353 1 416 1226 (IRE)

T: +44 28 9049 0979 (UK)

E: info@storm.ie

W: www.storm.ie