

Polymermedics overcome challenge to manage vast amount of data in highly regulated medical sector

polymermedics
part of TPI industries

Company: Polymermedics

Country: United Kingdom

Industry: Medical

Profile: Company with 30 years' experience in the design, manufacture and assembly of medical and pharmaceutical plastics products.

Key Drivers: Reduction in large admin resources to manage vast quantities of data. So looked for a system that could manage centrally.

Imagine a company that makes more than 1.8 billion plastic components and assemblies for the global medical, hygiene and pharmaceutical industries. Imagine the number of parts manufactured and the challenge of having to maintain full traceability from raw materials to finished products. Imagine the strict global standards the company has to meet, the annual audits and the records keeping required.

Meet Polymermedics: an ISO 13485:2003 certified company with 30 years' experience in the design, manufacture and assembly of medical and pharmaceutical plastics products.

We spoke to Lauren Tregilgas, former Administrator, now working in HR at Polymermedics, about managing documentation and compliance in such a highly regulated industry sector.

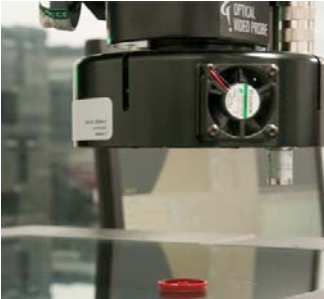
From warehoused paper to web-based records

The impetus to find a document management system arose at the time Polymermedics separated from West Pharmaceutical. The company no longer had large admin resources at its disposal to manage vast quantities of data on spreadsheets. So Polymermedics looked for a system that it could manage centrally.

After evaluating the document management market, Polymermedics selected Document Logistix' flagship product, Document Manager.

Today, five departments use Document Manager to capture, store, retrieve, archive and delete records: HR, Finance, Engineering, Quality and Warehouse.

CASE STUDY: Document Manager™ – Polymermedics



“We like the fact that the system is user friendly. We have had experience with other systems that are hard to understand, so the fact that people are familiar with the way Document Manager works is a big plus.”

Lauren Tregilgas - HR

Adding more and more document types to the system

Documents managed range in type from HR documents that include important training records, validation documents that can run to thousands of pages, and batch records that have to be kept for the lifetime of a product.

The longer Document Manager has been in place, the more information Polymermedics stores in the system. The system houses purchase ledgers, non-disclosure agreements, change control records, quality goods receipts and despatch records.

The Quality Department, in particular, uses Document Manager to manage documents that support Polymermedics' innovative manufacturing programme and to provide auditable evidence of best practice and compliance.

Getting the most out of a digital system

Polymermedics consistently explore ways to gain maximum value from Document Manager. An example of a way in which Polymermedics has simplified a highly complex task is the way the company records and manages its validation process.

Polymermedics is able to track validation history end-to-end in Document Manager.

In the first instance, the system holds records of tools, machinery and products. Another level of information includes machinery maintenance records and any change records. And yet another layer includes component drawings.

Document Manager has enabled a progressive company like Polymermedics to devise and implement a comprehensive record of events, which underpins quality procedures and ultimately saves the company a lot of admin time.

Instant answers to Auditor questions

Polymermedics is subject to annual audits. The company runs its own process audits and also complies with customer and BSI audits.

Accurate record keeping is essential to meet required standards. In the case of BSI, in the UK, and the FDA, in the USA, standards breaches can lead to penalties that, worst case, could lead to company closure.

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Lauren Tregilgas says that the way in which Polymermedics is able to organise and manage its records with Document Manager for compliance and audit purposes gives the company a lot of confidence. “An auditor may speak to a member of staff on the shop floor and ask to see their

training records to ensure that they have a specific competence. We can provide the information instantly.”

After digital document management: records management generates ROI

Lauren Tregilgas says it is not possible to quantify the savings Polymermedics has made with Document Manager but she suggests that “the amount of staff time saved is huge.

If we had any sort of query on a product in the past, someone from the Quality Department would physically have to find the batch records stored in a box in a racking system.

We can now conduct an instant search on hundreds of thousands of batch records and get an instant result. The digital management of batch records in Document Manager alone has generated a return on investment.”

Why was Document Manager selected?

Polymermedics went through a selection process and short-listed three potential suppliers. Lauren Tregilgas says the company had previous experiences with systems that did not grow with the company’s needs, so scored prospects against criteria that included an upgrade path.

“Document Logistix has a product roadmap that we could trust. We liked Document Manager’s scalability, its web access, its built-in workflow capabilities and its security and access protocols, which are critical to data protection.

A working relationship with Document Logistix: Help Desk, system changes

Lauren Tregilgas says system implementation and training went smoothly. The feedback from users about Document Manager is positive.

“We like the fact that the system is user friendly. We have had experience with other systems that are hard to understand, so the fact that people are familiar with the way Document Manager works is a big plus.

Document Manager enables us to be largely self-sufficient, but the Help Desk is on hand if we need it. The Document Logistix Help Desk is good and thorough and doesn’t use a lot of ‘tech speak’, so we are able to understand each other.”

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Lauren Tregilgas says that the successful implementation of Document Manager does not mean that it went without hitches, but Document Logistix stay close to Polymermedics issues.

“We found that we needed changes to Document Manager’s initial configuration and Document Logistix is working hard to accommodate us.

Document Logistix is not a company who call only when they have something to sell. We have a good working relationship with Document Logistix.

Polymermedics will always face new challenges and Document Logistix really want us to be successful using their system.”

What next: retention, GDPR, systems integration

Polymermedics has been speaking to Document Logistix about the potential extended benefits of Document Manager.

Potential future developments include the implementation of Document Manager’s retention module, which will enable Polymermedics to automate the storage and deletion of records by document type.

The relevance of automated retention has grown with the introduction of GDPR in 2018 as it will help Polymermedics to manage data privacy, such as the privacy of staff whose data is associated with product development records.

Lauren Tregilgas says a longer-term goal is to explore integration with the company’s ERP system once their new ERP system is fully installed.