Shaping IT for the ambitious business

Working Together to Build a Compliant Electronic Records Management System for Veryan Medical

Background

Veryan Medical was formed in 2003 as the result of a technology spin out from Imperial College, London. The company has designed, patented and developed a highly innovative three dimensional (3D) Nitinol (nickel-titanium alloy) stent, BioMimics 3D, which is currently used in the treatment of blocked or narrowed superficial femoral arteries, the large artery in the thigh which is the main blood supply to the lower limb. The company's head office is in Horsham, West Sussex and its research and development facility is based in Galway, Ireland.

As Veryan are responsible for running clinical trials in the US, they are required to comply with strict regulations laid down by the Food & Drugs Association (FDA), the obligations to Title 21 CFR Part 11 specifically in regards to the management of electronic records. As an M2 Assist Gold partner, Veryan Medical contacted M2 Computing to discuss SharePoint Online Title 21 CFR Part 11 compliance and granting access to independent auditors. To meet this need, M2 Computing set up a project plan to design, develop and deploy a Records Center in SharePoint Online.

Veryan

"Implementing the Records Center has introduced a completely new way of working for us. It provides complete visibility of records, properly organised and stored in a protected environment. We can also sit comfortably knowing that this system complies with FDA regulations. I wish we had this a year ago."

Blythe Lindsay, Clinical Project Director, Veryan Medical Ltd.

Moving to a SharePoint Online Solution

Since migrating to Office 365 with M2 Computing in 2016, the team at Veryan were using SharePoint Online to collaborate and store documents. This solution provides a simple way to work on documents in real time, from any location, at any time with an Internet connection. This provides substantial business benefits, however it does not comply with the legal requirements laid down by the FDA, as documents are not tracked, secured and stored in the correct way. The filing system for such records needs to comply with FDA guidelines Title 21 CFR Part 11. Prior to this project, Veryan were using a paper based system to keep all their audited records. Printing out documents and physically storing them. This frequently involved large Excel documents which are difficult and time consuming to print. With a compliance audit approaching, it made perfect sense for Veryan to move to an electronic solution. Paper based filing can only be stored in one location, which makes auditing and controlling changes increasingly difficult, as Veryan is an International operation with employees requiring access to documents across the world.

Shaping IT for the ambitious business

Working Together to Build a Compliant Electronic Records Management System for Veryan Medical

Putting Together a Project Team

As Veryan were successfully using SharePoint Online in Office 365, M2 Computing recommended developing a Records Center in SharePoint Online. This allows the management team to build a customised system designed around their specific needs. Over a period of a few months, M2 Computing and the key stakeholders from Veryan held a number of brainstorming and planning meetings to establish exactly what was required from the system.

M2 Computing designed the solution and associated workflows for submission, approval and record declaration. The system was designed, developed and adapted by those who needed to use it, ultimately creating a completely bespoke solution.

Records Management in SharePoint Online

This new system works so well for Veryan because it has been designed from the ground up and tested by the very people who use it.

In order to be FDA compliant, electronic records cannot be updated, amended or deleted and an audit trail is required for each record declaration. If updates are subsequently required, a new record is submitted for approval.

With the correct levels of permission, Veryan can assign users to submit records for approval. Rather than filing a document in the traditional way, when the approver authorises the record submitted, they will apply the correct meta data tags (categorisation and compliance details) to each record. This meta data allows users to efficiently navigate and filter records without the use of folders.

To ensure the system was adopted quickly by those in the team assigned to use it, M2 Computing supported Veryan by holding regular training sessions with the team to ensure there were no delays in adopting the new technology.

The Result

Because the system was created as a team, Veryan were able to take ownership of the design, rather than being forced to purchase an 'off the shelf' software system. It was developed as a collaborative process with M2 Computing, with testing sessions to update elements of the system to get it working in the most beneficial way. Compared with the alternative pre-designed solutions for records storage, Records Center in SharePoint Online is far more cost effective in terms of both time required to set it up and cost to implement.

"We knew what we wanted so it was great to work with a team prepared to shape and design a solution just for us. The new system, by far exceeds our original expectations. The Records Center works in the exact way it needs to and in practical terms it is leaps and bounds better than previous solutions." comments Alan Quigley, Clinical Project Assistant, Veryan Medical Limited.

For an international organisation like Veryan Medical, this record storage system saves both time and expense. Internally, it makes it possible for anyone to remotely add to or check where records have been filed, without the need to physically travel to the location they are kept. It allows for international collaboration in a completely secure environment. Veryan can also open up secure access to an external auditor located anywhere in the world. This eliminates the high costs involved with an on-site audit.

Summary

By working with M2 Computing to build a bespoke system with Records Center in SharePoint Online, Veryan were able to design a solution that perfectly fitted their needs and complied with the FDA regulations. Because the team were involved from start to finish, they now have a system they are comfortable with and find incredibly easy to use.

"Implementing the Records Center has introduced a completely new way of working for us. It provides complete visibility of records, properly organised and stored in a protected environment. We can also sit comfortably knowing that this system complies with FDA regulations. I wish we had this a year ago." concludes Blythe Lindsay, Clinical Project Director, Veryan Medical Ltd.