

Case Study

Consolidation Helps Megadyne Medical Products Successfully Comply With Multiple Regulatory Agencies





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A Schiff Solution: Thinking Outside the Box

Electrosurgical devices are commonly used to help surgeons make precise cuts, as well as limit blood loss during a surgical procedure.

Numerous medical facilities, operating rooms and surgical centers in 72 different countries use electrosurgical devices designed and manufactured by Megadyne Medical Products. Megadyne entered the medical device manufacturing community in 1985 with a line of non-stick electrosurgical electrodes. Since that time, the company has evolved into an end-to-end, full-solution electrosurgical equipment and accessory developer and manufacturer.

Megadyne Medical Products has a global customer base, which means the medical device organization must comply with the requirements of multiple regulatory agencies, including:

- US FDA 21 CFR Part 820
- ISO 13485
- Canada Medical Device Requirements
- European Medical Device Directive 93/42/EEC
- Japan MHLW Ordinance No. 169

Megadyne's Challenges With a Paper-Based System

Before MasterControl, Megadyne used a paper-based system for document control and change control processes, which required many administrative tasks. "A paper-based system required people to do a lot of different things to make sure the quality system regulations, as well as regulations and standards outside the US were met," said Haven McCall, vice president of quality and regulatory affairs.

With their paper-based system, a large amount of time was spent routing change orders for review and approval. During routing processes, they discovered that many employees from different departments were making changes to the

documents. This caused more delays because the revised documents needed to be routed through the approval process again.

"The paper-based system was constraining for us. It soaked up a lot of time, money and resources just to make a minimal change. It presented challenges that we hoped to simplify," said McCall.

Megadyne's paper-based system also caused delays during audits with regulatory agencies. Their warehouse contained stacks of banker's boxes for storing documents. When auditors requested specific documentation to show compliance, the document control staff needed to sort through piles of hard copies to find the documents they needed.

Implementation of MasterControl

In July, 2014, Megadyne went live with MasterControl. They implemented the Change Control solution and found that it made their lives much easier.

Megadyne's IT infrastructure is an on-premise operation using a unique, self-contained virtual environment with five server racks. The hardware they use to run MasterControl consists of virtual machines that run 24/7. With a controlled document environment, Megadyne likes that MasterControl is not sitting out on their server relying on network permissions.

"Working with MasterControl support was pretty painless," said Quaid Reynolds, IS manager. "They are willing to jump on a call and work with you. We have always quickly gotten to the source and resolved any issues we've had."

Solutions Implemented at Megadyne

Change Control Management

Megadyne uses the Change Control module to coordinate their document review and approval tasks. "We immediately found that we had several process improvements, and that we were able to eliminate some of the challenges we had related to the amount of time spent looking for documents and the amount of time spent routing documents for review and approval," said McCall.

Training Management

Megadyne uses the Training module to create training based on employees' roles. On their first day of work, employees are assigned a packet for training. After reviewing the training materials, employees complete an examination to ensure they are competent to perform the work. That entire process is captured automatically in MasterControl. "It's nice because it's something we don't have to manage. We let the system do it," said McCall.

According to McCall, a common question during an audit is 'how do you know employees are competent to perform their assigned work?' With MasterControl, employee training folders can be accessed at any time, which show the procedures, work instructions and industry trainings that employees have participated in to show compliance to that requirement.

Complaints Management

Before MasterControl, Megadyne used a lot of paper and folders for their complaint processes. If there was a conversation or pictures associated with the complaint, a log was kept. When the information was updated, they needed to print everything related to the complaint again. Megadyne had three full-time coordinators oversee all of the complaint paperwork. MasterControl significantly reduced the time and number of staff required to manage complaints.

Non-Technical Personnel Maintain MasterControl

When Megadyne implemented MasterControl, they needed an onsite employee to be the system's administrator. Their document control manager was able to fill that position. With training from MasterControl during the implementation, she could answer almost every question users had related to MasterControl functionality. "This is a person who doesn't have an IT background, she has a background in document control and training," said McCall. "It was easy for her to learn the system and lead the company as a whole through any MasterControl support type issues we've needed help on."

What Megadyne Didn't Realize They Were Missing

According to McCall, since implementing MasterControl users immediately noticed several process improvements and the elimination of some of the challenges related to the amount of time spent routing, approving and searching for documents.

Automating Routing, Collaborating and Approving Documents

"One of the neat things we found is that you could do this in parallel. When we had the paper-based system, it was a serial process. Documents would go from one reviewer, to the next, to the next. If there was a change, it would have to go through that process again. What MasterControl brought to the table for us was a collaboration piece, where we could collaborate on a document, review and approve it and do it all in a timely manner," said McCall.

Timely Turnaround for Change Orders

McCall said the time to review and approve documents went from weeks and months to days. It has also allowed them to have more reporting and visibility into where a change order is located, where it is in the process, who it has been sitting with and if it's open and aging.

Document Traceability

"Another excellent advantage it gave us is traceability. In two years we lost 28 change order packets. If you can imagine the amount of time and resources that went into revising a quality system document and have it lost and have to go through that process again, it's incredible and it impacted our business in a significant way. With MasterControl, we no longer lose change order packets," he said.

Time back in their day

MasterControl reduced the administrative time and busy work that comes with change control. This allows them to be more proactive with tasks that really impact the business.

How MasterControl Helps Megadyne Comply With Multiple Regulatory Agencies

Megadyne is able to coordinate and meet the compliance standards of all the different regulatory environments by centralizing the various requirements. At any time and from anywhere, users can log in and see where a quality document is and its status for being reviewed and approved.

"One of the main reasons we go with MasterControl is because it helps us consolidate all the requirements we have from the different regulatory agencies throughout the world," said Rob Farnsworth, CEO of Megadyne Medical Products. "All the different agencies have different requirements, which is a lot of work. But MasterControl helps us be more efficient with these processes."

Audit Experience With MasterControl

As CEO of Megadyne, Farnsworth is involved with audits at the beginning with the initial meetings and at the end when all of the findings have been identified and the assignments have been given to the staff. They had around 10 audits within a year of implementing MasterControl. "We found that the audits went smoother with MasterControl because we have been able to quickly find the documents the auditors requested," he said. "Auditors acknowledge that we have things better under control, and our findings reduced significantly since implementing MasterControl."

How MasterControl Helps Megadyne Improve Their Life Changing Products

At Megadyne, quality is emphasized throughout the organization. Employees are encouraged to take pride in their work because their own family members may use the products one day.

"MasterControl makes it possible for us to focus time and energy on designing and creating products that could have a great effect in the marketplace, that are easy to use and that provide value to the customer," said Farnsworth. "Overall, we make life better for the clinicians and provide a good outcome to the end user, who ultimately is the patient."

Conclusion

With MasterControl, Megadyne can demonstrate to the FDA and other regulatory bodies throughout the world how they comply with record retention requirements, as well as documentation record keeping and change control.

"MasterControl makes all processes more efficient, which is the key to doing things that bring value to your customers, employees and stakeholders," said Farnsworth.

About MasterControl Inc.

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

Contact information and addresses for other regional MasterControl offices and MasterControl partner offices are listed on the MasterControl website at www.mastercontrol.com.

