



**PATHWAY**  
MEDICAL TECHNOLOGIES®

## PATHWAY MEDICAL TECHNOLOGIES ENGINEERS MORE PRODUCTS AND EASES ISO COMPLIANCE PROCESSES

### Customer

Pathway Medical Technologies, an innovator of endovascular treatments for Peripheral Arterial Disease (PAD) and maker of a device that clears out blockages in clogged leg arteries, received the U.S. Food & Drug Administration (FDA) 510(k) clearance in 2009 to market its JETSTREAM G3™ peripheral atherectomy catheter for use in the treatment of PAD in the lower limbs (below the knee). JETSTREAM G3 is Pathway's latest technology innovation and is capable of treating the entire spectrum of disease found in the PAD patient, including hard and soft plaque, calcium, thrombus and fibrotic lesions.

Pathway is committed to bringing unique technology to the marketplace to treat severe PAD. This technology, combined with national screening initiatives, is increasing the options for patients suffering from PAD and helping them avoid long-term complications of the disease.

### Challenge/Situation

Pathway Medical was using a paper-based system for managing all of its product documentation, part drawings and engineering changes. The company utilized a room that housed all of the paper procedures and hard drawings with a checkout system similar to a library. "Since it was paper-based, you physically had to go to the vault to obtain any of Pathway's product blueprints and drawings," stated Ken Perino, Sr. Director of Quality Assurance & Regulatory Compliance at Pathway Medical Technologies. "If you found someone had checked out the documentation you were looking for, you had to go and find that person which was a time consuming effort."

Mr. Perino spearheaded Pathway's initiative to automate their product development process. He has worked in previous medical device start-ups and has become well versed in the benefits of a Product Lifecycle Management (PLM) system to support his efforts. Mr. Perino was interested in bringing in a PLM system to streamline the entire engineering change process, implement better security with document vaulting,

### Key Benefits

- Affordable, easy to use, quick to implement system for start-up
- Ability to engineer more products with resource time-savings
- Streamline entire engineering change process
- Improve Bill of Material (BOM) management
- Eliminate tedious paper-based, hard copy system
- Centralized and secure product information
- Ease ISO compliance audits/processes
- Compliance with quality system requirements
- Integration with **Exact MAX ERP** system
- Single system for product data, quality and training management



**JETSTREAM G3 Peripheral Atherectomy Catheter**

#### For More Information:

t: 978-988-3800

e: [info@omnifysoft.com](mailto:info@omnifysoft.com)

w: <http://www.omnifysoft.com>

# CUSTOMER SUCCESS

improve Bill of Material (BOM) management, and make product information (drawings, blueprints, revisions, and supporting materials) easily yet securely accessible to appropriate team members.

## **Omnify Solution**

Pathway selected the Empower PLM solution from Omnify Software because of its ease of use, fast deployment time and low cost. Document control, engineering change, BOM and regulatory conformance processes are now managed via the Empower PLM system. All departments that have governing procedures are using the system including: design engineering, quality, regulatory, manufacturing engineering, purchasing operations, and even facilities management. Any changes made to any procedures are performed and managed within Empower PLM.

“Gone are the days that a physical folder is being passed around and emails flying around in regards to where the folder is in terms of going through the different teams for an engineering change,” said Mr. Perino. “Because Omnify completely automates this process, when you submit your engineering change for review, the system sends it out to everyone who is a signer or observer in parallel and the engineering team can view engineering changes in real time.”

## **Easing the ISO Audit: Quality, Training and Validation**

Pathway Medical is required to meet ISO (International Organization for Standardization) certification. ISO auditors will check to see how Pathway (or any company they are auditing) manages its product documentation, change orders/ change management, and engineering processes. Prior to automating with PLM, Pathway used to have to show and explain its manual process and walk an auditor through their vault that housed all of their documentation. Now they can show the ISO auditors how it is accessed and tracked online. Custom reports can now be easily generated to show specific information as well.

“Managing compliance data with Empower PLM has simplified our audit process, making it much easier to show auditors how product information is accessed and tracked online and prove the audit trail of activity for documentation as well as get requested documents much faster than through our previous paper-based vault system, said Mr. Perino.”

For quality regulations and compliance, the company is implementing the Omnify Empower Quality Management module to document and track all non-conformances and customer complaints. “There are some fifteen to thirty non-conformances reported per week depending on Pathway’s product volume,” stated Mr. Perino. “These non-conformances typically occur on the production floor and during the inspection process; often due to a part failing a test or parts not matching up correctly.” “When parts come in, they are inspected, and if a part fails the inspection it needs to be written up, documented and entered into the non-conformance database,” added Mr. Perino.

ISO auditors also request to review the software validation and FDA requires it. Pathway Medical went through the proper channels and procedures to validate their processes, including the integration with their ERP system, Exact Max, proving that they applied security for authorized viewing and electronic signatures and showing the audit trail of activity for documentation.

# CUSTOMER SUCCESS

Another benefit of the Omnify Empower PLM system for medical device manufactures like Pathway Medical is the Training Management module. Pathway is using this module to manage all internal and external training events. It alerts trainees for training/re-training and assigns comprehension checkpoints to gauge understanding.

If training is needed, it is configured in the Omnify system as a task. Pathway has implemented an escalation process that automatically keeps reminding staff members that need to be trained. "I particularly like the automated training setup on policy, product, or document changes and the fact that it easily identifies recurring training events," said Mr. Perino. Combined with the Quality Management module, this supports Pathway's compliance with closed-loop CAPA system requirements.

Within only a few months of deploying Omnify Empower PLM, Pathway has already seen major advantages and cost savings. "Pathway now has the capability to engineer more products because the Omnify system has freed up Pathway's resources and has more bandwidth to do more," stated Mr. Perino.

*"Gone are the days that a physical folder is being passed around and emails flying around in regards to where the folder is in terms of going through the different teams for an engineering change. Because Omnify Empower completely automates this process, when you submit your engineering change for review, the system sends it out to everyone who is a signer or observer in parallel and the engineering team can view engineering changes in real time."*

**-Ken Perino, Senior Director of Quality Assurance and Regulatory Compliance, Pathway Medical Technologies**