Vessix Vascular Prepared for Growth and Compliance with PLM Solution

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Vessix Vascular [1] is a privately held, venture-backed company developing novel radiofrequency balloon catheter technology directed toward a variety of clinical applications, including the treatment of medication resistant hypertension via percutaneous renal denervation as well as peripheral in-stent restenosis.

This new technology has the potential to help the one in three adults in the world who suffer from hypertension—a condition that is more common than cancer, diabetes, and coronary artery disease combined. Their newest product, the V^2 Renal Denervation System for hypertension, recently received a CE Mark and promises to greatly simplify the renal denervation procedure.

Manual Product Development Processes

Vessix Vascular offers a unique approach to treating uncontrolled hypertension that is faster, easier to use and less painful for patients than any renal denervation system currently available on the market. Comprised of a group of individuals with previous experience at successful medical device companies, one of their first priorities was to formalize their product development processes to prepare for their market introduction, successfully meet regulatory guidelines, and implement best practices early on.

As a small group, Vessix could “get by” with their paper processes for managing engineering changes, product documentation, and Bill of Material (BOM) information, but knew this process would not be effective as they grew—particularly

where they needed to track engineering change history with full audit trails to meet regulatory requirements.

“Even as a start-up, we faced multiple challenges using a paper-based system to manage product revisions,” stated Rinda Sama, director of operations and quality for Vessix Vascular. “Documents would pile up on people’s desks, which meant that items were not reviewed right away, causing delays, and many times, by the time it was reviewed, the product was already in the next revision.”

Implement Product Lifecycle Management Early On

The team at Vessix had previous experience with Product Lifecycle Management (PLM) software as a tool to automate product design and development processes. They wanted to implement PLM early on as a best practice for managing BOMs, engineering changes, product documentation, training records, and Corrective and Preventive Actions (CAPAs).

“Implementing a solution early on prevents the company from being bogged down by legacy data and processes when transitioning to an automated system in the future and also helps to eliminate resistance to change from employees entrenched in those practices,” stated Sama. “Tools like Omnify that are affordable, already configured to meet the needs of medical device

manufacturers, and can adapt to a company's processes make it easy to adopt PLM as a start-up and get off on the right foot."

As they evaluated PLM vendors, they were looking for a solution that did not require huge backend support and that they could install on their existing servers. Omnify Software [2] was recommended by a colleague at another medical device company using the Omnify Empower PLM system.

"We looked at Agile due to previous experience with the software but found it to be very expensive and not quite what we needed as a start-up," stated Sama. "After viewing a demo of Empower PLM, we found the tool to be identical to Agile, and even better in some areas, but with a much more affordable price tag."

Vessix selected the Empower PLM solution because it met the company's needs as a small start-up with an easy to use and configure system, and also delivered the features they needed for controlled product development processes to meet compliance requirements. The scalability of Empower PLM ensured Vessix that they would be able to continue to use the tool as the company grew.

Time to Process ECOs Is Transparent

Empower PLM has supplied Vessix Vascular with a proven scalable solution as they have already grown from ten users to twenty-five. "Empower PLM is part of our day-to-day life at Vessix and the employees here love it," commented Sama. "Empower PLM addressed Vessix Vascular's manual revision management issues by providing team members with the ability to see all Engineering Change Orders (ECOs) in real-time. ECOs no longer pile up on people's desks. All of our product design and development processes are streamlined and viewable in a single snapshot and the time to process an ECO is transparent."

"We converted the Vessix Approved Supplier List from a static Excel spreadsheet to a dynamic Omnify list," said Joseluis Espinosa, project manager and Omnify administrator at Vessix Vascular. "In this way, vendors are now able to be linked with individual parts and assemblies. Opening a vendor record displays every part acquired from them. Another advantage to dynamic vendor management is the simplicity with which secondary vendors are able to be qualified and linked to preexisting parts."

Omnify Empower Vendor Management provides an additional layer of information not available through the legacy paper system. Similarly, all tools and equipment are now managed through the Omnify Empower Training Management Module in order to track calibration and preventive maintenance. "Since we have test and manufacturing equipment both in-house and offsite at various contract manufacturers, using Omnify Empower PLM for automated equipment tracking and maintenance has substantially increased our overall efficiency," added Espinosa.

Prepared for Regulatory Compliance

Vessix Vascular is ISO 13485:2003 compliant, which specifies requirements for a quality management system. The company has already been through two ISO 13485 Quality System audits using the Omnify Empower PLM system. Prior to

Empower PLM, they would have to find and print documents to pull for an audit. Now, they can quickly search in Empower PLM to show the necessary documents along with change history, who approved the change, when it was released, change justifications, and links to any other Omnify items relevant to that part.

The company recently received their CE Mark, which will allow Vessix to begin marketing the product throughout the European Union, making their Renal Denervation System available to the wider number of people suffering from drug-resistant hypertension.

“Omnify PLM offers some subtle yet powerful advantages to the CE Marking application and review process,” stated Espinosa. “Design history files and phase completions were enhanced by citing project deliverables with dynamic links through the Omnify BOM structure, which increased the response speed when regulatory bodies inevitably requested more information. In addition, the web interface kept overseas employees in the loop with time-sensitive signoffs and item releases, and uploading legacy design documents en masse was a breeze, facilitating research into previous-generation projects to address regulatory concerns.”

Alaine Portnoy is VP of product marketing for Omnify Software and is responsible for marketing activities for the company. She has over 15 years of experience in manufacturing, medical device, and PLM markets.

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