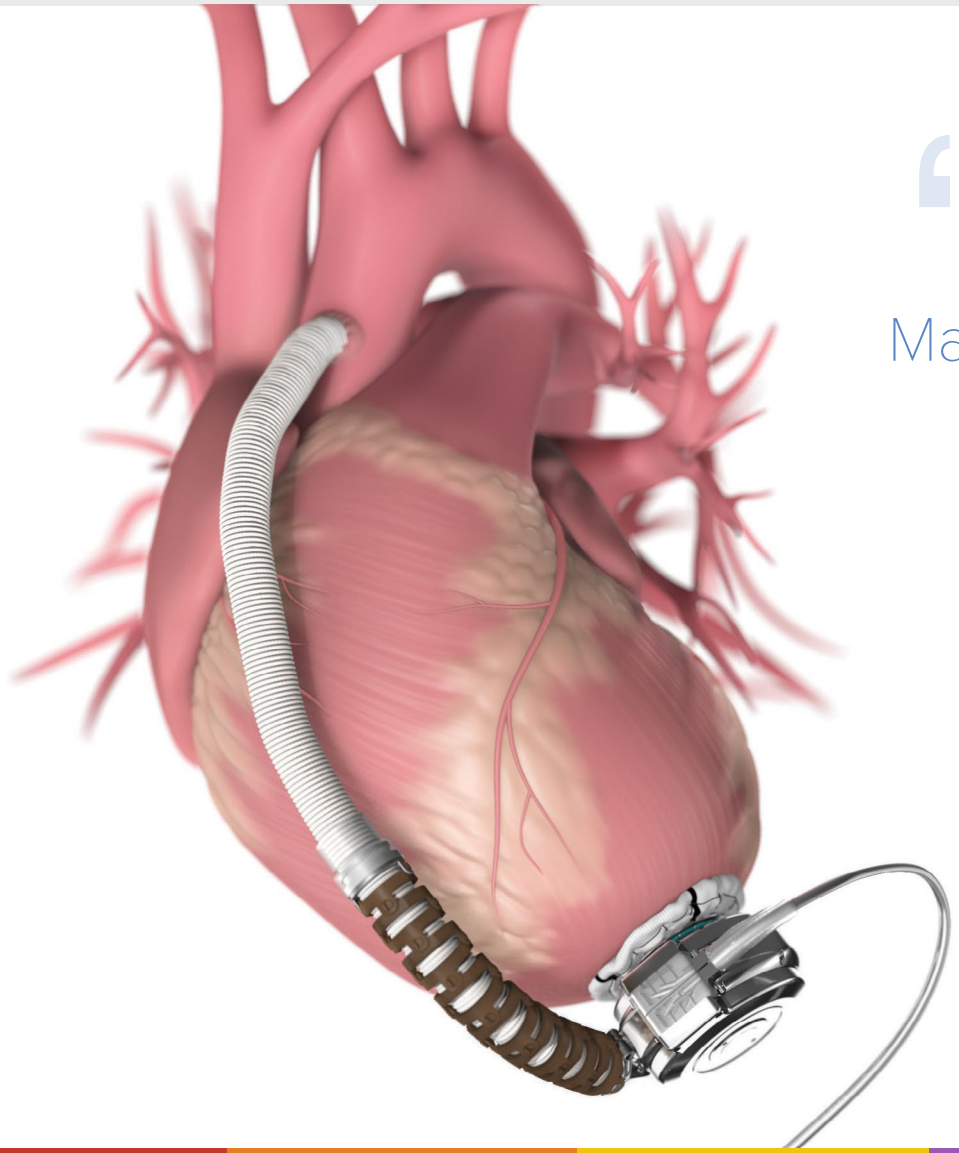
CUSTOMER CASE STUDY

HEARTWARE



> “HeartWare plays a role in saving lives every day and QAD Quality Management System (QMS) provides faster and better management of patient complaints.”

Maurice Plourde, Senior Director of IT for HeartWare

CUSTOMER CASE STUDY

HEARTWARE

QAD QMS STREAMLINES LIFE SAVING COMPANY'S COMPLAINT MANAGEMENT PROCESS

THE COMPANY: HEARTWARE

HeartWare is a global medical device company dedicated to helping patients who are experiencing advanced heart failure. Their Ventricular Assist Devices (VADs) are surgically implanted within the pericardial space to assist in supplying oxygenated blood to the body as patients wait for a heart transplant.

The HVAD System is a bridge-to-transplant therapy for patients with advanced stage heart failure. The device obtained a CE Mark (a mandatory conformity marking required for certain products sold within the European Economic Area or EEA) in 2009, followed by U.S. market approval in 2012 from the U.S. Food and Drug Administration (FDA) and more than 10,000 patients worldwide have been implanted with HeartWare's HVAD System in over 47 countries around the globe.

HeartWare is also actively engaged in clinical trials for Destination Therapy (DT) which will be a permanent solution for patients not eligible for transplant. DT is currently in testing and is estimated to be available in the near future.

The company's operating and manufacturing activities are located throughout the world including the United States, Europe and Australia.

HIGHLIGHTS	
Company	HeartWare
Headquarters	Framingham, MA
Industry	Life Sciences
Products	Ventricular Assist Devices
Solutions Utilized	QAD Quality Management System (QMS)

THE CHALLENGE: EFFECTIVELY MANAGING COMPLAINTS IN ACCORDANCE WITH FDA REQUIREMENTS

HeartWare's VAD carries a Class III designation, meaning they are high risk devices and subject to the highest level of regulatory control. Prior to being marketed, Class III devices need to undergo clinical trials and obtain approval from the FDA as well as the regulatory bodies of other nations where it is being sold. Once approved, there are strict regulations governing the safety and efficacy of the devices during the manufacturing process and throughout the entire lifespan of the device.

"Product quality and patient safety are our top priority at HeartWare and we are under very strict FDA regulations," comments Maurice Plourde, senior IT director with HeartWare. "Everything we design, manufacture and distribute is highly regulated. We have tight controls over record keeping, employee training and corrective action as well as all of the software we run. Anything that can impact product quality and affect patient safety receives a significant amount of scrutiny."

As part of its inspection process, the FDA performs unannounced company-wide inspections several times a year. One aspect of these inspections is a review of how HeartWare handles and resolves patient complaints. Complaints can come from a variety of sources including surgeons, VAD coordinators within the hospital, or even relayed from HeartWare's own field team. The information contained in these complaints allows HeartWare to evaluate any potential safety concerns and determine the root cause, but also address any longer term issues and improve the design of the current VADs as well as future products.

After a comprehensive, cross-functional review process, HeartWare defined and designed a new complaint management process that would streamline and automate many steps and eliminate manual processing errors.

The work flow process includes:

- Receiving and documenting the complaint
- Gathering relevant information from surgeons, VAD coordinators or field personnel
- Determining the nature and severity of the complaint
- Reporting any adverse events to the FDA
- Reviewing and completing a CAPA (Corrective Action/Preventative Action) as required

During inspections, the FDA determines if HeartWare has handled complaints in a timely manner, if all documentation is in order and if HeartWare is following their own complaint management processes.

"Before we had QAD QMS, our complaint handling process was manual, error prone, time consuming and costly," adds Plourde. "We had a home-grown system with multiple different databases. There were many steps involved and it was siloed without integration among the design teams, manufacturing, distribution and Quality Assurance (QA)."

"We needed an integrated complaint management system which would eliminate redundancies of information," notes Plourde. "We needed a holistic approach that used information from QAD ERP and QMS."

THE SOLUTION: QAD CONFIGURES QMS FOR HEARTWARE'S EXACTING COMPLAINT MANAGEMENT NEEDS

"HeartWare had looked at various QMS systems for years, but we were never able to commit to a new approach," comments Plourde. "HeartWare has been a QAD customer since 2005 and when HeartWare had discussions with the QAD QMS team, we were very impressed with the workflow engine and how we could automate functions and integrate quality into core processes. We knew we could depend on QAD to help us develop what we needed."

HeartWare defined an extensive list of user requirements for the complaint handling solution.

There are 14 steps in the process and many departments can be involved; the people who

receive the complaints, those who analyze, plan and implement corrective action and field staff working directly with the hospital. A great amount of input was gathered from across all of the departments and all of those users needed to be trained. The training was done in-house by the IT team who worked on the implementation.

"Many HeartWare employees use the new QAD QMS complaint management system on a regular basis," notes Plourde, "and they are very happy with the new system. There were a few hurdles, as always expected, but I give credit to the HeartWare and QAD QMS teams. It was a lot of hard work, but we stuck with it, no one gave up – and we got it done."

THE BENEFITS: FASTER, MORE EFFICIENT COMPLAINT MANAGEMENT RESULTS IN SAVING TIME, MONEY AND EVEN LIVES

The new QAD QMS complaint management system has proven beneficial both for HeartWare, and patients with faster and better management of complaints.

> "Quality is literally the "heart"of our business and complaint management is part of our continual improvement. Our QAD QMS complaint management system has improved our processes."
>
> Maurice Plourde, Senior Director of IT for HeartWare

54% IMPROVED
COMPLAINT CLOSURE RATE

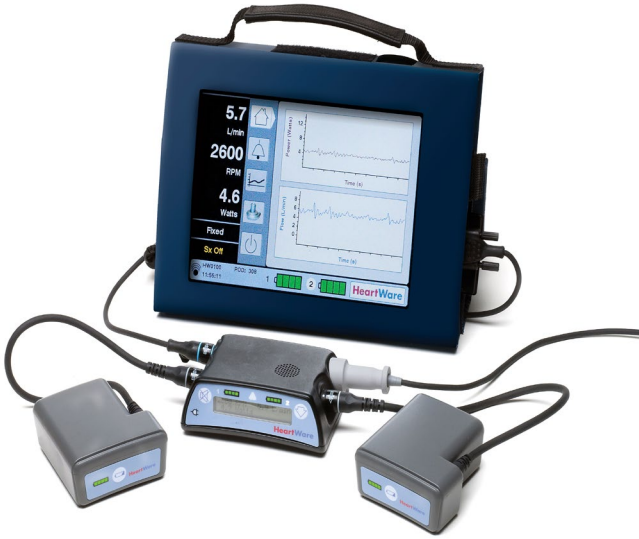
53% REDUCTION
IN OPEN COMPLAINTS

62% REDUCTION
IN LATE REPORT SUBMISSIONS

Some of the benefits that HeartWare has experienced with QAD QMS include:

- The timeframe for investigating and resolving complaints has been reduced leading to a 62% reduction in late report submissions.
- There has been a 53% reduction overall in open complaints and a 54% improved complaint closure rate.
- There is now greater visibility of complaints during the entire process across multiple departments with data more easily and quickly accessible.
- Reports and information can now be pulled in a fraction of the time it took in the past, whether internally or by FDA audit request.

"Before we had QAD QMS it took a lot more effort to get things done," concludes Plourde. "It makes a big difference day-to-day for the people involved in complaint management – the process is quicker and much more efficient."



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