

Design to FDA Contract Manufacturing: Surgical Visualization

Medical device manufacturers drive innovation that is drastically improving the quality of diagnosis, treatment, and procedural outcomes for patients. They would like to spend the bulk of their product development time perfecting the clinical efficacy and market acceptance of a device or solution, and less on the technology platforms that enable the solution, logistics, and supply chain that will be needed to take it to market.

EmbedTek's expertise in creative engineering, integration, supply chain management and the Good Manufacturing Practices as a registered manufacturer with the U.S. Food and Drug Administration (FDA) provides medical device manufacturers with the operational infrastructure they need to manufacture their product line and grow their business. That way, they preserve capital and can allocate their own research and development resources where they know they will maximize ROI.

The Evolution of a Trusted Partnership

A medical device manufacturer first engaged EmbedTek in 2012 to help with a new line of surgical visualization tools. Their software provided real-time, patented visualization and guidance to surgeons, with additional capabilities for recording and editing the images. This cutting edge technology was quickly gaining market acceptance, but the supply chain had trouble keeping up.

Almost immediately after starting to commercialize their product, our customer was plagued with quality and consistency struggles throughout the supply chain: components reaching end of life prematurely, thermal and

aesthetic issues in the physical form factor, and all-around difficulty managing revision changes.

EmbedTek was first brought on board to evaluate the communication inside

Controlling Cost (and Liberating Resources)

EmbedTek addressed cost controls in three ways:

1

Providing prompt, experienced design and validation at a nonrecurring engineering (NRE) cost that compared favorably to inhouse development (but without taking resources away from the customer's core competency)

2

Reducing the cost of procurement and providing lifecycle management over the program lifecycle;

3

Providing scalable manufacturing capacity operating to FDA and ISO13485 standards with no capital outlay.

of the image generator (IG) computer. We established a trusted relationship with the customer by developing a new computer system that incorporated powerful graphics technology and conformed to the physical and design standards of the rest of the device. The more we worked with them, the more we could gather a comprehensive view of their entire system. It was not long before we identified additional ways their supply chain could become more flexible, scalable, and cost-controlled.

Our relationship has grown into a true partnership over multiple years, with EmbedTek providing computing, visualization, mechanical, electrical, and other design and supply chain support. Beginning in 2016, EmbedTek became the (FDA Registered) contract manufacturer of the entire device.

As a registered FDA Contract Manufacturer of Medical Devices, EmbedTek now provides advanced embedded technology capabilities, complete manufacturing, and delivery. We have the ability to take on all responsibility for the manufacturing and direct shipment of the surgical visualization device and accept joint responsibility for the quality of the finished product.

The Initial Challenge

Our first challenge with the medical device manufacturer was to design the IG computer, and timing was essential. A new line of graphics cards was about to be introduced by a major supplier, and our customer wanted to be first-to-market.

EmbedTek engineers started by considering commercial off-the-shelf (COTS) central processing units (CPUs) and video processing components. EmbedTek maintains close ties with Intel, as well as strategic graphic processing unit (GPU) providers such as nVidia and AMD (ATI). By consulting

The computer needed to match the design aesthetic of the finished device, a cart with a very slim console.

with supplier roadmaps, we were able to select products from their embedded line and make sure that key components would be available over the lifetime of the product line. As a result, the customer was able to plan for a family of products at different performance levels and price points.

Project development was already underway for the cart and optical system in which the computer would function. This included a new, specialized positioning of the visualization tools ergonomics for the surgeon; and a slim console that left a very small opening for the chassis, and little room for airflow. The computer system needed to address high thermal output from the video cards but was constrained by acoustic standards for a point-of-care medical device.

3D design software helped us quickly develop several candidate chassis designs. We used our in-house 3D printing capabilities to further validate selected designs and produce physical samples of the chassis and ducts. Working closely with the customer, our engineering team designed a flow-through chassis that included a large fan with a low acoustic footprint. This promised adequate cooling even with some of the more aggressive graphics card selections. EmbedTek worked with the appropriate regulatory agencies to help the customer get the needed approvals for the medical device.

Results

At the same time that we were working on the computer system, the customer focused their efforts on the rest of the cart, including the high-resolution camera and software. Our two teams had established a solid project plan that assured close program coordination. After two rounds of prototype systems, EmbedTek was able to deliver the Production First Article just sixteen weeks after the initial engagement.

Designing for Long-Term Success

The system took advantage of state-of-the-art components (especially the graphics cards) and had the potential for 5+ years of market availability. That was considerably longer than the scheduled availability of most video cards.

EmbedTek took responsibility for sourcing the entire bill of materials (BOM), managing the purchasing function and ensuring that component availability was aligned with the program life. Most of the COTS components were embedded products with extended product availability of 5 to 7 years. We then used our purchasing and inventory resources to extend the lifetime of the selected video cards. Any hardware upgrades were coordinated with the customer's planned software updates to maintain program consistency across the product family.

Results

This work on the front end resulted in the customer only having to manage one SKU instead of multiple components, which greatly reduced their cost of purchasing. Our highly flexible production capability also meant that the customer could address variations in demand, including end-of-quarter upside.

Full Product Manufacturing as FDA Registered Manufacturer

The product launched successfully, and all parties were satisfied that the system matched the design aesthetic of the finished device. Our customer continued to focus on developing a suite of applications for microsurgery. Today, their software is in use in hundreds of leading hospitals and institutions around the world.

Over the next two to three years, EmbedTek worked closely with the customer to help optimize their software for the embedded computing in the device and resolve quality problems in the field that were associated with computing, but not internal

The finished system provides the physician with “heads up” enhanced visualization of the surgical site providing improved detail and ergonomics.

to EmbedTek’s product. We even evaluated escalations in the field that were of unknown origin to both rule out an association with computing and determine the source and solution for the issue. This included how the system communicated with other medical devices.

The customer came to rely on EmbedTek’s expertise in all areas involving and surrounding the computing platform. When we were at a point where we were being brought on to handle all BOM and design additional devices, the partnership transitioned to Embedtek building the entire device.

Results

Complete manufacturing now takes place in our Waukesha facility. This scalable, cellular manufacturing facility operates to the ISO 13485 and ISO 9001 standard and maintains electrostatic discharge (ESD) controls. Clean room, engineering test and validation equipment and multiple production cells are all within steps of the manufacturing area. This trusted partnership means that the customer can drive to the next innovation in the medical device field without having to also be an expert in how to get there.

Some project details were changed to protect the confidentiality of the customer.

EmbedTek designs, invents, and manufactures computers, software, sensors, cameras, and displays for original equipment manufacturers. Our systems improve the quality of imaging in healthcare, simulation programs in the military, video analytics in security, and much more. Throw any challenge at us, from demanding environment and ergonomic requirements to High Level Assembly and nonstandard I/O. We'll evaluate it, carefully attack it, and solve it.