

Simplify and Scale

Get to Market Faster by Avoiding These Common Hurdles

Table of Contents

Executive Summary.....	3
The Pressure is On.....	3
Find A True Partner.....	5
Clear Hurdles Early and Often.....	6
About EmbedTek.....	8
Case Study: Design to FDA Contract Manufacturing: Surgical Visualization.....	9
Case Study: Portable High Performance Medical Image Generator with Touch Screen.....	12

Executive Summary

Market acceptance. It's a critical juncture in the life of a new medical technology. As demand builds, so does the importance of a scalable supply chain. The device that was designed on a small scale is at risk as it scales. Risks include unreliable supply, unplanned changes to critical components or unexpected obsolescence.

These scenarios happen often in the rapidly-evolving medical device industry. The urgency of proving a concept overrides developing a supply chain designed for growth. At EmbedTek, we've seen it many times and it can change everything.

EmbedTek is a Wisconsin-based designer and manufacturer of medical equipment and subsystems including computers, displays, imaging and vision systems, sensors, and cameras, that have reduced cost and increased speed to market. Our problem-solving, creative engineering mindset and our mature, disciplined supply chain, regularly aid medical device OEMs in simplifying the scaling process.

Over the years we have identified common hurdles regarding manufacturability, supply chain, and quality control that could have been addressed at the very beginning stages of research and development. This white paper shares our experiences in the field and what device manufacturers can do to set themselves up for a successful, simplified scale following market acceptance.

The Pressure is On

Medical device manufacturers are revolutionizing healthcare treatment and patient outcomes, from advancements in diagnostic images and data collection to 3D visualization and robotic assistance. The core technology of each device is what makes it special. But there is a lot more to the device than the technology, including protective housing, quality standards and regulation, communication, and integration with a larger equipment system. Throw in the constant pressure for release dates and/or price points, and suddenly there is a lot more to getting the device into clinical use than the breakthrough technology it holds.

Take for example an EmbedTek customer that had developed an aberrometer – an instrument which provides information on a patient's eye during cataract surgery – but needed a small, quiet, high performance image processor, a display that could be seen clearly under operating room lights, and a touch screen that could withstand frequent wipe-downs. Or another customer that excelled in building review and replay programming but could not move forward with a project unless multiple audio/visual components could be consolidated into a single package.

Throw in the constant pressure for release dates and/or price points, and suddenly there is a lot more to getting the device into clinical use than the breakthrough technology it holds.

Device manufacturers benefit most when they are able to focus on their core technology.

Device manufacturers benefit most when they are able to spend the bulk of their product development time perfecting the clinical efficacy of their core technology. They know the healthcare market best and they know what they want and need their device to be. Adjunct manufacturing experts, like EmbedTek, can be brought onboard to focus on what they do best – designing how a device will be produced and maintained, through a supply chain, over the course of its lifetime.

To solve the image processor and display challenge for the aberrometer manufacturer, EmbedTek leveraged previous designs, best practices and its network of commercial-off-the-shelf (COTS) component suppliers.

- We used a chassis that protected internal components from RF and EM interference, limited emissions and regulatory compliance and addressed thermal management.
- Our engineers tested and tuned a capacitive touch screen for a gloved surgeon to use.
- A plastic bezel and glass laminate over the touch screen provided protection from disinfectant liquids.
- We paired an Intel™ processor with a chipset and motherboard that had the video assets to run the display.
- We selected COTS components based on their production roadmaps and a confidence that they would be available through most of the product's lifecycle.

In the case of the A/V review and replay programming device, the original device consisted of several components connected to a computer via multiple connections and power supplies. Consolidating these disparate devices into a single, more ergonomic solution at a lower cost, with an improved supply chain, reliability, and end user experience. (Complicating things further), EmbedTek's design solution needed to fit within nonnegotiable software and lifecycle requirements and work within the customer's demand schedule. Here's how we solved it:

- Our engineering team leveraged an existing image capture device that met all of the requirements except Linux driver support. Our software team wrote new drivers.
- The audio on the original device involved four high quality balanced XLR inputs with a discrete power supply. We designed a 4-port balanced XLR audio board via USB that does not require a discrete power supply and came with excellent reliability and indefinite availability because we control the design.
- We leveraged a long life Power over Ethernet (PoE) solution to provide power and connectivity to cameras without a separate box.
- EmbedTek selected COTS computing components from our existing supply chain, which passed volume discount pricing, consistent availability, and revision control onto our customer.
- Our custom chassis design accommodated all of the components and offered an optimized thermal environment.
- Not only did the resulting solution cost \$1,600 less, but the custom components represent less than \$100. That means the customer can apply them to other embedded computers without modification, allowing them to participate in new computing developments and software releases.

These types of solutions are not built in a day's work. Even with seasoned experts on the project, they require trial and error and months or years to plan and perfect. The timeline only multiplies when a manufacturer is new to the large scale production side of a program. Compromising these mid-to-long-term business requirements can impede growth and have lasting effects on a company's ability to compete.

Find a True Partner

To get results like the ones described above, you need to find a manufacturer that has the breadth of skills to take the burden of production and supply chain off of your plate as early as possible. The goal is for your company's team to focus their time on product development and sales. Introduce the manufacturer in a tangible way to avoid constraints on R&D once the concept is accepted. As production volume increases, you have the time to vet the partner properly. In turn, the partner gains the product experience needed to take on a more strategic role that inspires confidence.

EmbedTek has expertise in creative engineering, integration, supply chain management and Current Good Manufacturing Practices (CGMPs) as a registered U.S. Food and Drug Administration (FDA) Contract Manufacturer of Medical Devices. We leverage this to provide device manufacturers with the operational infrastructure they need to manufacture their product line and grow their business.

For example, we began to work with one medical device manufacturer when they were launching 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 of the image generator.

We developed a new image processing 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 the customer, the more we could gather a comprehensive view of their entire system. It was not

Medical Device or Subsystem

- Display
- Computing
- Interfaces
- Driver/Firmware
- Regulatory
- Cart
- Enclosure
- User Interface
- Software Image

EmbedTek takes a product from concept to completion, eliminating the need for other suppliers.

Engineering Design Firm

Software Company

Metal Fabricator

Contract Manufacturer

Computer Supplier

Distribution

EMBEDTEK



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. Two years ago, EmbedTek became the (FDA Registered) contract manufacturer of the entire device.

As an FDA registered manufacturer, 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.

Complete manufacturing now takes place in our Waukesha facility. This scalable, cellular manufacturing facility operates to the ISO 13485 and ISO 9001 standards 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 on how to get there.

Clear Hurdles Early and Often

Our engineering and manufacturing teams at EmbedTek have seen and solved all different types of challenges that would have prevented medical device manufacturers from scaling up production. Following are the most common and how to avoid them in the early stages of product development.

1. Be careful using consumer grade components that don't offer the traceability and life cycle management required for scale.

Designers tend to use products that are most easily accessible (i.e. purchase from Newegg/Amazon) or limited in quantity when they are at the beginning stages of product development. When they only need one unit to test a concept, they buy what works best at the time, not thinking about price per unit or if the manufacturer is likely to be around in a year.

Consumer grade components available with the latest technology today should be considered with caution. Over time, there is no guarantee of consistent supply, and there is always the risk for unannounced changes to components that could significantly impact your product's lifecycle. Another factor is traceability and process control.

You also need to be in control of your product's lifecycle by developing a comprehensive maintenance and replacement schedule for each component used. This includes the creation of a bill of materials (BOM) and end-of-life (EOL) report listing each component, relevant certifications, when the component needs to be replaced, and other components that will need to be replaced along with it. Maintain the BOM by communicating with strategic suppliers on a regular basis to learn about pending updates or changes.

1

Be careful using consumer grade components that don't offer the traceability and life cycle management required for scale.

2

Watch for easy paths to growth and scalability.

3

Seek out business development partners early in the process who can take on broad areas of supply chain design.

4

Work with manufacturers with a proven track record of helping companies scale.

2. Watch for easy paths to growth and scalability.

It is possible to develop a concept with reliable components and high volume production in mind. In fact, it is necessary if OEMs want to maintain realistic production and market launch timelines. An experienced manufacturer and supply chain expert can take this on while planning for future growth and simple scalability.

EmbedTek was responsible for sourcing the entire BOM for the surgical visualization device outlined in the Find a True Partner section of this white paper. From the beginning, we managed the purchasing function and ensured that component availability was aligned with the program life. Most of the COTS components were embedded products with extended product availability of 5 or more years. We used our purchasing and inventory resources to extend the lifetime of the select components. Any hardware updates are coordinated with the customer's planned software updates to maintain program consistency across the product family.

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.

3. Seek out business development partners early in the process who can take on broad areas of supply chain design.

Working with one company that can help take a product from concept through to production, shipping, and lifecycle management means they can grow with a product line. This helps provide continuous improvement to the product as well as supply chain efficiency. If needed, they can even take the entire supply chain over, finding ways to consolidate vendors and reduce costs even as production volume increases.

EmbedTek clients work with one account representative throughout their relationship with us, which means one person to funnel all accountability through. This type of relationship creates opportunities for vendor consolidation and supply chain simplicity because the account rep is as close to the product as the medical device company.

When the surgical visualization device completed a successful product launch, our customer continued to focus on developing a suite of applications for microsurgery. Today, their device is in use in thousands of leading hospitals and institutions around the world.

EmbedTek has the ability to take on all responsibility for the manufacturing and direct shipment of medical devices and accepts joint responsibility for the quality of the finished product.

Over the next two to three years after launch, EmbedTek worked closely with the customer to help optimize their software. We also helped resolve reliability problems in the field that were associated with computing, but not related to EmbedTek's custom-designed product. We could not have provided this value to the device manufacturer if we did not have a deep understanding of their entire device, its components, and the vendors who supported it throughout the supply chain.

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 the entire BOM and design additional devices, the partnership transitioned to EmbedTek building the entire device.

4. Work with manufacturers with a proven track record of helping companies scale.

There is a big difference between manufacturing for the short-term inventive R&D phase and confirming product design for reliable and regulated manufacturability over the long haul. Just the floor space, personnel, and training alone can derail a growth opportunity.

You need reliable suppliers who can produce within your quality and cost objectives, and have the availability of product within your lead times. And they all need to serve the medical device marketplace. It can be difficult to find a fit to begin with, let alone one that can become a long term partner.

Your manufacturing partner needs to understand how to mate your product with all of the requirements for technical performance. They need to vet, then manage suppliers that get your cost, quality, and delivery metrics in line for successful production.

Don't let scalability be the factor that undermines your product success. When you take steps to align the agility of your R&D-proven technology with building a scalable supply chain, you can create a manufacturing approach that will support growing the business as the product demand increases. A trusted, vetted, knowledgeable manufacturing partner can get you there.

About EmbedTek

EmbedTek creates, designs, and builds medical equipment and subsystems, including computers, custom software, sensors, cameras, and displays for original equipment manufacturers. We make it as easy as possible for OEMs to leverage and embed superior technology for truly differentiated products. Our mission is to create the platform that best serves our customer's business. Our first engagement with customers is often designing a purpose-specific computer, display, or camera system for an existing product. We see and feel production pain points that we work to identify, carefully evaluate, and solve. The more we get to know our customers, we can design additional features and functions for their product lines to improve reliability, cost, and performance in a new way. Then, when market needs arise that can be solved through technology, we work with customers to create entirely new products, equipment, and solutions that put them miles ahead of their competition. Few things are more disruptive or costly to an OEM than unexpected changes to their platform. All aspects of EmbedTek's process are organized around the need to provide our customers with proactive product transitions as opposed to reactive transitions. We take on the toughest technology, manufacturing, and integration challenges, evaluate them carefully and solve them. Check out our products and case studies at www.embedtek.net.

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 ISO 13485 and ISO 9001 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.

Portable High Performance Medical Image Generator with Touch Screen

When a medical equipment company wanted to offer a mobile version of their image-guided surgery device, they needed to introduce the new product with as little timeline risk as possible while ensuring that they met challenging technical, regulatory and ergonomic requirements. The existing device featured proprietary control and power systems, so the company sought a partner that could achieve their desired aesthetic and performance. EmbedTek's established portfolio of portable, high performance image generators and its certifications in medical device manufacturing made it a strong partner for the challenge.

Critical performance requirements

The portable image generator would be used for image-guided surgery, where a camera tracks instruments during an operation and a processor controls some of the surgical instruments itself. Image-guided surgery aids in operating on hard-to-see areas of the body and for minimally-invasive procedures, increasing accuracy while drastically reducing patient recovery time.

Often times, the surgeon is looking at the display screen instead of the patient, so the combination of high performance computing and high quality graphics are critical for image-guided surgical devices to work. Our customer needed to make their existing image generator portable, durable, and medically-rated in a short period of time.

EmbedTek has designed and manufactured many portable image systems like this, for example the Burke BD67, which was originally created for mobile medical imaging and diagnostic applications. It accommodates a large image acquisition card, can process incoming data at high speed, and can display data for immediate review. Or the Burke G456, originally created for mobile military simulation markets but has the protection from heavy shock and vibration needed in the medical device industry.

System Requirements

-  High performance computing
-  High resolution real-time 3D graphics
-  Commercial off the shelf (COTS) computing components
-  Proprietary control and power systems
-  Medically-rated for safety and regulatory compliance
-  Lightweight, sleek and ergonomic

We've also developed a variety of integrated touch screen displays such as the Kopis 1117, made to withstand medical wipe down and comply with 60601 EMC and 1PX1 standards for dripping water.

Results

Products like these could be used as building blocks to design and manufacture the customer's mobile solution affordably in a short timeframe. In fact, our non-recurring engineering (NRE) costs were so affordable that we

needed to prove they were possible. Our FDA registration as a Contract Manufacturer of Medical Devices, and our ISO 13485 certification meant the customer could follow its normal supply chain and minimize the risk of bringing the new device to market.

Low risk to market

In just under 4 months, EmbedTek produced a functional first article for a high performance mobile image generator with touch screen. We developed a prototype within

8 weeks, a production prototype in 16 weeks, were ready for regulatory in 20 weeks, and produced the first article in 24 weeks.

Our electrical, mechanical, and software engineers met this timeline by modifying proven technologies and manufacturing processes of existing EmbedTek products – both mobile and stationary – to meet the customer's standards and requirements. Our in-house team validated for thermal, shock and vibration, electromagnetic compatibility (EMC), electrostatic discharge (ESD) and overall reliability.

The image generator features a full HD touch screen display that can be used with a gloved surgical hand and is biocompatible for easy cleaning. The multi-touch projected capacitive (PCAP) screen has an extended area below that can be used for custom touch controls and/or LED indicators and branding. The processor uses an NVidia GTX 1080 graphics card.

A robust design helps the system survive in a mobile and surgical environment. Its chemically strengthened glass overlay and outer band enclosure protect from front impact if dropped. The portable IG also has sealed front ingress protection with options to be further protected on the sided and rear.

Results

The portable image generator is medically rated with the high performance our customer needs for image-guided surgery. EmbedTek's proven expertise in mobile imaging technology and medical device manufacturing made it possible for our customer to create the high performance portable solution they wanted, built to ISO and FDA standards, and following a normal supply chain with long-term consistent revision control.



In just under 4 months, EmbedTek produced a functional first article for a high performance mobile image generator with touch screen.

8 weeks – developed first prototype

16 weeks – developed production prototype

20 weeks – ready for regulatory review

24 weeks – produced the first article

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.