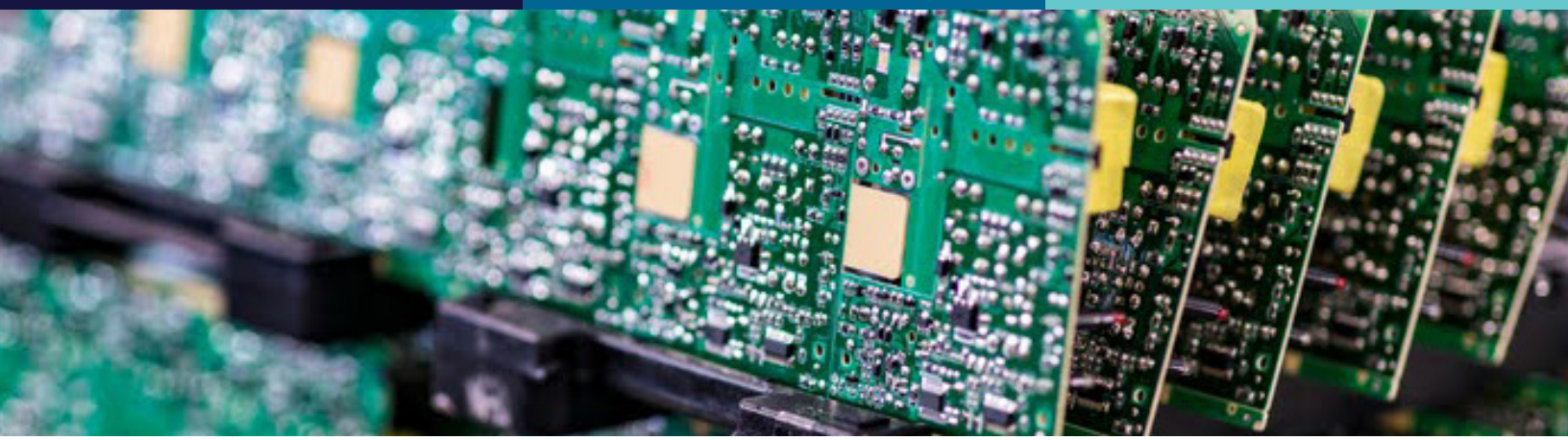
Ultimate Guide to Medical PCB Assembly

MATRIC GROUP

MATRIC | DYNAMIC MANUFACTURING | WINDURANCE

TABLE OF CONTENTS



DESIGN

First things first: HDI PCBs are able to incorporate a high volume of internal wiring by using advanced technologies to make them more compact. The new technologies help reduce size without sacrificing performance, giving engineers multiple options for construction depending on the application.
HDI boards require additional manufacturing technologies such as:

- Sequential laminations
- Stacked microvias
- Staggered microvias
- Buried vias
- Plated through holes
- Laser drilling

WHY ARE HIGH-DENSITY BOARDS VITAL TO MED TECH?

Medical device manufacturers must meet the highest standards, meaning they produce the best HDI technology currently available. There's also the matter of quality of life -- the less invasive and intrusive a device is, the earlier it'll be for a patient to live with it.

The need for cutting-edge technology in the design of medical electronic devices is most obvious when you look at implants. For example, pacemakers need to be small, lightweight, and reliable. The high-speed transmission in HDI PCBs is highly desirable for medical devices where device response times can mean life or death.

Demand for smaller boards and better performance have resulted in HDI PCBs that allow for more components to be placed on each side of the raw board. Designers can use increased I/O in smaller spaces. The signals can transmit more quickly with less signal loss.

HDI PCBs are more challenging and expensive to design and manufacture, but often the gains are worth the cost. Medical PCB assembly often demands HDI tech, even at increased per-board costs.

LIMITATIONS

Every technology has limitations, and HDI PCB technology is no exception.
For most medical device manufacturers, the biggest limitation of HDI technology is its cost.

Manufacturing HDI boards requires expensive equipment and expertise that not every board manufacturer possesses. The yields are lower because each board requires more time to build. The multiple layers of the board need to be built up with the right materials to achieve the intended result.

The technology is relatively new and evolving quickly, so what was true last year may not be true this year. You also have to figure out which of the six variations makes the most sense for your device -- a difficult task without an expert in-house.

COMPONENT SHORTAGES: WHAT MEDICAL DEVICE ELECTRONICS DESIGNERS NEED TO KNOW

The big reason why component qualification medical device shortages are so rampant is because medical technology changes in a heartbeat. When you combine these changes with an increasing demand for electronic parts, electronic component suppliers can't quite keep up with the pace of change.

And it's not just one type of component that's experiencing high demand -- it's everything from capacitors to resistors to integrated circuits. To further complicate matters, manufacturers might face any or all of the following issues:

- Lengthy lead times for specialized electronic components
- Supply chain interruptions because of natural disasters, political turmoil, diseases, etc.
- Dragged-out FDA approval for medical device electronic components

If you source all your parts from a single region or factory, and that region is hit with a tornado or a hurricane, or some other unpredictable event (see: COVID-19), it can really throw a monkey wrench in the supply chain.

Even though electronics manufacturing providers want to provide fast and easy service for medical electronics components, sometimes extenuating circumstances prolong the time to market in product development, which can irk end customers.

WHY ARE MEDICAL EQUIPMENT COMPONENTS SO SCARCE?

You might remember from your high school economics class the basic principle of supply and demand. With continued growth in the medical device sector, there will be high demand for components, often resulting in limitations in the supply chain -- at least in the short term. Not to mention that technological advances keep on coming down the line, changing the demand for certain components.

When will the shortage end? Your guess is as good as ours. The need for electronic components for medical applications is never-ending, so predicting when the supply chain will catch up to the demand is a bit of a guessing game.

That doesn't mean there's nothing you can do about it. Taking the necessary precautions to weather the storm can go a long way in traversing the shortage landscape, so to speak.

HOW TO AVOID ELECTRONIC COMPONENT SHORTAGE

How can your company get ahead of the component shortage and keep production flow moving and customers happy?

STOCK UP	FORECAST	BUILD RELATIONSHIPS
If your cash flow situation allows for it, purchasing your components well in advance can alleviate the strain of a component shortage. They'll be ready to integrate into devices when you need them. This is especially true for components with long lead times, which can slow device production and profitability if you're left waiting. However, buying in advance does have a risk to it, especially when you consider obsolescence management and how a great component for today may be worthless tomorrow.	Accurately forecasting your component needs can significantly lower the amount you have to shell out for components. If you scope out what you'll need months, or even years, in advance, you can hop ahead of the supply and demand curve. Your electronics manufacturing services provider should always communicate potential obsolescence or shortage risks to you.	Who do you work with to acquire components? Whether it's a supplier or a contract manufacturer, we encourage you to build a relationship with these entities so they're more than just a partner -- they're an extension of your business. By doing so, you're much more likely to have transparent discussions about the parts that you need and work together on solutions to overcome certain component challenges.

ADDRESSING OBSOLESCENCE

Most medical and electronic Printed Circuit Boards (PCBs) are produced overseas, however, even under ordinary circumstances, this leads to extended shipping times, translation difficulties, and potential issues during transit.

Further, when errors in manufacturing occur, parts are defective, or a wrong component is shipped, delays can stretch out months, and in some cases, years.

With the COVID pandemic still raging in some parts of the world, these problems have only been exacerbated by staffing shortages, global parts shortages, and shipping backlogs. Nearly every industry saw massive delays and increased shipping rates in overseas manufacturing.

In particular, for the medical industry, the global component shortage has delayed some orders 8-10 months, with legal and medical issues compounding, and medical device OEMs have had to face serious concerns over device obsolescence.

The shortages and bottlenecks in the supply chain have made obsolescence risk mitigation much more difficult. Some medical device manufacturers may need to plan several years ahead to ensure their equipment does not become unserviceable.

While obsoleses in medical devices is a major problem for medical professionals and healthcare organizations, the patients are those who suffer the most.

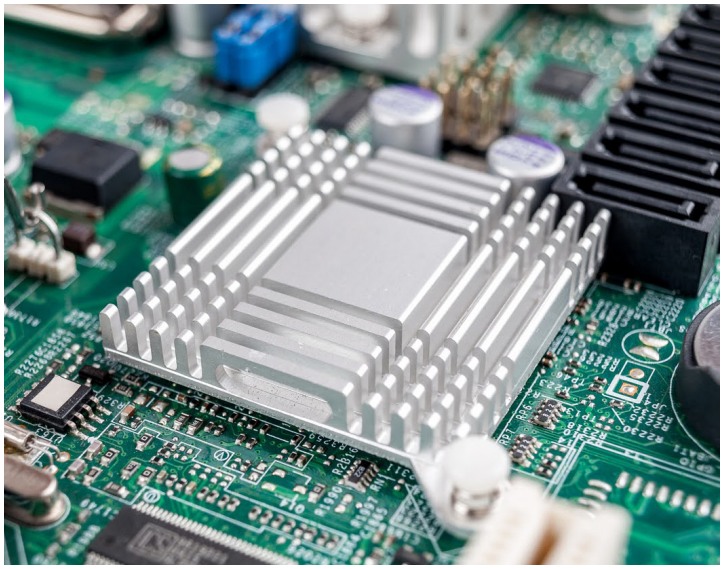
But the good news is that coping with these growing difficulties is no longer complex, thanks to domestic electronics contract manufacturers. While ECMs can’t solve these problems overnight, finding a reputable ECM with experience in the medical industry can protect your patients and reduce the risk of obsolescence.

MEDICAL DEVICE OBSOLESCENCE MANAGEMENT WITH DOMESTIC ECMS

More and more medical device manufacturers are turning to ECM's to produce the electronic components in their devices. The advantages of working with onshore ECMs are straightforward: They help maintain inventory and ensure timely shipments.

But that's just the start of what an on-shore ECM can provide a medical device manufacturer. Domestic ECMs also offer:

- A Single Point of Contact: If you have a problem, one phone call can set the solution in motion
- Faster Concept To Finish Processing: With shorter shipping routes, fewer checkpoints, and simple contact lists, new designs can find their way to the production floor more quickly
- No Loss in Translation: Translation inefficiencies lead to all manner of problems including the wrong electronic component being shipped
- Reverse Engineering: If you're working to understand a piece of equipment to perform on-site repairs, having a domestic ECM makes things much easier
- On-Site Engineers: With engineers on-site at your original equipment manufacturer, you can work with them to solve technical problems and optimize your equipment
- Vetted Suppliers: With foreign ECMs, often you don't know who is doing the actual supplying. You may be working with a dispatcher who routes your order to a supplier you might not ordinarily want to work with. With local ECM, you work with the suppliers you trust most.
- Local ECMs are more able and willing to provide technical support when something goes wrong. In the medical industry, having a good medical device electronics design is just part of the equation. For competitive functionality, you need an ECM that is close enough to provide the service you require.



MANAGING OBSOLESCENCE IN MEDICAL DEVICE PRODUCT LIFE CYCLE

Medical devices need to be reliable and up-to-date to ensure the safety of the patient. With that said, any electronic device will move through the life cycle and ultimately need parts replaced. If the part happens to be obsolete, then issues can occur. Obsolescence management is the way to be proactive and reduce the occurrence of these issues.

4 GUIDELINES FOR MEDICAL DEVICE PRODUCT LIFE CYCLE MANAGEMENT

The medical equipment life cycle is delicate and complicated. If we had to shave it down to four facts to remember, they'd look like this:

1. Component suppliers will drop a product line in a heartbeat.
2. Regulations make obsolescence management time-consuming.
3. Careful planning in the design stage can patch up obsolescence issues.
4. Your contract manufacturer should help you navigate component obsolescence.

1. COMPONENT SHORTAGES CAN CAUSE SERIOUS HEADACHES AND FINANCIAL LOSSES

When a part goes obsolete, a component supplier may end production of it before you can properly react. This can lead to major disruptions in your ability to produce life-saving equipment.

Situations like COVID-19 only increase the frequency of supply chain snags. During the crisis, some component vendors shut down, not realizing the havoc they were causing to OEMs. Just one missing component can prevent the shipping of a product.

In highly regulated industries, some components are already hard to come by, making the slightest disruption a challenge:
A customer of ours once had an application that required ceramic capacitors. The component supplier suddenly decided to stop making the part, even though the customer had in-progress orders from multiple major auto manufacturers. The supplier's response? "Sorry. Too bad."

Matric Group itself once had to pause production of an aerospace product because the one facility in the world that built the component shut down due to COVID.

Even just a few weeks' delay in sourcing a component can leave your electronics contract manufacturer (ECM) unable to continue producing your device.

2. REPLACING OBSOLETE COMPONENTS CAN BE DIFFICULT AND TIME-CONSUMING DUE TO REGULATORY COMPLIANCE

Just like with aerospace manufacturing, medical device manufacturing requires cutting past a lot of red tape to comply with current laws. While it might be OK to absent-mindedly switch out parts in the rest of the electronics industry, the same is not always true for medical devices. You have to wait for the whole regulatory process to play out every time you make a change to the guts of your device.

If you have an issue with a component on your medical device PCB that the FDA signed off on, you can't replace it without getting it cleared. Now you have a $10,000 piece of medical equipment that's waiting for months on a $1 part.

3. CAREFUL PLANNING DURING THE DESIGN STAGE CAN HELP AVOID OBSOLESCENCE ISSUES

Situations, where you have to stop everything due to a component shortage, are deeply frustrating -- but some of them are avoidable. There are a few useful approaches that can minimize such risks:

- Be as vague as possible on specifications. This makes it easier for the ECM to find a suitable alternative when necessary.
- Use software to follow parts through their lifecycle. Third-party component obsolescence software like SiliconExpert can help you follow your components throughout their life cycle so you can identify when problems are likely to arise. You can spot problems early on and proactively resubmit components for FDA approval.
- Make a large last-time buy. If you know obsolescence could really harm your product line, be ready for potential last-time buys to minimize downtime. Third-party software and the watchful eye of a good PCB manufacturing partner can help you do this.

4. THE RIGHT ECM VENDOR WILL HELP YOU MITIGATE THE RISKS OF OBSOLESCENCE

Work with an electronics manufacturing contractor that has experience in medical equipment life cycle management, and the tools to do it. Early on in the medical device electronics design process, your ECM can help you identify opportunities for proactive obsolescence management.

Your ECM can take the lead on managing software like SiliconExpert to track the parts you need for your product. Your partner should also be well-practiced in identifying and sourcing alternative parts that are compatible with your design.
And of course, your PCB supplier should absolutely have ISO 13485 certification.

ISO STANDARDS: ISO 9001 VS. ISO 13485 CERTIFIED MANUFACTURER

You may be asking, if the issue is quality, isn't ISO 9001 -- and its emphasis on continuous improvement and customer satisfaction -- enough? Not in the medical world.

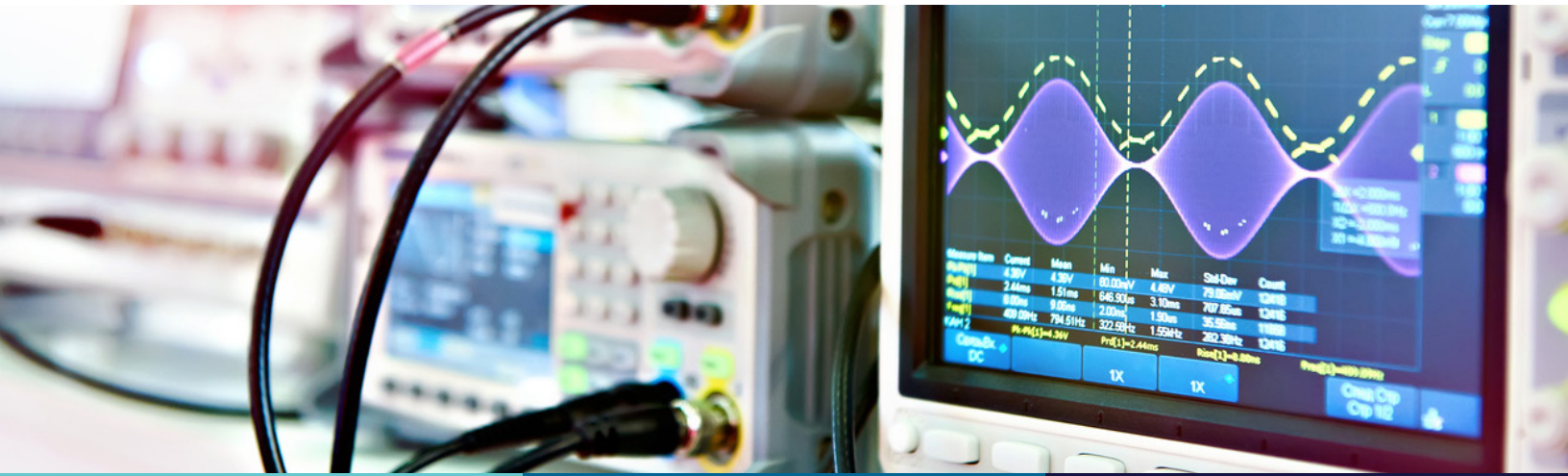
If a contractor has ISO 13485 certification, it also has ISO 9001 certification. However, ISO 13485 adds critical requirements around devices, documentation, and safety.
A standard for quality management systems aimed specifically at medical devices, ISO 13485:2016 (the full name of the latest version) focuses on covering your butt in case of an issue. More specifically, the emphasis is on managing risk -- on foreseeing and fixing problems before they occur:

- Record keeping
- Device history records
- Regulatory requirements for documentation and records
- Product and process verification procedures are carried out on protocols specific to medical devices
- A contractor's entire supply chain is re-evaluated
- Auditing occurs annually

In other words, ISO 13485 represents an exhaustive effort to make sure each component meets rigorous medical device manufacturing standards.

In many cases, the electronics contract manufacturer is ISO 13485-certified, but the OEM ordering that PCB (printed circuit board) assembly isn't. OEMs are strictly regulated by FDA medical device regulatory requirements and have to comply with Current Good Manufacturing Practices (CGMP), which focuses more on the finished product than the guts within.

The spirit of those same guidelines is baked into ISO 13485, so certified manufacturers have shown to auditors that they've applied CGMP, too. That's yet another valuable layer of support behind a medical device manufacturer!



ISO 13485 CERTIFICATION: A CRITICAL EXTRA LAYER

IPC (another standards org you're probably familiar with) lists medical equipment as Class 3 electronics. Unsurprisingly, this is because failure of a circuit board or component could put lives at risk.

A manufacturer doesn't have to be an ISO 13485-certified company to meet medical device manufacturing regulations. And it doesn't have to be certified to make and sell medical device components or the finished devices.

However, a medical device manufacturing certification tells everyone -- regulators and customers included -- that your electronics underwent an objective evaluation by a third party and are proven to be safe.

An electronics manufacturer can be part of a long supply chain. With a specific ISO certification for medical devices on its side, a contractor can ensure its end of the deal meets the highest standards.

MEDICAL DEVICE CONTRACT MANUFACTURING WITHOUT ISO 13485

Such rigor is not mandatory -- you can legally release a product to the market without using a certified supplier. It's up to you whether to add this layer of quality control.
So, what could go wrong if this "unnecessary" certification isn't accomplished? What if a component manufacturer doesn't have ISO 13485 certification and something goes amiss when the device is used in the emergency room?

Chances are the FDA will investigate the OEM. And that means the OEM will need lots of records to verify compliance with regulated processes. If the medical device contract manufacturer can say with confidence that all the necessary records are available, any OEM will sleep easier.

OEMs want validation of a contractor's manufacturing processes as a way to help validate their final products. A PCB manufacturer's records must meet strict medical requirements.

Some contractors go a step further in the validation process. They audit their critical component suppliers annually to make sure they meet the contractor's testing and inspection standards. Working with such a contract manufacturer is a great way to reinforce the safety chain without lifting a finger.

Medical PCB Assembly | Final Thoughts

As with any technology, the medical PCB assembly is the heart of the medical device. We have pointed out necessary steps to ensure success in the design process, discussed notable limitations to consider and how to avoid component shortages, the best ways to keep obsolescence management in mind, and the importance of adhering to ISO standards.

This guide is intended to share the key points of the medical PCB assembly journey and have your project finalized on the most manageable timeline.

MATRIC BRINGS EXPERIENCE TO YOUR PROJECT

A project involving medical PCB assembly requires attention to standards and meeting strict regulations. We hope our resource answered some essential questions and that you can now consider the next steps in your medical PCB assembly process.

ANY QUESTIONS?

ANY QUESTIONS ABOUT MEDICAL PCB ASSEMBLY?

Our engineers can provide some insights, and our resource library is full of potential content to answer lingering questions.

In short, Matric Group can help.

ABOUT US: Matric Group has invested in state-of-the-art machinery to improve the speed, accuracy, and reliability of our products since 1971. With a focus on improving for the future, we committed to an expansion in 2024 that will offer space and equipment to meet the growing needs of our clients.

ADDITIONAL RESOURCES

Your Go-To Guide to Reducing PCB Assembly Cost

Robotics & Current PCB Manufacturing Techniques: The Latest

REACH Compliance: Understanding Electronics Manufacturing Standards

Intrinsically Safe Equipment: What It Is and Its Importance

Electronics & the Basics of Obsolescence Management