

A Comprehensive Guide to **OEM vs. Third-Party** Medical Device Parts

Navigating
the Healthcare
Equipment
Supply Chain



ELITE
BIOMEDICAL
SOLUTIONS

Introduction

Hospital profit margins are rising post-COVID-19, but expenses, **increasing by up to 3% annually**, pose challenges. Choosing suitable replacement parts suppliers is crucial and requires balancing care quality and ROI amid various considerations, such as compliance, patient needs, safety, technology advancements, cybersecurity, and supply chain resilience.

Under such pressure, most purchasers of medical device replacement parts will face a pivotal choice: **either stick with the original equipment manufacturer (OEM) or trust parts made by third-party manufacturers**. Deciding between these two options involves a multifaceted and nuanced decision-making process with various considerations. These can differ broadly depending on the organization.

Furthermore, individual medical device components can significantly impact device function, patient safety, and the bottom line. For optimal clinical performance, medical devices require compatible, high-quality device components. Even parts that seem insignificant can compromise functionality and, therefore, quality of care. While the capital expense of replacement parts may threaten the bottom line, the same can be true if inferior parts cause extended downtime, excessive repairs, or adverse patient events.

To make the best decision, healthcare professionals need information and resources that shed light on contributing factors and assist in tailoring the decision to their organization's unique circumstances.

The purpose of this guide is to assist buyers at all levels, including:

- Hospital administrators,
- Purchasing agents
- Health technology managers
- Biomedical Equipment Technicians (BMETs)

This guide will help those buyers to understand and evaluate their options by exploring the following:

- Overview of OEM and third-party parts
- The pros and cons of both options
- Organization-specific factors to consider
- Comparing these options in terms of patient safety and cost savings
- The importance of choosing a reliable third-party manufacturing partner
- The advantage of partnering with a U.S. parts manufacturer



For optimal clinical performance, medical devices require compatible, high-quality device components. Even parts that seem insignificant can compromise functionality and, therefore, quality of care.



Understanding OEM replacement parts

OEM replacement parts are crafted with materials and specifications identical to the original components.

The FDA requires OEMs to adhere to rigorous quality controls outlined in the [U.S. Code of Federal Regulations Title 21 part 820](#) (21CFR820) when designing and producing medical devices.

Advantages of OEM parts:



COMPATIBILITY

OEM parts are typically manufactured on the same tooling, using the same manufacturing process as the original device. Theoretically, they should fit the machine seamlessly, ensuring functionality.



RELIABILITY

The OEM must satisfy the FDA's quality standards and the parts must undergo testing to ensure compliance with the design, and fluid ingress, when necessary. Because of the adherence to the quality standards, Buyers can expect OEM parts to perform as promised, and they can count on them to function well and keep patients safe.



WARRANTIES AND MANUFACTURER SUPPORT

OEM warranties typically offer a broad coverage range. The warranty may include the part itself, and even the labor costs for installation or repairs, as well as technician support. OEMs may cover more issues than some third-party warranties.

Disadvantages of OEM parts:



HIGHER COSTS

OEM parts usually come with a premium price tag. Original manufacturers, like some third-party manufacturers, invest in research and design, quality control, regulatory compliance, warranty coverage, tech support, and brand reputation. Specialized supply chain requirements can limit vendor options for OEMs, increasing expenses. Additionally, most OEMs have name recognition value, which can result in a cost premium, as well as higher overhead due to their typically larger scale. All those costs then get passed on to the customer.



PROCUREMENT CHALLENGES

A variety of factors can interfere with the availability of OEM replacement parts. These may include prolonged negotiations with the manufacturer or distributor, OEM supply chain interruptions, or lack of parts for discontinued equipment. Many OEMs experience backorders for shipping replacement parts.



SUPPLY CHAIN ISSUES

OEMs may rely on multiple overseas suppliers. Although the global supply chain **continues to improve** following the COVID-19 pandemic, the average delivery time for production materials **has yet to return to pre-pandemic levels**. Overseas suppliers, whose process already includes built-in pauses due to international trade laws, are most likely to face extended turnaround times.



DISCONTINUED COMPONENTS

Additionally, advancing technologies push OEMs to innovate new designs and systems continually. As a result, older models often reach end of life, including parts production and tech support. Without replacement parts, hospitals and health systems may be forced to retire functional, mission-critical equipment that otherwise could help keep patients safe and provide quality care for years.



Factors potentially contributing to OEM supply chain challenges

- Shortages of raw materials, such as metals, alloys, and resins for plastics
- Lack of skilled labor
- Cyber attacks on technology in supply networks
- Geopolitical volatility
- Energy crises
- Climate change

OEMs may focus on one area of expertise, such as R&D, so they may rely on contract manufacturers to make many device components. These contractors have their own supply networks, meaning the parts production process could have multiple points of vulnerability to supply chain setbacks.

Exploring Third-Party Replacement Part Alternatives

The existence of third-party replacement parts introduces an alternative to the medical equipment procurement landscape. These components, produced by entities distinct from the OEM or end-users, generally provide a cost-effective option compared to OEM parts.

However, unlike OEMs, the FDA doesn't regulate parts or individual components, so the quality of third-party parts varies between vendors. Some companies voluntarily implement a rigorous quality management system and manufacture reliable products of OEM level, but plenty of mid to lower-quality third-party parts are also on the market. Thus, it is imperative that buyers select their third-party manufacturers carefully and ensure they identify a trustworthy business partner.

Advantages of third-party parts:



COMPATIBILITY WITH OLDER EQUIPMENT

Third-party manufacturers often produce replacement parts for legacy and discontinued medical equipment. This allows healthcare organizations to extend the lifespan of devices the OEM no longer supports. [Safely maintaining older devices](#) can save thousands of dollars, significantly lowering capital asset expenditure.



COST-EFFECTIVENESS

Due to various factors, third-party parts are typically more affordable than their OEM counterparts. Third-party businesses usually have lower overhead and production costs. They can also utilize alternative distribution channels—including selling directly to the end-user, bypassing some costs associated with traditional OEM distribution networks. Third-party manufacturers may have more control over their supply chain, allowing them to optimize for better cost efficiency and source materials at lower prices. These savings are reflected in the product prices.



TRANSPARENT PRICING STRUCTURES

Transparent pricing allows healthcare organizations to plan and allocate resources more effectively. Some OEMs use complex pricing models, and distributors and vendors can negotiate tiered pricing structures for different customers. This complexity and variability can result in hidden costs.



RAPID PROCUREMENT

Streamlined supply chains and leaner manufacturing processes, among other things, usually enable third-party companies to produce and deliver parts faster than most OEMs. Faster delivery allows hospitals to maintain tight schedules, reduce asset downtime, prevent the interruption of patient care and clinician workflows, and a range of other benefits.

The lack of these factors results in a generally competitive third-party sector, encouraging transparent pricing. Transparency allows customers to compare costs among different suppliers easily. It also allows buyers to make informed decisions because they can evaluate the overall value proposition.



How procurement time impacts healthcare organizations

Longer wait times for replacement parts can lead to extended equipment downtime, affecting quality of care, operating costs, and more.

IMPACT ON COSTS

Extended downtime can result in increased operating costs, including:

- Emergency procurement costs
- Costs due to missed maintenance and repairs
- Transportation costs for either devices or patients to accommodate for low device inventory
- Soft costs accrued due to factors such as inefficient workflows, care interruptions, and extra labor hours related to device downtime

IMPACT ON PATIENT CARE

The impact of device downtime on patient care may include:

- Delayed diagnosis and treatment
- Disruptions in care continuity resulting from rescheduled appointments, canceled procedures, and other care interruptions
- Compromised patient safety due to lack of device availability

Extended asset downtime can also increase stress levels for healthcare professionals, leading to burnout. Delays in services and treatments and reduced care quality may cause patient dissatisfaction and compromise the organization's reputation.

Disadvantages of third-party parts:



QUALITY CONCERNS

Because third-party manufacturers aren't legally required to comply with 21 CFR 820, many companies do not implement a rigorous quality management system, often resulting in inferior parts. Some manufacturers, including overseas companies, cut corners in the production process or in their commitment to quality, because doing so increases their profit margins.

The good news is that reliable, trustworthy partners are out there. Some third-party manufacturers participate in voluntary quality certifications, such as the ISO [13485:2016](#) standard outlined by the [International Organization for Standardization \(ISO\)](#). This standard outlines a [quality management system \(QMS\)](#) similar to the 21 CFR 820 guidelines.



LIMITED MANUFACTURER SUPPORT AND PRODUCT WARRANTY

Third-party companies may not provide robust product support, potentially increasing the workload of hospital BMETs or third-party maintenance providers. However, some third-party manufacturers understand that product quality goes beyond the point of sale, so they provide their customers expert maintenance and repair support.

Not all third-party parts come with a comprehensive warranty. Again, this varies between companies. Some third-party manufacturers provide virtually the same warranty coverage as the OEM.



POTENTIAL IMPACT ON DEVICE WARRANTY

Many OEMs prohibit the use of third-party parts while the device is under warranty. Buyers should read all warranties carefully before deciding to purchase third-party parts.



Organization-specific factors to consider

Every healthcare facility has specific needs regarding clinical asset maintenance. Some aspects to consider include:

- Size of the organization
- Age and size of equipment fleets
- Standing OEM contracts
- Asset management strategy
- Skills and availability of onsite BMETs
- Purchasing strategies
- Capital asset budgets
- History of device repairs

It's also wise to determine if the organization has suffered revenue loss or compromised care due to asset downtime or malfunction. Review records that reveal whether replacement parts contributed to the issue, and if so, who made them and what may have caused the problem.



Comparison: patient safety

OEM PRODUCTS

In general, OEM parts provide optimal compatibility and functionality, ensuring a high level of patient safety. Still, no OEM is infallible. Remember to check the [FDA's list of medical device recalls when considering any OEM product](#).

THIRD-PARTY PRODUCTS

Third-party parts designed to meet OEM quality can ensure the same level of patient safety as the original part. Stakeholder comments on a [2018 FDA report](#) expressed confidence that third-party entities with ISO 13485 certification are equipped to provide safe and effective parts and repair services for medical devices.

Comparison: cost-effectiveness

OEM PRODUCTS

- Consistent quality can lower maintenance and downtime costs and reduce total cost of ownership (TCO)
- Warranty may cover more maintenance costs
- Higher ticket price
- May not use transparent pricing structures
- Longer procurement times can raise operational costs

THIRD-PARTY PRODUCTS

- Lower ticket prices
- More transparent pricing structures
- Can extend the lifespan of older devices
- High-quality third-party parts match OEMs for cost-savings
- Faster delivery times minimize asset downtime costs
- May not offer full warranty coverage
- Low-quality parts can raise TCO

American Excellence: The Third-Party Advantage on Home Turf

A low sticker price can be tempting, but the initial savings on cheap third-party parts could evaporate if inferior parts cause device failure or, worse, affect patient safety. Organizations considering a third-party biomedical manufacturing partnership should prepare to invest some time and resources in vetting potential partners.

Requiring ISO 13485 certification is an excellent first step in assessing whether a third-party company prioritizes exceptional quality. It's also necessary to confirm the business adheres to its QMS, can deliver products on time and as expected, and provides dependable customer service. To do so, buyers can ask to see a demonstration of the QMS, observe production runs, review documentation, and communicate with various representatives along the chain of command.

The “Made in USA” difference

To evaluate potential third-party partners effectively, purchasing agents need a clear picture of how the business handles manufacturing, quality, the supply chain, customer relations, and pricing. Choosing domestic third-party manufacturers makes it easy to observe the facility, review documentation, speak with customer service, and query representatives in person or on the phone.

A significant advantage U.S. manufacturers can offer is a comprehensive view of their supply chain. To use the label “Made in the USA,” a business must document that **“all, or virtually all” parts, processing, and labor originate in the United States.** That means the manufacturer must vet the supply chains of their own suppliers to ensure virtually all aspects of production occur stateside. Fully domestic supply chains carry less risk because components come from closer and more stable locations.

In comparison, vetting overseas third-party manufacturers is a significant challenge. Time differences and language barriers can interfere with communication, viewing production onsite may be out of the question, documentation may not be available or forthcoming, and insight into the supply chain can be impossible.



U.S. medical device parts: dependability meets affordability

The price for US-made parts is higher than overseas components. But typically, the cost is still lower than OEM replacement parts. That's because **U.S. manufacturers with complete control over their supply chain,** product design, and facilities also have vendor relationships and other resources that allow them to keep prices affordable. In addition, the cost of shipping is usually lower for U.S. products.



Reaching a Decision: Risks, Benefits, and Beyond

Both OEM replacement parts and third-party parts have their risks and benefits. When choosing between the two, the best course of action is to gather as much information as possible. This requires purchasers to exhaustively evaluate third-party manufacturers, thoroughly question vendors and OEM representatives, read the fine print in OEM contracts, and gather granular equipment data from the healthcare organization itself.

Although the process is complex, decision-makers who take the time to evaluate from multiple angles may discover that choosing a replacement parts supplier becomes a valuable opportunity. Determining the best choice for the organization can effectively enhance patient care, streamline clinician and BMET workflows, reduce administrative burden, and improve fiscal health.

Expert Insights and Additional Resources

For additional resources on high quality standards and vetting a reliable partner, see the following Elite Biomedical Solutions resources and articles:

- [The Ultimate Guide to Vetting Quality Medical Equipment Partners](#)
- [Case Study: How We Helped an HTM Partner Cut Costs and Boost IV Pump Repair Quality](#)
- [Debunking Myths: Third-party Biomedical Equipment Services in Healthcare Explained](#)
- [How to Reduce Medical Device Costs with Quality Third-Party Biomedical Replacement Parts](#)

Elite Biomedical Solutions is an ISO 13485:2016-certified, U.S.-based manufacturer. Our industry-leading QMS, cutting-edge reverse engineering process, and commitment to the highest standards produce affordable, OEM-quality parts that can boost ROI and extend the lifespan of infusion and telemetry assets.