The **Ultimate Guide** to Vetting Quality Medical Equipment Partners

Critical steps towards a robust RFP that demonstrates quality, cost savings, and patient safety

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Introduction

As a leader in the healthcare sector, you know strategic partnerships provide a competitive edge and help you achieve your goals. When it comes to choosing the right medical equipment partner, you also know that a strong partnership ensures mission-critical biomedical devices perform and facilitate essential medical care that improves health, supports procedures, and saves lives.

Infusion pumps, telemetry devices, and other hospital biomedical devices work hard. For example, **in a 2018 survey, hospitals of all sizes reported high use of smart infusion pumps when administering IV medications (99%), IV fluids (96%), and blood transfusions (93%).**

Such devices aren't cheap, so they're expected to last for years. Repairs are inevitable. And replacement parts are a cornerstone of medical device repair.

Unfortunately, creating strategic supply partnerships for medical device parts is more complicated than partnering with an OEM, ISO, or 3rd Party Companies. Differences in regulatory standards, legal liability, economic power, and other factors mean that product quality may vary widely between companies.

Under these circumstances, patient safety values, functionality, and ROI comes down to the practices of the individual business. When health technology managers take a meticulous, values-based approach to qualifying and vetting candidates, they set themselves up for success in achieving a mutually fulfilling partnership.

This guide outlines an actionable approach for quality vetting and assessing the ethics, reliability, and other offerings that a OEM, ISO or 3rd-party biomedical equipment business brings to the table.

Topics covered include:

- **Advantages of a Values-Based Partnership**
- **How to Approach Deep-Dive Vetting Before the RFP**
- **Going Beyond Standard RFP Requirements**
- **Vetting Tips for Busy Hospital BMETs**

Finding a partner with a values-driven business model, leveraging ROI and cost savings in service of patient safety, comes with some challenges. But the process will lay the foundation for a long-term relationship that supports exceptional healthcare delivery and life-saving risk reduction. For patients, these benefits are priceless.

STRONG PARTNERSHIPS FOR INDIVIDUAL HOSPITALS

* Robust biomedical equipment partnerships offer benefits regardless of the organization's size, from the largest independent service organizations to individual BMETs working for stand-alone hospitals.

At the hospital level, BMETs can also use a values-based approach to develop solid relationships with companies that provide parts and repair services.

See page 9 for helpful tips BMETs can use to qualify a new parts and repair partner.

The Advantages of a Values-Based Partnership

Forging strong partnerships takes time and resources. The good news, however, is that your effort can have a tremendous pay off — if done correctly. A contract with a values-based, 3rd-party biomedical equipment company provides an advantage for healthcare leaders across multiple vectors.

Values-based partnerships can help address common HTM concerns, including:

- **Product quality variations**
- **Customer service issues**
- **Slow repair turnaround**
- **Back-ordered parts**
- **Extended device downtimes**
- **Inconsistent repair quality**
- **Inefficient use of BMET labor hours**
- **Extra stress for clinicians and technicians**
- **Complex hospital supply chains**
- **Bloated equipment spending**

One area that decision-makers may overlook when evaluating prospective manufacturing partners is risk sharing. When an OEM device fails, customers take a hit. Risk mitigation may be even more challenging if the OEM refuses to absorb any related customer expenses, such as cost of temporary rental equipment. And there's no guarantee that a company will stand by the healthcare partner.

However, a values-driven USA manufacturer that truly prioritizes patient safety will take responsibility for risk sharing. That means the partner stands by the healthcare organization publicly and financially. A partner that helps the organization with unexpected costs and takes a responsive approach to problem solving can significantly offset the impact of a product recall or patient event.

How to Approach Deep-Dive Vetting Before the RFP

Vetting a 3rd-party manufacturer and/or repair company is not the same as vetting an OEM brand. OEMs are subject to rigorous FDA medical device standards as outlined in the U.S. Code of Federal Regulations (CFR) Title 21 part 820. But 3rd-party companies that manufacture "after-market" medical device parts aren't legally required to comply with 21CFR820. That can result in a less rigorous quality management system (QMS) and a lack of transparency regarding sourcing and manufacturing processes. Ensure that your selected 3rd-party company is FDA registered, is ISO 13485:2016 certified, and does comply with 21CFR820.

In the end, it falls on HTM decision-makers to investigate the operations of 3rd-party partners entirely on their own. Deep-dive vetting helps purchasers uncover insightful information so they can narrow the candidate pool before dropping the official request for proposal (RFP).

Vetting the Supply Chain

The level of quality a manufacturer can deliver is directly tied to the supply chain. Global shipping delays, reduced inventory, new tariffs, and other factors can affect production and delivery. Additionally, insufficient regulation in some locations means parts may cost less but are substantially inferior to parts made by US manufacturers.

Of course, unforeseen factors do affect the domestic supply chain, but federal regulation limits those unknowns. And an unexpected issue in one link is less likely to negatively impact multiple branches of the US chain.

The most practical way to avoid unforeseen supply chain issues is to build partnerships with US manufacturers. Biomedical equipment parts that display the "Made in the USA" label must be made from domestically sourced materials under ethical labor practices.

Relying on the US supply chain also means that a 3rd-party candidate is capable of vetting all of *their* suppliers. It also means the candidate—and therefore the customer — can review or observe all production processes and QMS procedures.

MADE IN THE USA

* According to Federal Trade Commission (FTC) guidance, a product advertised as "Made in the USA" must have "all, or virtually all" parts manufactured in the United States. US FDA quality standards exceed the established standards of many other countries.

When you "buy American", you're also supporting secure US jobs, ethical labor practices, and the health of the domestic supply chain.

Look for US Manufacturing In-House

Limiting candidates to US manufacturers will eliminate many loose ends that can derail the vetting process. Complications are more likely if a candidate outsources partial fabrication to another contractor.

Issues can occur if the sub-contractor does not:

- **Use a robust QMS**
- **Specialize only in medical devices**
- **Employ trained labor**
- **Perform regular maintenance on production equipment**
- **Ensure the facility is clean and safe for employees and production integrity**

The partnership candidate may excel at assembling the final product. But gaps in technical experience and quality management prior to in-house assembly can have serious repercussions. Selecting a US business that does all manufacturing in-house increases confidence in a potential biomedical supply partner.

Always Investigate Engineering and Design

To raise the confidence level even higher, purchasers should qualify the product engineering process in addition to the QMS. After-market parts manufacturers that produce cheap parts fast typically disassemble the OEM part and quickly copy its measurements. Unfortunately, copying tends to result in parts that lack mechanical integrity.

A “reverse engineering” process is more time consuming. But reverse engineering allows the design team to carefully analyze the OEM part, then use an independent design process to guarantee product uniformity. It also allows for selection of superior materials, often resulting in a 3rd-party component that is higher-quality. Ask to meet with the in-house engineers to better understand their process.

Evaluating the Quality Management System

UNDERSTAND WHICH CERTIFICATIONS INDICATE HIGH QUALITY STANDARDS

Third-party biomedical companies can choose to participate in voluntary quality standard certification programs. The following certifications indicate the business has committed to producing higher-quality replacement parts.

ISO 13485

The International Organization for Standardization (ISO) is an international, non-governmental organization that develops technical, industrial, and commercial standards that help streamline global trade. The ISO 13485:2016 standard outlines a QMS designed for medical device manufacturing. Like FDA 21CFR 820, ISO 13485 requires constant risk mitigation from research and design through market launch.

FDA REGISTRATION

Voluntary FDA facility registration indicates the candidate has agreed to follow the FDA's Current Good Manufacturing Practices (CGMPs). FDA registration requires routine facility inspections for recertification.

Observing the Facility

Certifications are important, but if the manufacturer doesn't adhere to the required quality standards, a certification is just a piece of paper. The benefits of personally touring a potential partner's facility shouldn't be underestimated.

A tour allows purchasers to:

- **Verify the QMS is in active use**
- **Evaluate company culture through staff attitudes, helpfulness, and body language during calls and tours**
- **Review the candidate's organizational structure**
- **Talk to members of the quality department and other departments involved in meeting HTM supply needs**
- **Ask questions about troubleshooting, risk mitigation policies, emergency response protocols**

If the candidate also provides repair services, a tour helps verify that qualified BMETs are conducting repairs and that the business doesn't outsource any repairs.

Assessing the Customer Service Experience

When assessing customer service before the official RFP, start simple. Go through the company website. Fill out a contact form. Pick up the phone and call the customer service line. Ask about their process for ordering and repairs.

After doing so, ask yourself the following questions:

- **Is the website informative and easy to use?**
- **Are product listings easy to find and understand?**
- **Did you receive a contact form response with helpful information within 24 hours?**
- **Are staff polite and friendly during interactions via phone or email?**
- **Could a team member clearly describe the steps for ordering parts or submitting a repair?**

A clean, informative website with helpful resources indicates that the business cares about their customer experience. The same is true when team members have good manners and take the time to clarify or answer questions on the phone. Typically, when employees sound happy and appear to enjoy doing their jobs, it indicates that the business cares about maintaining a supportive company culture.

Going Beyond Standard Requirements in the Proposal Process

HTM purchasing agents can elect to go beyond standard requirements for RFPs. In addition to the ISO certification, FDA registration, QMS documentation paperwork, and quality audit results, consider requesting the following documentation to take your selection process one step further:

- All validation/ verification testing results
- 3rd-party lab test results
- Metrology results
- IPX (water ingress) testing
- Quality return rates
- Copies of the “product traveler”
- Manufacturing and production scrap rates
- Mission statement and outline of core values

One common mistake HTM companies make during the RFP is to over-emphasize pricing. Lower prices look great on paper, but if the candidate isn’t enforcing the QMS or outsources some repairs or manufacturing components, those savings can disappear from the bottom line.

Vetting Tips for Busy BMETS

Deeply vetting a new parts company takes time that busy hospital BMETs just don't have. But BMETs can use these tips to obtain background info on a 3rd-party business without taking up valuable time or resources.

Look critically at company websites

Browse as many landing pages as possible to locate all available info about the parts and services you need. Then make notes on any of following:

- Are products listed?
- Does it have useful product info?
- Is the text easy to read and understand?
- Does it use a lot of hard sales language?
- Do they have info on the website to back up sales claims?
- What's included in the about section or mission statement?
- Is it obvious that they're ISO certified and FDA registered?
- Can you tell if parts are made in the USA or overseas?
- Can you easily locate contact info? Is it complete?
- Is the site mobile friendly?

Tactical internet research

Before making calls, do just a few online searches on each competitor (disregard results from the company website) to gauge how reliable their equipment is. You can try using these search parameters to get started:

- Company name + "device recalls" or "medical device failure"
- Company-branded product name or SKU + "recalls" or "issues"
- Company name or product name under the News search category

Phone calls can offer insight not available online

Call customer service and ask about some of these topics:

- Product availability
- Ordering processes
- Shipping times
- Quality protocols
- Repair support
- Anything that you couldn't find on the website

Additionally, ask questions about any recalls or other issues that came up during online searches.

Final Thoughts

Remember that the work involved in gathering detailed data before and during the RFP empowers more informed choices about 3rd-party biomedical device partnerships.

Values-driven partnerships condense equipment spending, making expenses easier to track and cost-spend analysis more meaningful. A replacement parts company that makes ordering and tech support easy and efficient, while also freely providing relevant info will support the valuable work done by BMETS.

In the final analysis, this level of effort translates into better diagnosis, precision medication dosages, accurate vitals monitoring, and so many other elements of outstanding hospital care. That's how biomedical device partnerships help build a strong foundation — by building on the simple core values that enhance safety and take patient care quality to the next level.

ABOUT ELITE BIOMEDICAL SOLUTIONS

Elite Biomedical Solutions supports hospital biomed departments with new replacement parts, re-certified parts, and repairs that keep clinical equipment performing at optimal levels. Our industry-leading QMS, cutting-edge reverse engineering process, and commitment to the highest quality standards produce OEM-level replacement parts that can extend the lifespan of infusion and telemetry assets.