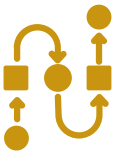
6 steps to vet the quality standards of third-party medical device manufacturers

1 Confirm the QMS aligns with FDA CFR 820

CFR 820 includes guidelines for a QMS that thoroughly documents the safety and efficacy of the new device. It also prevents medical facilities from taking on additional risk when purchasing new devices.



2 Verify ISO 13485:2016 certification can be traced back to the IAF accreditation body

To remain certified, the manufacturer must be ready to demonstrate an ISO 13485:2016 compliant QMS at any time. For this reason, certification guarantees that a 3rd-party manufacturer is following the processes and procedures put in place.

3 Consider whether the product is made in the USA or overseas

Overseas parts may be cheaper, but they often compromise on quality. A values-driven US manufacturer won't jeopardize patient safety and product reliability over increasing profits.

4 Discuss how suppliers are qualified and evaluated

Companies who source in the US can vet all suppliers, allowing them to make targeted decisions in the production cycle. This includes selecting types of steel for molds, contracting an independent testing lab, and purchasing the machinery involved in full-scale production.

5 Request an audit or documentation of the QMS

A quality-driven partner will have no problem sharing details about any part of the production cycle or demonstrating how they control and document quality in each phase.

6 Ask to observe a live production run

If you are asked to observe a live production run, then take it as a sign that a potential partner has nothing to hide when it comes to ensuring quality.

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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.

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