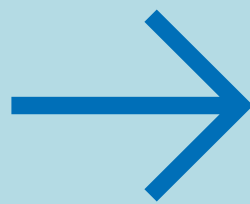




6 Key Considerations When Choosing a Medical Device Contract Manufacturing Partner





1. Company Culture

First and foremost, it is important to ensure that your partner has an organisational culture and values that are similar to yours. This is because your relationship usually lasts for the entire lifecycle of your product, due to the initial OEM and partner investment required





2. Quality Management System (QMS)

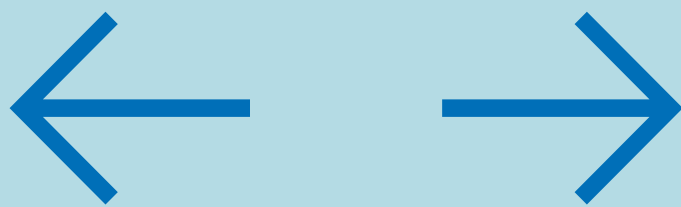
Quality is one of the most important factors in this decision-making process as a focus on quality will ensure product safety and save you both time and money in the long run. The first question you should ask a potential partner is: “Are you ISO 13485:2016 certified?”





3. Trust & Reliability

Both parties need to have complete trust and confidence in each other's capabilities, processes, and structures. The best contract manufacturers will be transparent with you from the beginning. Establishing trust and accountability is key to a truly collaborative partnership.





4. Medical Device Experience

Does the potential partner have a track record in manufacturing medical devices? How long have they been in business? What type of products have they experience in manufacturing? What are their current assets and equipment?





5. Technical Expertise

Do they have the expertise and capabilities required for your particular project? Who is on the team and how experienced are they? Ask for customer testimonials or speak to a current customer with their permission.





6. Visit - In Person

What to do on the visit?

- Meet the project team
- Ask lots of challenging questions
- Have a conversation with the production line and not just management (if allowed)
- Make sure their manufacturing standards meet your expectations.

