



East West

FREE GUIDE

# Medical Device Manufacturing: Where to Start?



It's time to find a manufacturer for your medical device, but where to start? Get familiar with the regulations and requirements about such factors as materials, quality and production conditions. Because of the critical nature of medical device manufacturing, the industry is closely monitored and regulated. No one company is an expert in everything. Perhaps capability or third party validation drives your decision. Maybe your device is electro-mechanical and you need a strong EMS partner who can help with electronics, plastic or metal housing, and complete assembly, validation, and quality assurance testing. Do you need your device to be manufactured in an ISO 13485 Class II or Class III certified facility? Here are some basic questions to ask:

### What experience do you have in medical device manufacturing?

In many cases, medical devices are complex combinations of materials and parts. Your manufacturing partner needs to have experience in making these types of intricate parts. If not the same type of device, they should have experience with something similar.

### What is your Quality Process?

You want to know if your manufacturer will make your product without defect every single time. Any manufacturer should have a written Quality Plan that they can show you. Do they have expertise in the type of testing required, such as ISO 13485 compliance?

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An East West Vietnam employee inspects components through a microscope.





East West factory workers assemble health and beauty devices in Vietnam.

### Are you a manufacturer or are you simply sourcing?

It's great to have access to the types of capabilities a manufacturer can bring to the project. Can they provide things like Design for Manufacturing, Tooling and Engineering Support, Supply Chain Optimization and Cost Reductions?

### Who's in your supply chain?

Your manufacturer should be willing and able to tell you how they vet their suppliers and ensure quality and compliance of regulations, such as RoHS.

### Can you support the volume during the life cycle of this product?

You want to find a manufacturing services partner with the capacity to take your product from the initial run to full scale commercial production, but be honest with your annual projections. Manufacturing partners have 'sweet spots' when it comes to volume.

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### Do I trust you?

This is a biggie and you really can't quantify trust. Do your due diligence. Check with references. Look at their record. Do a gut check. Culture and compatibility are important. You should be able to live with your decision.

As you look to find the right medical device manufacturer for your project, we hope asking these questions provides a solid foundation as you begin your search.