

# How to Choose the Right Medical Device Design and Development Partner

*Have an outstanding product idea that meets a specific end-user need within the healthcare industry? Have the capital and ready to get the ball rolling?*

Don't just dive into the medical device design and development process blindly, clearly define which partner is right for you and your product.

Aligning with the right design and development partner early in the process not only saves time and money, but paves the way for launch success, especially within medical device. Design flaws caught early in the process are easier and less expensive to address, plus you avoid bigger hurdles down the road that can halt a project.

## 3 Top Considerations When Choosing a Medical Device Development Partner

### ✓ 01. Research partners that specialize in medical clients only.

Choose a design and development partner that is aligned to assist medical device clients from initial concept to commercialization. Not a jack of all trades design and development firm - you want one that has expertise within the highly regulated industry of medical device and life science.

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### NEED A QUOTE?

Email us at  
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### About MedTech Launch

*MedTech Launch by Genesis Plastics Welding, a leading source for excellence in medical device design and engineering services, is powering innovation and evolving Go-To-Market strategies for clients worldwide through a proven and collaborative design, development and pre-production product launch process that strategically takes OEMs, start-ups, innovators and entrepreneurs from initial concept to commercialization all with the human factor and user experience in mind.*

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Your contract medical device developer should have a proven process in places with defined steps and timelines to take you smoothly from idea to market launch. They should be willing to show you what that process looks like and how it covers usability, documentation, risk management and validation.

### ✓ 02. Review your potential partners.

Ask your short list of potential partners to see their medical device development experience. You may not be able to get actual references to speak with due to confidentiality, but they should be able to share their vast experience especially in medical device.

### ✓ 03. Design to meet ISO 13485 requirements.

Medical devices are not immune to design challenges and a robust quality system helps ensure less bumps in the road. Part of your journey to a successful launch and sustainable manufacturability rests within a specific quality management plan for your device, not a cookie cutter one. Having a design and development partner that is well-versed in ISO 13485 and regulatory compliance ensures a launch rooted in quality assurance at every turn.

### Other design and development considerations

- What design software tools are they utilizing?
- What types of engineers are on staff? What's their expertise?
- What does routine project communication with the client look like?
- Are their milestone meetings and/or reports?
- What prototyping capabilities do they have in-house?
- 3D printing for quick turnaround of custom components?
- In-house soft tooling?
- How are project changes addressed? Are timelines updated and sent to all parties?
- Does the partner have the ability to do prototypes in-house or do initial short production runs?
- How will product documentation be packaged and provided to you?
- Do they have the ability to help you source long-term manufacturing, whether domestic or offshore?