



7 STEPS TO MEDICAL DEVICE MANUFACTURING

A GUIDE TO CONCEIVING,
DEVELOPING, PRODUCING, AND
RELEASING A NEW PRODUCT



WELCOME

INTRODUCTION



OVERVIEW

Inventors are not as rare as one might think, but what made them inventors is having an idea and the mettle to turn that idea into a product. And it starts with a belief in that product. Perhaps it solves an age-old problem, even one that has stood right in front of every other human for years or more. The product is something that makes life easier through simplifying a task and giving credence to the adage “work smarter not harder.”

It's looking at a situation and not only identifying there is an obstacle – and seeing the challenge (and the opportunity) is half the battle – but thinking “there has to be a better way to do this.” From something as huge as the wheel to as simple as the toothpick, the inventors of those products had a vision and made it reality. They created a “product” they needed, and they took it from ideation to creation to distribution so that others could use it to solve that very some confounding problem. It's putting the genius in ingenuity.

This guide is a step-by-step approach to production design and development, specifically as it applies to the manufacturing of surgical, dental and life science equipment and devices. At Stripes Global, we provide total product realization solutions, taking a product from concept through manufacturing – from the earliest idea stage to seeking FDA approval.

Visit [Stripes Global](#) to learn more about us and to schedule a consultation with a medical device manufacturing expert.

STEP 1: THE IDEA

If you have designed a completely new product, lots of thought has to be put into how it will be viewed; how it will be received. Plan for the naysayers who think it can't possibly work

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Ideas are great, but not all ideas merit follow through. We've all seen plenty of bad products on infomercials and wonder how it made it past the idea stage and on to our TV or phone screens. There's a reason you came up with the idea, so test it out. Ask a friend, do some research to see if anyone else has thought of it and, if not, survey friends, family and complete strangers (their unbiased nature is important) to see if they react with a "wow, that's amazing" or a "you're kidding, right?" If the prior happens, your instinct is on to something, and more thought and exploration is in order.



In your survey, ask what they like about your idea and why. What would they recommend for improvements? This is where you need to start thinking like a marketer. If your uncle or that anonymous bystander really believe in what you are offering, ask them how it makes them feel. What about it gets them excited? Similarly, what is off-putting? What's missing? If you have designed a completely new product, lots of thought has to be put into how it will be viewed; how it will be received. Plan for the naysayers who think it can't possibly work. If your product is an improvement to an existing device, think about why your upgrade is needed – and wanted.

STEP 2: THROW THE BOOK

AT YOUR IDEA

For some products, throwing the book at it might actually be worthwhile to test your new idea's durability and toughness. Take the survey info you gathered, add some extra ingenuity, and see how you can make the product better before it even becomes a product. Examine the challenges of product development:



- What are the best and most cost-effective materials?
- Where will those be sourced?
- How much would this new device sell for?
- What is the best way to package it? To transport it? To market it?
- What kind of overhead expenses should be considered?

As your idea iterates, continue to seek feedback, especially from those who provided your biggest kudos, as well as your harshest criticisms. Have a customer in mind? Ask them. Know who will be on your product development team? Gather their input. Have financial backers funding your venture? See what they think. It's OK to scrap the original design and overhaul or start anew. As long as it's what best for the end user.



STEP 3: BUILD A PROTOTYPE



Create a real-life version of your product – it's actual size, with full functionality, all the necessary moving parts (if required) so you have a physical device that you and others can hold, feel, examine, and be ready to test. You will know fairly quickly if you are going back to square one or if the physical product needs to iterate just as it did at the idea stage.

Don't go cheap on this stage. If a slick, hard polymer is what will be the final material for the product, don't make your prototype out of duct tape and epoxy. Adequate expenses up front will save you money – and time – in this and later steps.

While Stripes Global can help at any stage, this is perhaps where we offer the most benefit. We're professional engineers who have the equipment, materials and know-how to create the prototype you envision. We'll add credibility to your invention by coming at it with ideas for more suitable material options, design improvements and offering advice from years of experience helping other products pass the eye and sniff test. If we see something that can be done better, we'll tell you.

We'll offer suggestions for packaging, ways to bring down (or up) the device's weight, provide our thoughts on potential branding and marketing, and share general product development and prototyping dos and don'ts that can help avoid headaches down the road.



STEP 4: MORE IMPROVEMENTS

If you haven't gathered already, Stripes Global will be your partner throughout the entire process. Revealing your prototype to your investors and early champions and critics is exciting and nerve-racking. What will they see that you didn't? You need their buy-in and approval if your new device is going to see the light of day. How do they feel about:

- *The final product look and feel. Again, do they ooh and aww or look aghast? Is the size and design right? Does it do what you said it will do? Will it appeal to the end user to whom you will be marketing? What are the potential risks (weak spots in the device, too high of a price point, other concerns)? Where will those be sourced?*
- *The appeal of the brand. Does the product look good? Is it believable and marketable? Does it create a positive emotion right away and scream "buy me"? Is the color and shape right? Does the packaging work well and follow the device branding?*
- *Functionality. Again, does the device do what it claims to do? Is it making the world – or a specific situation – a better place by solving a challenge? Are there other potential uses or offshoots of this product?*

Take in all of the feedback. Listen to what your stakeholders have to say. Know that their constructive criticism is meant to help. Defend your idea, but don't get defensive. Make improvements. Iterate and perfect. Then do it some more. The real world won't be so kind.



STEP 5: TEST THE MARKET

Now it's time to put your product in front of real users – actual potential customers. This isn't full launch into the marketplace. This is strategic, targeted outreach to put your device in the hands of someone who will actually use it. You're looking for their insights, not their dollars. Select a small pool of recipients. Pick at least one or two that you know will be skeptical and who will put your device to the scrupulous test. Select someone that might be a fringe customer, but who might reveal that your marketplace might be bigger than you thought. Or not; maybe more focus will be needed based on that person's input.

The key is to listen, just as you did with your internal stakeholders. Ask some of the same questions you did of them. What do they like or don't like? Does the device look appealing? Does the brand resonate? But most of all, does the product work and make their task(s) easier?

OTHER FACTORS TO CONSIDER

One aspect we will advise you on is timing, durability or disposability of your product, and other factors that could affect your go-to-market strategy. What is the right time to go to market? Is there a particular time of year when users will be more receptive? Likely not with medical devices, but there could be. Is your product a one-time use, then it is disposed of? Then you need to think about reselling and refilling inventory. And all of that affects storage and supply chain. We have the experience to advise on all of these factors



STEP 6: THE ALMOST LAUNCH

With test marketing and product reveal to your test users, it's time to get serious about filling the supply chain by ramping up production and thinking about distribution channels.

Set goals with firm deadlines and work backward from there. When are you launching? What date, time, location(s)? What will it take to get product from your distribution hub(s) to your customers furthest away and those closest?

Are there any factors you need to consider – bigger picture items that you might not even have control over, such as political upheaval, a pandemic, material shortages, gas prices, etc. Is a competitor planning to launch a similar product at around the same time? What if that competitor receives bad reviews? Will that negative feedback affect you? We'll help you keep an eye on those "outside influences."



STEP 7: LAUNCH

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Use all feedback to advertise and market better. Who's the happiest? Market to more people like them. Who are your most challenging customers, and what did you do differently to satisfy those segments?



Put your product in front of your customers, watching your device turn from idea into reality by landing in the hands of the very people you invented your product to try and help. Then listen some more. Take in the good reviews. Act on the bad ones, if there are any. Just as you adjusted your device in pre-testing and testing phases, now is not the time to stop improving.

Use all feedback to advertise and market better. Who's the happiest? Market to more people like them. Who are your most challenging customers, and what did you do differently to satisfy those segments?

Enjoy the successes and bounce back from any failures. If your product is just not resonating, we'll help you analyze what went wrong and where. Then it's time to roll up the sleeves and get to improving. Was it a design flaw? Was it poor marketing? Were there distribution issues? Does the branding need updating? Address it, fix it, and get back out there.

THAT'S A WRAP

There are lots of factors to consider when getting into the invention game. We know the rules and are here to help, along with this guide. We'll feed off your enthusiasm and add a dash of our own when needed.

We love to see our customers succeed and hang our hat on these core offerings:

- Determining the Technical Specifications of Your Device
- Engineering and Design for Usability
- Selecting and Optimizing the Appropriate Materials
- Building, Integrating, and Testing Software Solutions
- Prototyping and Testing
- Packaging Design, Including Labeling Requirements
- Design Controls and Quality Assurance Processes

Visit us at www.stripesmanufacturing.com and let us get to work for you.



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AND MEDICAL PRODUCTS FOR YOUR NEEDS**



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