ROOT3LABS℠

Getting the Product Development Process Right

Reducing Risk from Strategic Prototyping to Design for Manufacturing and Beyond

www.Root3Labs.com

All About that Process

What does it take to turn an idea into a prototype and a prototype into a finished product? Whether it's an endoscopic surgical tool, wearable device with accompanying app, or personnel tracker for First Responders or the military, success always comes down to the process, no matter the scale.

When we talk to entrepreneurs, small-businesses, or manufacturers exploring how to bring a new product to market, they always share their concern about spending a lot of money and not getting the outcome they (or their customers) need. They struggle with the frustration of choosing which idea is worth the investment or become overwhelmed and not know where to begin. Sound familiar? At Root3 Labs, we pair the product development process with specialized engineering know-how to quickly map the path to success, regardless of the application.

So, let's get started with understanding the Product Development Process and see how to increase the odds of success while reducing risk along the way.

First Things First

First, we need to understand that each product life cycle has two core components to be successful: Technical and Business. Keeping these two components in mind is fundamental as we ask the hard questions about the product, market, and manufacturing.

Technical Questions: How it works	Business Questions: How it creates profit
How big (or small) is it?	How do the sales and marketing work?
What kind of materials will be involved?	What is distribution like?
How does it work?	What's the business model for the company?
What is the effect of a malfunction?	What are the projected sales volumes?
What are the features & benefits?	What is the market willing to pay for it?
What Regulatory Standards are involved?	How much will it cost to manufacture?
How much power does it consume?	How is it better than the competition?

The Technical and Business questions are closely tied together and influence each other. High technical performance requirements cost more than less complex systems and low sales volumes make high-volume manufacturing techniques cost prohibitive. Once you start to form answers to these questions, you can estimate whether the margin between the lowest retail cost and the highest manufacturing cost makes the product viable.

Once you've outlined these key questions along the Technical and Business spectrum, it's time to really focus on your Product Requirements Specification. This is where you list all the different performance, functions, features, and everything that goes into your product and defines how the end user will use it. These all need to be objective and testable, so don't include "looking pretty" (let your marketing people write that later). Now, it's time to tackle things like functioning at 104°F, surviving a drop of 30 feet, or running 36 hours straight on battery.

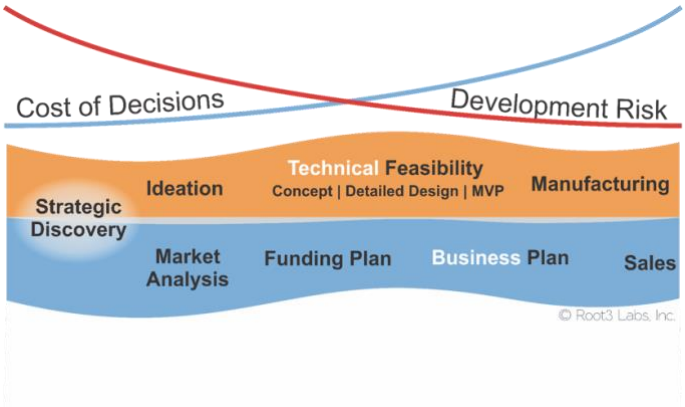
Pro Tip: *Divide the retail cost by 4 to 8 to get a maximum manufacturing budget, including overhead, R&D, distribution, service, warranty, and company growth.*

Whatever your Requirements are, list them so that you can run performance tests and validate the design meets those criteria. It's also much more effective to have a basis for a Requirement, such as a Regulatory Standard or empirical data. Making arbitrary guesses at this point can become expensive if the 30-foot drop test could have been 6 feet and titanium parts could have been plastic. This will be a living document and take a lot of research but putting in the work up front can make or break the process when it comes to the total cost.

Risky Business?

Risk. It's a small word with big implications. In fact, the entire process of bringing a new product to market is, well... risky! We have technical risks of trying to meet high performance goals while meeting low cost targets. We have the safety risks of Class 2 or 3 medical devices. We have side effects. Efficacy studies. Risk of malfunction. And that's just for the product. On the business side you have the risks of a changing marketplace, fickle consumers, competition that pops up while you're in the middle of R&D, economic recession, regulatory risk with the FDA, medical device tax, or insurance reimbursement issues. That's not to mention getting funding, budgets, and the unknown risk that you don't even know about!

Depressed yet? Just because there is risk doesn't mean there aren't things we can do to reduce it. At Root3 Labs, we use a risk model based on a cost of decisions vs development matrix (see chart). Essentially, we recommend attacking the riskiest components first so that we can get those out of the way before you venture down the path of more involved engineering time, performing tests, etc. Better to change it early on before it gets too expensive to change down the road.



This isn't to say that all risk can be identified up front or that Technical aspects of the project are unrelated to Business aspects. As you overcome one Technical hurdle, it may lead to a challenge of the Business Plan, or vice versa. So, the Business and Technical aspects of the project will require some back-and-forth over the development process but using a risk-based model that's focused on Process is the absolute best way to stack the deck in your favor.

Let's Concept

With this risk-based framework in mind, now is the time to start conveying the product idea and getting feedback from it. We want to understand what the best way forward is. This means sketches and CAD models and really understanding the use case scenarios. We can inexpensively start to visually bring to life answers to questions like:

- How will it be used?
- Who's going to handle it?
- What does a use case look like from start to finish?
- Where does it live and what prompts its use?

With this feedback we can now filter out the concepts by weighing them against the criteria defined by the Product Requirements. By thinking through the various concepts, we can better understand the risk in context to the product– be it technology integration, sensing, price point, or something else.

MOCK UPS

Building on this risk-informed concept phase, it's time to move on to mock ups. Something tactile, that you can touch, hold, and handle just like the real product will feel. This exciting stage of the process is where we crank up the 3D printers or get out of the foam or clay- but we still want to keep our thinking simple and avoid very involved fabrication. Hey, even cardboard can work fine too at this point. With the learning from this phase, we then move on to building a benchtop prototype.

BENCH TOP PROTOTYPE

With a benchtop prototype you want to look to the Product Requirements and figure out, "What are the real essential components for this product?" This means understanding how it works and what the technology looks like. We might use some off-the-shelf components to get started, maybe an Arduino with a motor, and figure out how it all works together. We'll avoid custom parts at this stage so we know some aspects of the product will be limited, but it's a way to evaluate the idea without going further down the road and spending cycles without this functional validation.

SOFTWARE MOCK UP

Of course, with anything using electronics we're going to have some software needs along the way. Maybe it's a mobile app that talks to your device over Bluetooth or integration with a PC or web app. Either way, the same philosophy applies to software as the product itself. You don't need to go through the effort of building out all that functionality yet. It can take months to flesh out the software side so at this stage, focus on using screen mocks created in Photoshop or Canva. You can say, "Here are the 5 screens we're going to use," and then you can move elements and interface objects around without getting into a complicated code base. No app store, no dev, just focus on a set of screen mocks to help tell the story.

WORKS-LIKE, LOOKS-LIKE

If the trade-offs of an off-the-shelf prototype are too much, you can consider a *works-like* prototype in concert with a *looks-like* prototype. Works-like prototypes use off-the-shelf (and maybe a few custom parts) to show how the product will work, with limited functionality and little consideration to appearance. Looks-like prototypes have the form of the final product (or an intermediate step) but lack functionality. Think rapid prototype.

Pause. Set the Stage.

At this point in the process, it's worth a reminder that what you're holding in your hands is NOT the product. Building on all that you've developed, it's time to present what you have in person, being fully prepared to show off everything the prototype can do as well as discuss all the ideas for what the device can be. Don't ship it off. Don't give the prototype away. It's only a tool to help you communicate your vision and now is the time to tell that story.

Technical Feasibility into Design for Manufacture

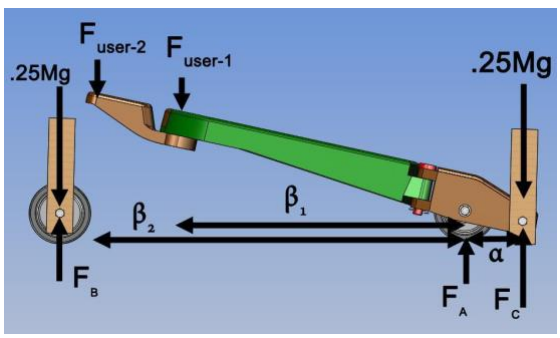
As the process moves toward the Design for Manufacturing stage, we'll focus a good amount on testing. Can you see through it? Can you put weight on it? What amount of force should it handle? Where are the weak spots? Identifying these issues is the low-hanging fruit of the pre-manufacture phase and it's all made possible by making (and breaking) 3D prototypes.

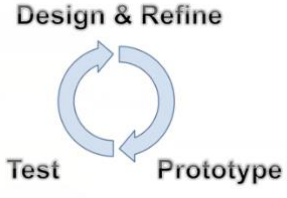
CASE STUDY
MILLI MOVA

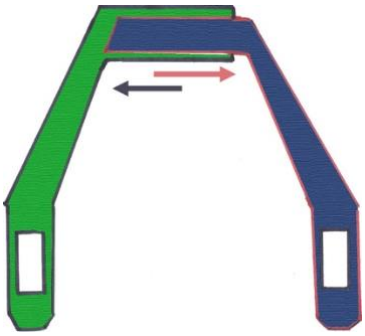
Milli Mova Chair

Milli Mova is a mobility system for the elderly or disabled which safely allows a static chair to be moved on wheels with the lowering of a wheeled bar. For the technical feasibility stage, we moved from the early sketches to a 3D CAD model. At this point we were focused on the ability to think of things visually for the chair system and be able to run all the calculations of force and simulations, in order to optimize the design. We 3D printed multiple prototypes so that we could test out these models. With that process complete, we then moved into the Design for Manufacturing stage.

In the case of the Milli Mova, we built CNC machined plastic parts to test the strength of the real material before incurring the high costs of injection molding tools. While you can CNC a few of these chair bars, they're expensive. With injection molding, you can frontload the cost of the initial tooling so that you can produce thousands of the pieces relatively inexpensively. Buying the tooling is a large upfront investment so you have to know that your part is fully reliable because it's going to be extraordinarily expensive to rebuild later on. With manufacturing ready to go, you can now ramp up into production and sales and eventually scale. Depending on the production quantities, you might assemble these by hand or you might eventually switch to robotics to reduce the unit cost and increase margins.







Now, you might be thinking to yourself, "But, I don't want to get into manufacturing or mass produce my concept. How can I just sell my idea for 10 million dollars?" Unfortunately, it may not be that simple. By themselves, ideas just aren't worth much. The trick is that every step you take down the product development process reduces the risk and exponentially increases the value to a potential buyer. Remember the risk chart? You can build a team of internal and external resources – such as engineering firms and contract manufacturers – to develop prototypes, create the commercial product, and increase the product's value. With each step forward your ability to trade risk for reward increases.

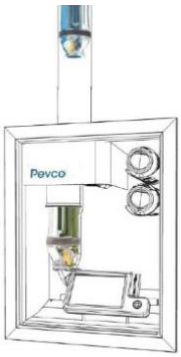
Process is Power

Development of a regulated medical device requires another dimension of documentation, risk analysis, and validation. All aspects of the design must be verified and validated and traced back to the Product Requirements. Every design file and calculation must be checked, reviewed, approved, and added to an ISO-certified revision control system. Electrical devices will have to be tested against safety protocols such as IEC 60601 or 61010 and, the requirements for manufacturing and quality assurance are far more rigorous and expensive. In other words, bringing a new product to market is complex.

It can be tedious. There are as many unknowns as knowns when you're starting out. But by using the process outlined here and applying rigor to each step of the process, you can drive out risk and focus on value creation for your product as it comes to life.

If you're ready to partner with a team who pairs strong product design chops with specialized engineering experience, Root3 Labs is for you.

Contact us today to discuss your project and where you want to go.



Schedule a Call

Root3 Labs is an engineering company specializing in the research, development, and prototype process of complex devices for the medical device and defense industries.

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