

# DESIGN – ENGINEER – BUILD

## An OEM's Guide to COMPLEX Product Development and Manufacturing

PREPARED BY



*Experts in Engineering Design and Contract Manufacturing*

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## Introduction

Launching a new product is no small task.

No matter what size your business, creating a product from scratch is a major commitment of time, money and resources.

It's not something you can afford to take lightly. Not if you want to be successful.

Too often though, a product launch doesn't get the commitment or focus it needs. It always starts with good intentions and realistic expectations, but at some point, the process falls apart. Deadlines are missed. Priorities get rearranged. Budgets get reallocated.



### **Why complex products are different**

Every product launch is challenging, but when your product also requires complex technology and engineering, the product development process is even more complicated.

In our experience developing complex instrumentation and devices for the medical, pharmaceutical and life sciences industries, the need for electro-mechanical engineering, automation and integrated systems has taken on even greater importance.

This technical complexity applies not only to the design and engineering process but also to manufacturing where we rely on highly trained technicians to assemble and test the finished product.

### **Our Product Development Guide**

In this guide, we've tapped into our many years of design, engineering and manufacturing experience to provide you with an outline of the product development process – as we see it.

Every product development project starts with identifying your market and defining your product capabilities, and it ends with product sales and distribution.

In between is a process that takes your product idea from initial concept and design to prototype and manufacturing. This process often combines specialized engineering skills with advanced manufacturing technology and capabilities.

Not all product launches are the same. We understand that. But we believe this process can provide almost every project with a useful roadmap from concept to delivery.

### **In-house vs. outsourced**

Every company wrestles with this same question: Can we do this in-house and or should we outsource?

*How you answer this question will depend on several factors:*

- the complexity of the project,
- your own in-house skills and resources, and
- your timetable and the availability of your in-house skills and resources

Even in large companies with robust internal skills and resources, there are times when outsourcing is the better option.

This is especially true with projects that require highly specialized engineering skills that are typically not part of an in-house engineering team.

Of course, the manufacturing part of this process is always farmed out to a contract manufacturer. But finding the right match is essential.

You will need to find a contract manufacturer that not only understands the engineering complexity of your product, but is also well-suited for the product quantity and quality you need.

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As you read through this guide, I hope you will keep Product Resources in mind as a potential resource for you. We bring many years of experience to the product development process – from highly specialized engineering design to contract manufacturing.

To explore partnership opportunities with Product Resources, please contact CEO John Erickson at 978-524-8500 x313 or Paul Ermanski at x335.

## Step 1 – Product Concept

### You start with an idea

Ideas come and go. The better ideas stick around awhile. The very best reach this stage in the process.

When you have an idea for a new product, you need to share it. It could be anything from a sketch on a napkin to a detailed schematic.

*Be prepared for a few basic questions:*

- What will this product do?
- Will it be a new product or an improvement of an existing product?
- Who will use it?
- What market will it serve and what market requirements will you face?
- What will it replace?
- How will they use it?
- What will they be willing to pay for it?
- What will it cost you to produce?

These questions will help you define the “form, fit and function” of your new product – and its overall viability as a profit-making product.

At this stage in the product development process, you will want access to latest design tools (CAD modeling or 3-D simulations) to generate a conceptual rendering.

### What you should expect

By the end of this step, you should have some type of conceptual rendering in hand. This may include a CAD model or a 3-D simulation depending on the design tools that are available.

You should also have an outline of the market requirements in the form of a User Requirements Specification (URS) or a Product Requirements Document (PRD).

## Step 2 – Product Specifications

### Working out the details

You know what you want to build. You've shared it with others, you have a consensus and you have a rendering.

Now let's get down to the details.

- What are the functional specifications of this product? Beyond the primary function, what else will it do? What additional features should the product have? How will it operate? How will it be powered?
- What are the design specifications? Will this be a hand-held tool, a desktop product or a standalone? What size and weight factors need to be considered? How will it be stored? What are the color options?
- What are the regulatory requirements? Have you considered the different safety, quality and package design requirements for different countries?
- What environmental factors should you consider? Will the product be used around water or in hot or cold temperatures? What about explosive environments? Will power limitations be a concern?
- And how does it fit your budget? Can the product meet all of the specifications and still meet your target cost? As you make your list of specifications, how many are "must haves" and which are simply "nice to haves."

By committing your product specifications and requirements to paper, every member of your team will understand the tasks and expectations.

### What you should expect

At the end of this step, you should have an objective, documented standard available to qualify the product function and design.

## Step 3 – Proof of Concept

### How feasible is the product

With your rendering and user specifications in place, it's time to prove your concept – to demonstrate that your product will actually work as intended.

This alpha prototype is not a finished design. It's often a group of off-the-shelf components integrated to perform the basic function of the product.

In most cases, the alpha prototype bears little resemblance to what the final product will look like, but it does help to demonstrate the viability of the product.

The alpha prototype allows you to test performance and determine which features and design elements are feasible and likely to be included in the final product.

The alpha prototype can reveal unexpected problems in the concept or design early enough in the process to avoid unnecessary costs.

It is expected that the alpha prototype will be modified extensively before the product goes to manufacturing.

### What you should expect

By the end of this step, you should expect to be working with an alpha prototype to verify the overall viability of the product's concept, and determine which features and designs are likely to be included in the finished product.

## Step 4 – Product Design

### Take a closer look at your design components

Product Design takes your initial prototype to the next level with a more finished and more functional version of your product.

This beta prototype takes into account the more complete user experience – and will bear a closer resemblance to the end product. It will not be an exact replica, however.

In this phase, the prototype should reflect what was outlined in Product Requirements (Step 2).

The beta design will help you assess individual components of the product – for their performance, manufacturing suitability and costs.

Depending on the type of product being developed, the beta prototype may be tested by an internal team, or, in some cases, by third party users.

### What you should expect

By the end of the step, you should have fully functional prototype for testing. This prototype should bear a strong resemblance to the finished product, but will not be an exact replica.



## Step 5 – Verification & Validation

### Will it work and will it comply?

This is hold-your-breath time as your prototype gets put to the test. In this step, we have two areas of review – design verification and product validation.

#### **Design Verification**

The design verification is one of the most significant quality steps in the product development process.

Your product design will be examined to show that the new product, as designed, will meet the product specifications, performance expectations and all applicable regulatory requirements.

This verification activity includes design reviews, testing, and regulatory approval.

#### *Regulatory compliance*

As part of the Design Verification process, your product must also be designed with an eye on regulatory compliance.

Which regulatory agencies and requirements you face will depend on your product and where you plan to distribute it.

Requirements for health, safety and environmental compliance will vary in the United States, Europe, Canada and other global locations.

Every effort should be made to engage with the appropriate regulatory agencies early in the design process.

## **Product Validation**

At the same time, the product needs to be validated against the marketing expectations.

It is important to test the product to be sure that it performs its intended function as originally described by marketing. Product validation may occur in a laboratory environment or under field conditions.

This is an often overlooked, but critical, part of product development process because it can uncover inconsistencies between the product specifications and the marketing claims.

### **What you should expect**

By the end of this step, you should know whether your latest prototype was able to meet user needs, performance expectations and regulatory requirements – and whether your finished product will be able to deliver on marketing claims.

## Step 6 – Manufacturing Process Design

### Matching your needs to the right manufacturer

Manufacturing Process Design lays the groundwork for your manufacturing partnership.

If you consider the manufacturing facility to be the machine that produces your product, it stands to reason that you want this machine to be properly designed, easily maintained, and flexible.

Above all else, it must meet the highest quality standards. You need to know that the last product off the line is exactly the same as the first.

*Key questions to ask:*

- Is the manufacturer well suit for the type of products you need produced?
- Does it have the in-house capability to meet all your needs?
- Will your production volume be the right fit for the manufacturer?
- What systems will be in place to ensure consistent quality?
- Are suppliers in place to provide the necessary raw materials?
- What is the turnaround time on production?
- What testing and calibration will take place before product is complete?
- Will the manufacturer handle inventory?
- What is the packaging and shipping process?
- Will the manufacturer be expected to handle accessories, spare parts and repair?

### What you should expect

By the end of this step, you should have a manufacturer selected that can meet all of your production and post-production needs. You should also have a list of expectations that are shared with the manufacturer.

## Step 7 – Manufacturing

### You're ready to go

If you've done your due diligence, you're ready to move your project on to the manufacturing facility.

This transition needs to be seamless and completely free of the types of problems you might expect when a product is designed by one organization and manufactured by another.

*At the manufacturing facility, you will want to oversee:*

- procurement of raw materials
- management of suppliers
- product assembly
- quality assurance
- packing for shipment

Depending on your project, you will also want to pay close attention to your designated facility section. The manufacturer will set aside some work stations or selected machinery for your project.

Regardless of the manufacturing process, you want to be sure that the personnel working on your product are properly trained.

### What you should expect

At the end of this step, you should have confidence that the manufacturer understands your expectations and has all the people and process in place to meet those expectations.

## Step 8 – Sustaining Services

### Preparing for product service and support

Your responsibility for your product doesn't end when it leaves the factory.

You will be expected to provide a range of sustaining services for product maintenance and repair.

You will need to have a fully equipped and staffed service and repair division, which is available to perform both in-warranty and out-of-warranty service, repair, and calibration.

Technicians will need to be fully trained to perform fast, reliable repair and re-calibration of your product.

You will also need to set up and maintain an inventory of spare parts and consumable replacement components.

In some cases, you will need a Field Service team – personnel trained, ready and able to go to your customer's facility and perform field maintenance and service.

### What you should expect

Whether it's through your manufacturer or your own company, your product will require some post-production support – for repair, replacement and calibration.

## How can we help?

If you are considering a product development and contract manufacturing firm, tell us about your product plans.

Let's see if there is a fit. Like you, we want to be sure our capabilities are compatible with your needs.

But let's get acquainted first.

### **Request a Telephone Consultation**

We can start with a phone call to discuss your project. If you are local, we'd be happy to meet in person, but generally an initial discussion can be done by phone.

We have a few questions for you, and no doubt, you have a few questions for us.

### **Review our Certifications**

Quality is important to you so take a few minutes to review our quality certifications.

We are ISO 9001 approved for engineering design, development, manufacturing and service, ISO 13485 approved for medical device manufacturing and service. Both approvals are certified by TUV.

We are also ISO/IEC 80079-34 approved for design, manufacturing and service, audited by TRaC Global, for equipment and instrumentation used in explosive atmospheres.

### **Review our Capabilities**

We have put together a list of our engineering expertise and manufacturing capabilities.

### **Request a Proposal**

When you decide it's time to explore a potential partnership with Product Resources, we are happy to prepare a detailed proposal for you.

### **Questions?**

If you have any questions about our capabilities, our facility or our process, please contact our CEO, John Erickson, at 978-524-8500 x313 or Paul Ermanski at x335.

## About Product Resources

Product Resources is a total design, engineering and manufacturing services provider.

Much more than a contract manufacturer, we have the electrical and mechanical engineering and industrial design capability to create entire products from concept to final execution.

We specialize in low to medium volume complex products such as scientific, medical and industrial instrumentation, but can be equally effective with almost any industrial product.

*Our turnkey approach includes:*

- Product Concept
- Industrial Design
- Multi-Discipline Engineering
- Regulatory Compliance
- Quality
- Continuous Improvement
- Manufacturing
- Sustaining Service

We invite you to visit us and take a tour of our newly remodeled 33,000 square-foot facility in Newburyport, Massachusetts

To learn more, please contact our CEO, John Erickson at 978-524-8500 x313 or Paul Ermanski at x335.