

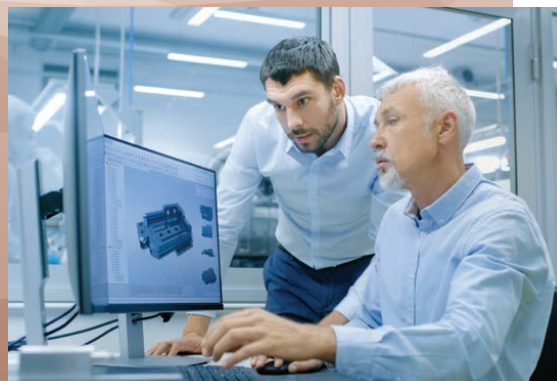
Product Development & Manufacturing

PROCESS CHECKLISTS

STAGE 3

Prototype

A Finished Prototype for
Presentation and Testing





STAGE **3**
Prototype

- STAGE 1 – Planning
- STAGE 2 – Design
- ▶ **STAGE 3 – Prototype**
- STAGE 4 – Design for Manufacturing
- STAGE 5 – Manufacturing
- STAGE 6 – Post-Manufacturing

About these Process Checklists

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

A successful new product development project also calls for a process – along with a full understanding and acceptance of that process by everyone involved.

We have broken down the product development and manufacturing process into six stages – from requirements and prototype to manufacturing and distribution.

We developed this series of Process Checklists to help you and your team plan, execute and monitor these six stages. We invite you to use these checklists as you plan your own product development and manufacturing project.

About Product Resources

Product Resources is a product design, engineering and manufacturing company with 35+ years of experience developing complex, technically advanced products and instruments for the medical device, biotech/life sciences and pharmaceutical industries.

We provide a full-service approach to product development meaning we handle all aspects of the product development process.

STAGE 3 – Prototype

Building the first prototypes is an important part of the product development cycle and marks the start the production process. The terminology means different things to different people, but we use the terms Alpha Prototype(s), Beta Prototype(s), and Pilot Production to describe the different phases of prototype development.

An Alpha Prototype is sometimes called a proof-of-concept model. It is designed to test, early in the design process, the fundamental technologies upon which the product is based. The need for one or more Alpha prototypes flows from evaluating the risk of proceeding with the design without demonstrating the riskiest parts of the product first. An alpha prototype is typically developed ad hoc by the engineering team from 3D printed parts and evaluation electronics, typically mounted on a wood base and hand wired.

A Beta Prototype is the first prototype which is representative of the entire product. It may be lacking packaging or maybe the color is not final, but it should be able to be used to test the design to the design specifications and the PRD. Ideally, the design and materials are close enough to the final product design that any regulatory testing can be done on the product with little risk that there will be changes when the product is released to manufacturing.

Pilot Production is used to verify the production process. The design has been finalized and the pilot units are used to show that the production processes are adequate and in control.

For the purposes of this Stage, we want to consider the Beta Prototype..

▶ Multiple Prototype Copies

We often think of a prototype as a single unit, but in fact, you may need multiple copies of the prototype for review by several parties. Prototypes can be required by:

- ✓ **Internal Testing** – the engineering team for verification and validation (V&V) testing. Although the software is supposed to be on the same schedule as the hardware, often there are software changes that are necessary once the Beta is built and the software team may require one or more for their purposes.
- ✓ **Regulatory Testing** – depending on the schedule (and it's always tight), two or more prototypes may be necessary for regulatory testing. Safety testing and EM testing can typically be done in parallel as they need different labs. If the product is to be used in explosive atmospheres (per the ATEX directive or NFPA), there will be additional requirements for prototypes. Regulatory testing for safety is not destructive, but EM testing (especially ESD testing) can harm the equipment, or at least weaken it, so plan on those prototypes to not be suitable for placement at a customer.

STAGE 3 – Prototype

- ✓ **User Testing** – if part of the plan, there may be some customers willing to “Beta Test” the product and give feedback.
- ✓ **Marketing / Sales** – there may be a requirement by the marketing and sales department(s) for demonstration units.

Together, these different requirements can increase the number of Beta Prototypes to as many as 6 units. Although you can always make more, considering the low volume and the setup charges for machined parts, sheet metal, etc. the Betas will be expensive. Purchasing all at one time will save considerable cash.

▶ Supply Chain

The prototype process provides you with an opportunity to work with the supply chain to identify items that may be difficult to obtain, or difficult to fabricate. This process is an important step to validate the cost targets for the product. Although you are ordering in small quantities, if the material is the same as you plan for full production, you will be able to get quotes for production quantities.

You can vet these suppliers for quality, lead times, landed cost, terms, efficiency, overall ease of doing business, and logistics. All of these must be considered in manufacturing, so this prototype exercise should cover more than just the product. Solve these problems now.

▶ Long Lead Times

Long lead times are not uncommon and need to be factored into your procurement plan. If you can't find another supplier with better lead times, there are options to mitigate the lead time issues which will put delivery at risk. They include:

- ✓ **Order Early** – planning is always a good idea, but when it's time to start production you know that the delivery is needed “as soon as possible”. Once the supply pipeline is up and running, this can be solved by planning, but it will be difficult to start production or re-start production if it is allowed to stop.
- ✓ Do a supply risk assessment during design and prototyping and either change components or hedge the supply startup issues by purchasing some number before the product is released.

STAGE 3 – Prototype

A more troublesome issue is varying lead times. Last time you bought the parts, the lead time is 4 weeks and now you're being quoted 24 weeks. This is a significant problem and you're in danger of shutting down the line. Here it is vital that you know the suppliers and stay in touch so that you can see the lead times extending before you need to order more components. Everyone else is paying attention to this, which only exacerbates the problem when they all place safety stock orders because the lead times are going out. Mitigating this issue is important and you should consider:

- ✓ **Blanket Purchase Orders for periodic deliveries** – these give everyone in the supply chain the visibility they need to keep the product moving. Highly recommended.
- ✓ **Multiple sources of supply** – works well unless everyone is buying from the same factory.
- ✓ **Safety Stock** – effective but expensive.
- ✓ **Identify alternate parts** – requires engineering input and an assessment of the validation requirements. If there is a regulatory impact, beware that may delay approval of a new part.

▶ High Cost Items

- ✓ High cost items can make it difficult for you to meet a target cost.
- ✓ If you can't find a lower cost supplier, review your design to see if a different part could work as well.
- ✓ At the very least, be sure to factor this cost into your budget.

▶ Feedback

Your CAD model does a good job of detailing your product, but it has difficulty predicting how the product will come together.

Maybe there is a screw that just can't be reached with a screw driver. Maybe two parts can't clip together as designed. Maybe building a cable takes too long and would be better suited as a circuit board or redesigned for efficiency.

This is the kind of feedback you will get during the prototype process.

This is also the opportunity to develop a test plan for manufacturing. During prototyping, the product is over-tested because it includes design verification testing as well as manufacturing process tests. The test plan should be designed based on a risk assessment of the various process points. A PFMEA (Process Failure Mode and Effects Analysis) can help identify what testing must be done and what can be skipped.

STAGE 3 – Prototype

▶ Deliverable

At the end of the Prototyping step, you will have a number of prototypes for testing, demonstration, regulatory testing, durability testing. You will also have significant information about the manufacturing process so that you can decide how to mitigate any identified risks.

Product Resources can aid this process by utilizing our experience and supply chain and will help identify any risks and offer assistance finding solutions.

STAGE 3 – Final Deliverable should be one or a set of beta prototypes

What we will cover in

STAGE 4 – Design for Manufacturing: Finished Engineering and Documentation

- ✓ Design and Beta Build Review
- ✓ Design for Manufacturing Analysis
- ✓ Cost Reduction Analysis
- ✓ Regulatory Testing
- ✓ Traceability
- ✓ Manufacturing Process Review



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