

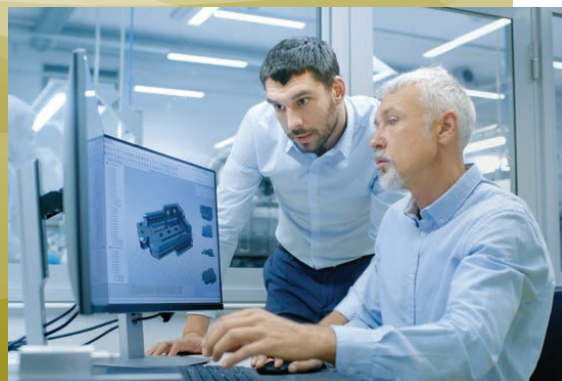
# Product Development & Manufacturing

## PROCESS CHECKLISTS

### STAGE 4

## Design for Manufacturing

### Finished Engineering and Documentation



**STAGE 4**  
**Design for  
Manufacturing**

- 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 4 – Design for Manufacturing

In the previous stage, we covered the building of prototypes of the product design. No doubt many lessons were learned during the process and “opportunities for improvement” have been identified.

At this stage, the product will undergo necessary design changes to correct any design deficiencies identified in the prototyping process and the design and manufacturing process will be updated to improve manufacturability and reliability. Now is the time to make it manufacturable on a larger scale – whether that’s just a few units per month or an order of several thousand units.

We often think of the design and prototype stages as the fun part of the job because you get to see what the product will ultimately look like. It’s where you really get a sense that a product is in the making. But it is the Design for Manufacturing stage, also known as DFM, where the serious business of manufacturing begins to take shape.

A prototype, in and of itself, is not ready for manufacturing. It’s just one unit (or several as the case may be) built and engineers have been looking over it at every step. But to produce that product at a production level, steps need to be taken to allow that product to be built efficiently and repeatedly, and without engineers.

Design for Manufacturing is also responsible for all the required documentation, assembly documentation to test procedures.

Let’s take a closer look.

### ▶ Design and Beta Build Review

Although we would always recommend performing a DFMEA (Design Failure Mode and Effects Analysis) during the design process, once the prototype is built there is another opportunity to tune the design. This is also the best opportunity to perform the Process FMEA (PFMEA). By the time the prototypes are built, you will have an initial build process to critique and the PFMEA will help to identify risk to the product manufacturability. Use this to identify:

- ✓ Can the product be built in volume with current design?
- ✓ What steps will you take to mitigate risk of improper assembly?
- ✓ Can design or assembly process be changed to increase quality?
- ✓ How can you ensure mis-assembled product is identified during manufacturing?

**PFMEA (See our downloadable template)**

**DFMEA (See our downloadable template)**

## STAGE 4 – Design for Manufacturing

### ▶ Design for Manufacturing Analysis

- ✓ Review the design of most current prototype looking for opportunities for increased quality and decreased cost (don't get these confused).
- ✓ Review of assembly documentation for accuracy and completeness.
- ✓ Correct any assembly issues with the prototypes.
- ✓ Review and identify control points for testing needed during the manufacturing process.
- ✓ Will assembly require any special processes (e.g. a flow hood, cleanroom, burn-in for stress screening)?

Based on volume, complexity and schedule, are there any more appropriate manufacturing methods available? Consider:

- ✓ Injection molded or cast parts vs. fabricated
- ✓ Cables designed for automated or semi-automated assembly.
- ✓ Circuit board test points for automated testing and troubleshooting.
- ✓ Appropriate connection ports for field service and calibration.
- ✓ Software should identify and notify personnel of error conditions.

### ▶ Cost Reduction Analysis

- ✓ Can the design be altered to use more cost-effective parts?
- ✓ Do you have alternative suppliers available for the components? It is important to have backup plans for both cost reduction and prevention of supply disruption.
- ✓ Are there certain parts that are sole-sourced (from only one supplier)? This is likely for some of the components and it's important that a risk analysis be done on the supply of the component to mitigate any disruption in manufacturing. Possible mitigation would include:
  - ✓ Safety stock of sole-sourced components
  - ✓ Engineering project to design alternate components

## STAGE 4 – Design for Manufacturing

### ▶ Regulatory Testing

Based on the required markets, the DFM process is also the time for regulatory testing of the product.

Using the Prototypes developed previously, or pilot units built for this purpose, collect all of the documentation required for submission to the regulatory body. This includes:

- ✓ **Market Plans** – this defines the standards to be applied
- ✓ **User Manual** – this is part of the review for appropriate safety statements and operating instructions to allow the regulatory body to appropriately operate the equipment.
- ✓ **Component Datasheets** – in many cases, the component specifications and regulatory marks will need to be confirmed. The testing lab will give a list of the required parts.
- ✓ **Electrical Schematics** – (typically the power distribution section)

### ▶ Traceability

- ✓ How do you intend to track product through production and in the field?
- ✓ Do any parts or sub-assemblies need to be Serialized or Lot Numbered?

### ▶ Manufacturing Process Design

This is an important consideration in the design of a product. Many products are manufactured in a very straight-forward manner and it may look like a simple test procedure at the end of production is all that is necessary. Even if true, the DFM process will benefit from a more formal look at the process. Using the PFMEA and experience with the prototype manufacturing, a reasonable design can be put into place. With appropriate review controls, a continuous improvement process should also be implemented to continue to analyze the process and tune for reliable and efficient manufacture.

Consider:

- ✓ Off-the-Shelf Test Equipment requirements. An example would be a digital voltmeter or oscilloscope.
- ✓ Custom Test Fixture requirements. An example would be an automated calibration fixture.
- ✓ Assembly Fixtures that improve quality by maintaining tolerances and alignment.
- ✓ Specialized assembly tools. A typical example would be a torque screwdriver.
- ✓ Rework procedures for product that fails at one of the process control points (if appropriate).

## STAGE 4 – Design for Manufacturing

Depending upon the market for the product, there may be verification and validation processes that must be followed for initial implementation and modifications.

It is possible that the design, verification and implementation of the manufacturing plan will be as complex as the design of the product.

**STAGE 4 – Final Deliverable should be a “ready to release to manufacturing” product with complete documentation**

### What we will cover in

#### STAGE 5 – Manufacturing: An Efficient and Repeatable Manufacturing Process

- ✓ Quality System
- ✓ Quality/Vendor Selection
- ✓ Infrastructure
- ✓ Tools
- ✓ Supplies
- ✓ Supply Chain Management
- ✓ Inspection & QA
- ✓ Production Control
- ✓ Inventory Management
- ✓ Test Department
- ✓ Order Fulfillment & Shipping



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