

Product Development & Manufacturing

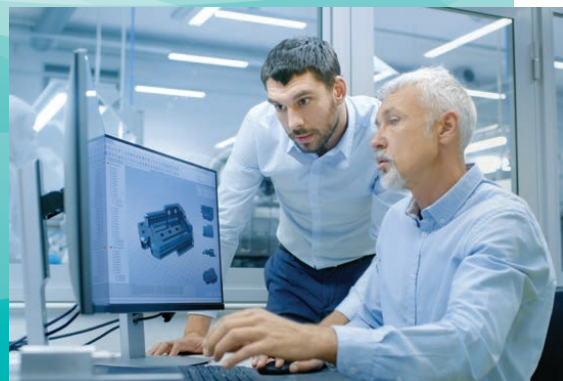
PROCESS CHECKLISTS



STAGE 5

Manufacturing

An Efficient and Repeatable
Manufacturing Process





STAGE 5
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 5 – Manufacturing

Manufacturing a product requires a significant investment in space, equipment, and personnel to build product repeatably and reliably. It is easy to imagine getting started in manufacturing – a few benches and some hand tools, a couple of technicians and some drawings, parts arriving at the door and voila, a product. That can even work for a time with a simple product and a few customers. There are a few things that you should consider when deciding how to build your product.

▶ Quality System

A quality system is a fundamental part of the manufacturing plan. Ideally based on recognized standards, it covers the details of the manufacturing process (and all other business and engineering processes). Product Resources' quality system is compliant with multiple quality systems (ISO9001, ISO13485, EN80079-34), suitable for the products we manufacture and quite likely your products as well.

▶ Quoting/Vendor Selection

- ✓ Are there any custom part vendors that need to be used for a specific reason?
- ✓ Are the vendors ISO 9001: 2008 certified?

▶ Infrastructure

To manufacture a product in significant quantities while maintaining the product quality at acceptable levels requires a well thought out system for manufacturing. It will include:

- ✓ Dedicated floorspace for Inventory, Inspection (and quarantine), Assembly (and storage for fixtures and tools), Test (and test equipment), Utility Equipment, Shipping and Receiving. A larger break room, etc.
- ✓ Utilities, including proper lighting, electrical power, water, sewer, possibly compressed air, HVAC, specialty items like liquid nitrogen, DI water, etc. This will vary depending on the requirements of course.
- ✓ Equipment, for example workbenches, chairs, anti-static workstations, flow benches, engineering machine shop, etc.
- ✓ Information Technology – no longer an option for manufacturing, an ERP system covering material planning, operations planning, inventory management, cost tracking, device master record management, purchasing, document control, change control, CARs, PARs, maintenance of calibration, etc., is a fundamental tool.

STAGE 5 – Manufacturing

▶ Tools

- ✓ **Hand Tools** – complete sets of hand tools (lock them in toolboxes – trust me), soldering workstations, calibrated crimp tools (all of them, at \$300-\$800 each), precision dispensing equipment.
- ✓ **Test and Measurement Equipment** – Digital Voltmeters, Oscilloscopes, Network Analyzers, Laser Power Meters, Temperature Instruments, Pressure Instruments, Flow Instruments, Power Supplies, etc.
- ✓ Potting Equipment, Vacuum Oven, Temperature Chambers, etc.

▶ Supplies

- ✓ Supplies – adhesives, thread-locker, sealants, potting compounds, etc.
- ✓ Hardware and the million other details needed to keep a manufacturing plant running.

▶ Supply Chain Management

Managing the supply chain is one of the keys to success in manufacturing. Starting and maintaining the flow of material, synchronized to your manufacturing cycle requires visibility into your customer's requirements and your supplier's capabilities. A streamlined process for identifying suppliers, ordering material, monitoring performance and mitigating risk is imperative.

▶ Inspection and QA

Inspection covers incoming inspection, in-process inspections, and outgoing inspection processes.

▶ Production Control

Production Control can be a bit of an art depending on the visibility into customer requirements. There needs to be solid communications between sales and production so that inventory levels can be minimized while still being able to hit on-time delivery performance. Consider:

- ✓ Is there a forecast for unit to be delivered?
- ✓ Will units be built to the forecast or order?
- ✓ What is the lead time to start production from zero?
- ✓ What are the lead times required to adjust the schedule (i.e. how fast can you respond to late changes)?

STAGE 5 – Manufacturing

▶ Inventory Management

The goal, of course, is to minimize inventory while also minimizing the risk of running out of material. This will require coordination with purchasing to identify supply risks while keeping an eye on shipping requirements.

If safety stock is required, depending on how fast production needs to respond safety stock can be for raw materials or for finished goods. Raw material safety stock is less expensive to maintain than finished goods. The ERP system is an indispensable tool for managing inventory, but like production control, there is a bit of art involved.

▶ Test Department

Depending on how you have organized the product build (e.g. cells or batch builds, or a combination of both), you may require a separate area for the test department to perform functional tests, calibration, stress screening, safety tests (UL / CE), etc.

▶ Order fulfillment and shipping

With finished goods manufactured, tested and packaged, you must now consider how to ship the product to the customer while maintaining product traceability. Product Resources is set up to handle bulk shipments to a company warehouse, or drop shipment of product to the end customer.

STAGE 5 – Final Deliverable should be a finished product and a consistent, repeatable manufacturing process

What we will cover in

STAGE 6 – **Post-Manufacturing: Installation, Service and Support**

- ✓ IQ/OQ/PQ Services
- ✓ Installation/Preventative Maintenance/Field Service
- ✓ Depot Repair Service
- ✓ Spare Parts Supply
- ✓ Training Services



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