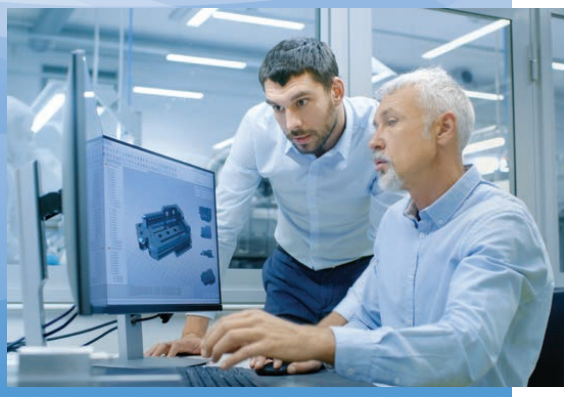
Product Development & Manufacturing

PROCESS CHECKLISTS



STAGE 2

Design

A Completed Design of the Finished Product

PRODUCT RESOURCES

DESIGN – BUILD – SERVICE

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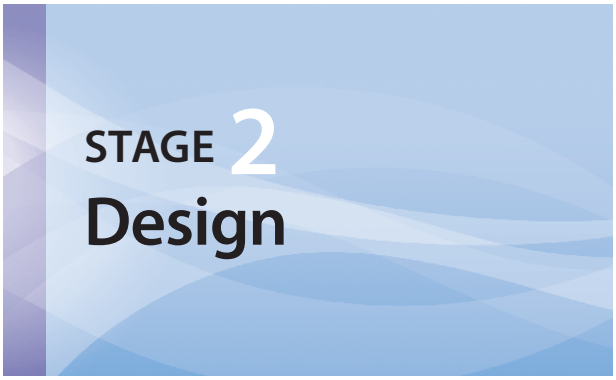
DESIGN – BUILD – SERVICE



- 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 2
Design

In completing the Product Requirements Document (PRD) from Stage1, you have defined the requirements for the product. The design team now has the parameters it needs to develop your product design. Obviously, there will be many checks along the way (design reviews) to ensure the product is true to the requirements but also to allow for updates to the PRD when additional requirements are discovered either by the design team or through research on the technology or the customer application. Updating the PRD will allow for a controlled way to change the direction of the design and will keep everyone on the same page. The PRD will also indicate how the requirements will be verified, whether by testing, inspection, or other means.

The deliverable for this stage, the output of the Design Process, can be in many forms but the minimum design output must be a set of documentation and design database information to allow people skilled in manufacturing similar equipment, to repeatably and reliably manufacture the product. The design process must also be controlled so that you can determine if the design output met the design input and has addressed all the design challenges that were discovered on the way. The design process must also have a Risk Management process to identify and mitigate any critical risks to safety, and to product function.

The Design Control process is a series of checkpoints that are necessary at major and minor design points. All Design Output should be reviewed before being released for manufacturing. One way to think about this – if you publish a document, a schematic, a part drawing, a procedure, etc. – it's time for a design review.

The Risk Management process is required for Medical Devices and we highly recommend them for all products. This is more than a series of FMEAs (Failure Mode and Effects Analysis), but those are a good start. Sometimes products are so simple that the risks seem obvious, but you'd be surprised.

The Design Process is also iterative, with prototypes of different scope and complexity built along the way to verify the technology and the design approach. The simplest prototypes might be a 3D printed part to show that tab A fit into slot B, but prototypes of the final product, covered in the next Checklist, are suitable for Verification and Validation should be production ready versions, perhaps even Pilot Production.

Product Resources uses ISO 9001, ISO 13485, and ISO 80079-34 as a basis for our quality system to cover Design Management and Risk Management.

STAGE 2 – Design

Industrial Design

This design process identifies possible configurations of the overall product and allows the product's look and feel to be identified and documented. The initial industrial design sketches of the product may include several different concepts of the product (typically 5) - each with a different look and feel. These sketches are then refined until there is one left, with the chosen look and feel, and a design suitable for meeting the PRD requirements.

Also consider the design of the software User Interface, if any, in this process. The most beautiful product in the world will fail if the UI is not up to the same standards. If you leave it to Engineering to develop the UI, that's exactly what you'll get – an Engineer's Interface (not that there's anything wrong with that).

The Industrial Designer will need to know how the different users of the product will interact with the product. The Industrial Design is not truly "design output", but the initial concept to base the design upon.

CAD Mechanical Models

A Computer Aided Design (CAD) model will allow you to visualize the product and see exactly how all components will interface with each other. These models are used for designing the product and documenting the design by outputting the component and assembly drawings that will allow the product's manufacture.

- ✓ Do you have a CAD database already in place?
- ✓ Will you be responsible for updating the database as the project progresses?
- ✓ Would you consider outsourcing this responsibility?
- ✓ Are you prepared to generate assembly and custom component documentation?

Product Resources uses up-to-date SolidWorks for its 3D parametric modeling software. The drawings generated and the database itself is considered Design Output.

Electrical Schematics and PCB Models

Electrical schematics are another design document which is used for PCB layout and product wiring. There are a number of schematic "capture" systems that feed into Printed Circuit Board (PCB) layout programs. Whether used for rigid or flexible circuit boards, or even cable assemblies, these databases are used to document the design.

For schematic capture software, Product Resources uses OrCad Capture, Pads Logic, Eagle, or PCBWebDesigner for designing and documenting the electrical components and circuits. For PCB layout software, we use Pads Layout, although we can work in several different systems. The electrical drawings and the databases are considered Design Output.

Software

Software, Apps, Firmware for embedded systems are a typical requirement for products today and need the same attention and control as the hardware. It is as important to document the source code and Integrated Development Environment (IDE) configuration as it is to document the output files that run on the hardware. Software tends to have a development process that parallels the hardware, with testing early on prototype hardware. The IDE and software toolchain choice is highly dependent on the hardware used and appropriate choices for both development and production deployment will impact design and manufacturing costs.

The software installation files, the source code, and the IDE configuration are considered Design Output.

Item Detail Database

The components, assemblies, procedures, and other "things" necessary to build the product are contained in a list of "Items" with the information necessary to completely define the item. This database is considered Design Output. The Item must have:

- ✓ **Part Number** – This identifies the part and ties the part to specific uses throughout your CAD databases and documentation. This is a number that must be unique within your organization. Product Resources has its own part numbering system, unique within our organization, and we use that system to track the different products we manufacture.

- ✓ **Description** – This describes the part and gives the most relevant details of the part; e.g. "Capacitor, 47uF 5%, 25v Electrolytic", or "Bracket, Laser Mount". When describing a component or assembly, try not to embed details on where it is used in the description. "Front Panel LED" leads to confusion if the same part is mounted on a different panel; "LED, Red, Panel Mount" would be a better description. Allow the BOM Assembly structure detail where the component is used.
- ✓ **Part Definition** – either it is COTS or it is Custom, see below…

Commercial Off-The-Shelf (COTS) Components

COTS components are the components and devices in your product that are manufactured to a published datasheet. They include the electrical components that populate your PCB, the hardware that fasten together the mechanical parts of your product, and typically make up most of a product. To properly define a COTS component, you should have:

- ✓ **Manufacturer and Manufacturer's Part Number** – this ties the part to a specific datasheet which will uniquely identify the component. This allows you to purchase the part from multiple suppliers and know that you will get the same part.
- ✓ **Supplier** – identifying which supplier to purchase the component (typically a distributor) is optional, unless you have a reason to use a specific supplier.

Custom Parts

Custom components are the components that are designed by the organization. They include the Assemblies, Machined parts, Molded parts, PCB Fabrications, Procedures and Assemblies, and other parts that are not sold by other manufacturers. Software written for your product is included as a custom part. To properly define a custom component, you should have:

- ✓ For Machined Parts, a detail drawing, with proper dimensions and tolerances of the part. Product Resources will typically send a PDF of the drawing and a STEP file to define the part.
- ✓ For Printed Circuit Boards, a set of photo-plots of the copper layers on the board and a fabrication drawing showing layers and interlayer spacings. This also defines copper thicknesses (weights), tolerances, etc. Also include a netlist so that automated test equipment can verify the integrity of the PCB. These files are separate files and are typically "zipped" into a compressed file for document control.
- ✓ For Molded Parts, a solid model of the part to be molded is necessary, and a drawing detailing critical dimensions and features. If there is a preference for the location of gates and other mold features, this is the document to show it.

- ✓ For Printed Circuit Board Assemblies, you also need a bill of material detailing the component locations (reference designations) as well as the Manufacturer and Manufacturer's Part Numbers.
- ✓ For Software or Firmware to be installed on the product, there are several methods for controlling the software versions. For manufacturing purposes, you will need to provide HEX or Binary files for loading onto embedded processors.
- ✓ For Assemblies, there is a need for a Bill of Materials (BOM) for the assembly, as well as any assembly procedures or drawings.
- ✓ Procedures are also linked to an assembly by including the procedure item on the BOM. This covers a broad range of documents from assembly procedure through test procedures and QA documentation.

Bill of Materials (BOM)

The single document that details or points to detail of each item and assembly in your product is the Bill of Materials. It will detail every component and assembly in your product. It will also outline, using sub-assemblies, the general assembly process. The collection of Bill of Materials is considered Design Output.

The BOM must have:

- ✓ **Part Number** – this identifies the unique component or procedure.
- ✓ **Description** – this describes the part and gives the most relevant details of the part to help the assembler recognize the component.
- ✓ **Quantity** – how many of these components are used on the assembly?
- ✓ **Reference Designator (sometimes "Bubble Number")** – if the assembly drawing points to a component or if the PCB assembly has designations labeled on the board, then the BOM must have those designations listed along with the Part Number to unambiguously identify the location of the component.
- ✓ Where another assembly is called on the BOM, this sub-assembly is treated just like a component (with descriptions, quantities and reference designations). A BOM printed with all the sub-assemblies expanded is called an Indented Bill of Materials.

Other Documentation and Detail

Consider the following documentation…

- ✓ Assembly and Test procedures written and validated
- ✓ Outgoing inspections requirements and reports
- ✓ User manuals
- ✓ Quick start guide
- ✓ Spare parts list
- ✓ Ancillary Material – printer paper and other consumables, power cords, spare fuses, etc.

What we will cover in
STAGE 3 – Prototype

- ✓ Multiple Prototype Copies
- ✓ Supply Chain
- ✓ Long Lead Times
- ✓ High Cost Items
- ✓ Feedback
- ✓ Deliverability

PRODUCT RESOURCES

DESIGN – BUILD – SERVICE

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