PHASE 3 ~ DESIGN FOR MANUFACTURING

Deliverable 11 ~ Manufacturing Specifications

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable11

INSTRUCTIONS. Create a manufacturing specifications document for your interim design. Your manufacturing specifications are due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and included in your design history file.

Purpose

The design process involves communication between different engineers. Design engineers interpret needs, develop concepts, and *refine the best concept* (interim design) into manufacturing specifications. These specifications are traditionally "thrown over the wall" to a separate group of manufacturing engineers that interpret the information and build what they "think" the designers want. To achieve a smoother transition from interim design to manufacturing, and to decrease development time, many companies use a contemporary, simultaneous development approach known as concurrent engineering. Concurrent engineering brings design and manufacturing engineers together early in the design process to *simultaneously develop the product and the processes for creating the product*.

Manufacturing specifications will be used later in the manufacturing plan (phase 3 closing event) to request approval for the design team to continue the design project into the production stage.

Critical Information

A manufacturing plan is a combination of drawings (e.g., blueprints, circuit diagrams, flow charts) and texts (e.g., parts lists, materials specifications, assembly instructions) that define the final product designed for manufacturing.

At the heart of the manufacturing plan, the manufacturing specifications must enable anyone (not only one of the designers) to make what the designers intended so that it performs as desired. ***The manufacturing specifications must be:***

- ***Unambiguous***. The role and place of each and every component and part must be unmistakable
- ***Complete***. Comprehensive and entire in their scope
- ***Transparent***. Readily understood by the manufacturer or fabricator

In general, the manufacturing specifications should answer the following questions:

Drawings

- Do you have a complete set of *drawings including tolerances and dimensions* to be used?
- Is the *final, manufacturable product clearly described* in terms of geometry, layout, and schematic representations?

Parts/Cutting Lists

- What will you do to *produce each part*? And how will you *use tools, equipment, etc.*?
- Are you aware *how the parts fit together*?
- Do you have a preliminary plan for the *order you need to procure or produce parts*?

Materials

- What *materials* have you decided to use (based on research)?
- Do you have the stock materials that you need to make your parts? If not, *can you get it locally or will you have to order it*?

Processes and Tools

- Do you have *preliminary processes or plans for the necessary production operations*?
- Do you have a *list of the tools you intend to use* for each process?

Specifications Document: A Step toward a Manufacturing Plan

In addition to other international standards published by the International Organization for Standardization (*see ISO 9001 and ISO/DIS 13485*), the U.S. Food and Drug Administration (FDA) has a Code for Federal Regulations (CFR) that requires each manufacturer to establish and maintain procedures to ensure that the device design is correctly translated into production specifications. (*see Title 21 CFR 820.30(h) for details*). These specifications must ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities. *Note, the FDA "production specifications" are representative of the "manufacturing plan" in this course*.

The FDA states production *specifications include drawings and documents* used to procure components, fabricate, test, inspect, install, maintain, and service the device, such as the following:

- Assembly drawings
- Component and material specifications
- Production and process specifications
- Software machine code (e.g., diskette or master EPROM)
- Work instructions
- Quality assurance specifications and procedures
- Installation and servicing procedures
- Packaging and labeling specifications, including methods and processes used

In addition, production specifications may take on other forms and the level of detail necessary to encapsulate knowledge about the device into production specifications varies widely, but is critical to device quality.