

## PHASE 3 ~ DESIGN FOR MANUFACTURING

### Deliverable 14 ~ Product Feasibility Report

Due Date: <http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable14>

**INSTRUCTIONS.** Create a product feasibility report for your device. Your report is due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

#### **Purpose**

A product feasibility report is a document describing the proof-of-principle (PoP) or proof-of-concept (PoC) studies demonstrating the potential success of a product, preventing costly errors, and ensuring the most successful way forward with the design process. *The feasibility report proves that the product can be made to meet the required specifications and it is capable of being used in its proposed way.* The product feasibility report is crucial for decision making and product development in almost any technical organization because managers decide where to commit scarce resources based these reports.

***Product feasibility information will be used later for the user evaluation (deliverable 15) and 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**

The goal of this deliverable is for the design team to prove to the stakeholders and instructors that the intended product design is feasible. All virtual prototyping, rapid prototyping, and preliminary test should be documented. Engineering software tools such as Computer-Aided Design/Manufacturing (CAD/CAM), Finite Element Analysis (FEA), and simulation are encouraged.

In general, the product feasibility report should cover the following areas:

- **Production.** Can the detailed design be manufactured?
- **Materials.** Are materials necessary for the design readily available?
- **Cost.** Can the working prototype be made within the allowable budget?
- **Quality Standards.** Will the prototype quality delight stakeholders and make an excellent case for continued product development?

#### **Product Feasibility Report: A Step toward Manufacturing and Regulatory Review**

The FDA reviews the non-clinical product feasibility data provided to support the basic safety and performance of the device. The type and extent of non-clinical data needed depend on several factors, including: whether the device is an in vitro diagnostic, an implanted device, or a device external to the body; the duration of use; and the expected performance requirements. Examples of bench data that may be needed include testing to demonstrate acceptable biocompatibility,

sterilization, electrical performance, mechanical performance and durability, drug or biologic characteristics for combination products, and software validation. In addition, computational modeling can be used for a variety of purposes to support the product feasibility report.

In the end, the conceptual, or interim, design along with hand drawings is not enough to demonstrate the product design is feasible; therefore, the team will need to present results of preliminary testing, computer simulation, virtual prototyping, and/or rapid prototyping.