Design Foundation Document: Design Context Review, Market Analysis, Customer Needs and Design Specifications

Why you do it

Prior to any engineering design, four questions must be addressed that will lay the foundation for successful product development:

- *What background knowledge or information do I need to know? (Design Context Review)*
- *Who is my customer? (Market Analysis)*
- *What are their needs? (Customer Needs)*
- *What will we, as engineers, deliver? (Design Specifications)*

Engineers are typically very skilled at designing to specifications or constraints given them. Without understanding where these specifications originate can result in unsuccessful products and even serious risks. Many products have failed due to lack of background knowledge, not selecting the appropriate customer, or misunderstanding their needs. The following steps are explained in greater detail in chapters five and six of Ulrich & Eppinger. The steps outlined in chapters three (Opportunity Identification) and four (Product Planning) were already performed by your sponsors and professors prior to the beginning of the semester.

Upon completion of this process, you should have sufficient information to develop a strong, clear need statement. Also, you will have focused, quantifiable target specifications to begin your concept generation and prototyping activities.

The Design Foundation Document

The Design Foundation Document should consist of the following four sections. Please use the Product Development Worksheet discussed in class and include a printed copy at the end of your document. You may wish to use the tables in the worksheet throughout your final document. The design context review should be a maximum of 2,000 words. The entire design foundation document should not exceed 4,000 words.

Section 1: The Design Context Review

Every project requires very specific knowledge that you likely have not learned as a student. At the end of the semester, you will be the experts on your product. The design context review will start you on that path. The design context review in capstone design serves two primary purposes. First, it ensures that your team has educated itself thoroughly about the problem your project will solve and the status of other currently used or proposed solutions. Engineering students must become familiar with the terminology, technology, and economics associated with their projects. Writing a design context review requires your team to locate appropriate source material, sort through background information, and write a focused document that describes the specific problem you plan to solve.

Second, it improves your team's ability to communicate with its audiences—managers, sponsors, advisors, and others standing to benefit from your project—who don't need to know as much as you do. In academic and industry work, a design context review (also called a literature review) is an essential requirement in proposals. This review puts you—the student team—in the role of expert and educator. Your design context review will persuade your audience that a problem exists. The written review also demonstrates your team's understanding of the problem and factors associated with solving it.

How to prepare the design context review

The design context review process consists of three steps:

1. Educate yourself about your project
2. Determine your need statement
3. Outline and write the design context review document

These accelerated techniques will assist you with this assignment. They will also help you organize complex information in other situations.

Step 1: Educating Yourself

Projects in Medical Device Design require your team to become experts on complex technical and business issues. To fully understand your team's

mission and begin to articulate a specific problem that will drive your project, your team will need to review literature in your project area.

Your self-education will be *more* extensive than the information you will ultimately provide to your readers. That's because your readers are interested *only* in the problem you plan to address and the reasons it should be addressed. To make your case, you will need to arm yourself with a broad range of information in your project area, including:

- Necessary background information about the environment of your design (e.g. medical projects, the physiology of the disease area or characteristics of the health application or process with which your project is associated)
- Identification of customers that will use, pay for, or authorize the use your design (More on this in the next section)
- References to applicable standards in the area of your project
- Descriptions of current technologies you might use in your design
- Current competitive products or existing intellectual property (like patents) in the area related to your product

Examples of research topics can be found in the product development worksheet. **Fill out the Product Worksheet with topics in each of these areas that you plan research, with at least three topics under each section.**

Step 2: Determining the Problem/Need Statement

Need statements define a problem and describe general points around which quantifiable design criteria can be established. According to Yock et al, they usually consist of:

- The PROBLEM to be solved
- The POPULATION that will benefit, and
- The OUTCOME that is desired.

These statements can be stated in the following way: A way to (PROBLEM) in (POPULATION) in order to (OUTCOME). For example, "A way to safely access the pericardium in patients with cardiac tamponade in order to quickly drain a pericardial effusion.

The need statement provides an organizing structure for your design context review. Knowing the need statement at this stage in your work will enable you to identify appropriate background information to include in the design context review. Note, however, that in the written design context review, you will *place the need statement at the end*. Introductions of research articles and design reports typically move from what is *known* about the topic to what is *not known* or *in question*, and end with the *problem or need statement*. While your design context review will cover substantially more information than the typical introduction, following this structure will help you when you ultimately condense your final design report in Phase 3.

Step 3: Preparing the Design Context Review

The process of researching your problem and developing a need statement, your research will leave your team well prepared to develop a problem-focused design context review. You only have a maximum of 2,000 words to make your case, so you will need to choose the information to report carefully. A well-written design context review will help your audience understand the motivation for your work. It will also help your team identify design criteria for successful solutions.

You will begin by preparing an outline from your design context review by transferring connections and ordering that you explored in the design context map to a traditional outline format. The process you have followed should result in a problem-focused outline.

Once you have settled on your outline, you can begin drafting the design context review. Your team contract should outline a process for collaboratively writing the review. Follow this process in developing your draft. As this is the first major document you will produce in this course, you should evaluate how the process works and make adjustments if you see areas that are inefficient or need improvement.

Section 2: Market Analysis

Armed with the background knowledge of you design context review, you are prepared to develop a market strategy and determine who is your customer. A simple market analysis can be performed by the taking the following steps:

1) Identifying Market Segments
2) Estimating Market Sizes
3) Assessing Competitive Products/Solutions
4) Assessing Willingness/Ability to Pay
5) Estimating the Total Addressable Market (TAM)
6) Write your Market Analysis document

While the text (U&E) doesn't cover market strategy, there are a number of online resources that are helpful, including the US Small Business Administration's website: http://www.sba.gov/category/navigation-structure/starting-managing-business/managing-business/running-business/marketing

1) Identifying Market Segments

Market segments are groups of people that share similar needs. Segmentation can be performed along several different dimensions, including geography, age, gender, hobbies/interests, etc. One helpful way to think about a market segment is a group that has a common "job" that needs to be done (http://www.christenseninstitute.org/key-concepts/jobs-to-be-done/). Give some thought as to what job(s) you are trying to accomplish, and what market segments may benefit from your product. For example, a product that is designed to help elderly patients with Alzheimer's eat independently may also benefit patients with disorders such as Arthrogryposis. Then, list at least three of these potential segments in the Product Worksheet. Be sure to be as specific as possible when identifying a segment.

2) Estimating Market Sizes

For each of the segments you've generated, estimate the number of people within the segment on the worksheet. Try to use as many reliable resources as you can find, but this may take some creativity. You may make assumptions, but list them with your reasoning. Market reports available

online and volumes of competitive products may provide some good indicators of market size. See the course lectures for more details.

3) Assessing Competitive Products/Solutions

For each segment, list competitive products or solutions available to the customer that might fulfill the same need/job that you will address. The current product might be only partially fulfilling the need, or no product may exist. In situations where there is no product, what solutions (such as avoidance, etc.) might the customer pursue?

It's very important to look at competitors closely at this stage. Many teams do not look closely at competitive devices, and find too late that the product they are designing is very similar to another product. Careful research now can prevent last-minute pivots toward the end of the year.

4) Assessing willingness/capability to pay

While it is hard to project what a customer might pay for a product, provide your best guess for each market segment. Consider carefully what customers are currently paying for competitive products, or what alternatives they might pay for. Keep in mind that in some circumstances, the user is not always the payer. For example, medical devices are used by physicians and/or patients, but are paid for by hospitals and ultimately, insurance companies.

5) Estimating the Total Addressable Market (TAM) for your top market segments.

Drawing from your market analysis, select one or two target segments that will be the focus for your product. Ideally, the segment you choose will have a large market size, few competitors, and willingness to pay a high amount for your product. In reality, it's rare that a segment will be the best in all dimensions. Also, several of the products we design in this course may have very small market sizes (such as pediatric or global health projects) but have very large impact. Give some thought as to what dimensions might matter most for you product. Estimate the Total Addressable Market (TAM) for each market segment by multiplying your estimates of market size and willingness to pay.

6) Write your Market Analysis Document

Your market analysis document should be no longer than 1000 words, and should begin by describing what segment(s) you are targeting size of the Total Addressable Market (TAM). The remainder of the document should describe how you arrived at this decision, including an explanation of your assumptions and reasoning. You should mention the other potential market segments. Be sure to include references where appropriate.

Section 3: Identifying Customer Needs

After identifying your target segment, the next step is to identify the needs of the customers in that segment. Customer needs are qualitative statements of constraints, features and characteristics of the final product. The research you performed in your design context review and discussions with your sponsor will give you a good place to start; however, it is important not to assume that you know all your customer's needs, and the relative importance of those needs.

In addition, many times sponsors or professors (and your future managers) may provide solutions as customer needs. As engineers, we tend to jump into solutions as quickly as possible. This is dangerous because it can lead to unexplored design space, and products that don't address true needs. It is important during this process that you (and your mentors) take a step back to understand the underlying needs and suspend all problem-solving. This will set the stage for good design.

The steps for identifying customer needs are explained in detail in Chapter 5 of Ulrich & Eppinger. These are:

1) Gather raw data from Customers
2) Interpret raw data in terms of customer needs
3) Organize these needs into a hierarchy
4) Establish the relative importance of the needs

Follow this process by generating a table of prioritized customer needs in your Product Worksheet. Importantly, include needs on the Product Worksheet that are from payers, regulators, and industry standards. Draw from the research you did in your Design Context Review. Depending on

your project, it may be difficult to gather raw data from customers. Do your best to interact with real customers to gather needs. Keep in mind, however, that formal surveys and interviews may need IRB approval. Please check with your professor prior to conducting any surveys or interviews.

In your customer needs document, explain the steps you took to gather, interpret, organize and prioritize your customer needs. This should not exceed 500 words. Also, share your customer needs table.

Section 4: Design Specifications

The last step prior to beginning concept generation and prototyping is to translate the needs (the language of the customer) into design specifications (the language of engineers). Whereas customer needs are qualitative statements of product characteristics, specifications are quantitative, measurable characteristics that satisfy a customer need. The specifications, when met by your final product, should fulfill all desired customer needs. Chapter 6 of the text explains the process of setting specifications, including:

1) Preparing the list of metrics
2) Collecting competitive benchmarking information
3) Set ideal and marginally acceptable target values

This year, students will use the House of Quality approach from the Quality Functional Deployment (QFD) toolbox. This is a simple way to map your customer needs to your design specifications. **Follow the steps outlined in class to fill out your House of Quality, found in the product development worksheet.** A couple of considerations:

- The U&E book uses the terms “metrics” and “specifications” interchangeably in many sections
- Make sure that each customer need you have identified is addressed by a specification. Some needs may be difficult to measure, in which case provide a written explanation below the table on how you will fulfill the need.
- On the row at the bottom of your table, there is a column for target value. For now, provide your best guess on the value

you'd like to hit. We recognize that these values will change as you learn more about your product. As discussed in the text, at this point these are "target specifications" which will evolve into final specifications by the end of cycle three.

In your design specification document, describe the process of creating metrics, gathering benchmarking data, and establishing your ideal and marginal values. This should not exceed 500 words. Also, share your specification table.

** This content was co-developed my Dr. Maria Oden at Rice University and Dr. Eric Richardson at Duke University.