

This page is intended to be a short, non-exhaustive guide that may address some FAQs and lead you in the right direction as you begin your medical device design process! The goal of User Needs Tips & Tricks is to further clarify the assignment instructions, expectations, and rubric.

### **Disease State Fundamentals Potential Keywords**

#### **Hip**

- Aseptic loosening
- Growth factors
- Osseointegration
- Osteoarthritis

#### **Bypass**

- Restenosis
- Thrombosis
- Restriction of blood flow through the limbs
- Atherosclerosis

### **Instructions**

- Clinical Need / Disease State Background
  - Define the clinical need (i.e. disease state) to be addressed with your final project
    - Research the key words we found in class on slides 27 and 28 listed above!
    - Why is this condition and its treatment important?
    - What are symptoms and means of diagnosing this condition?
  - Explain what drugs or growth factors would improve patient outcomes
    - If you had to choose, which one and why?
    - Consider the method of consumption, concentrations, how it binds, etc.
    - Look into commonly used products
    - Finding clinical studies can be helpful (not always possible)
    - Search for stats for the population you choose (how many people affected by disease)
  - Ensure it is detailed for reader understanding to justify the needs statement
- Existing Products & Regulation
  - Consider a patent search for predicate/related devices!
  - If an existing product(s) exists, how could this existing product(s) be improved to better fulfill your user needs?
  - If a predicate product(s) does not exist, what characteristics from other products would you like to use in your eventual solution to satisfy your identified user needs?
  - Avoid solution bias in your discussion.
- Stakeholder Analysis
  - Include ONE graphical representation of your findings (e.g. flowchart with stakeholders as nodes and indicators of positive/negative effects.)

- Market Analysis of your future device
  - Pie charts are useful here! TAM encompasses SAM, and SAM encompasses SOM.
  - Who do you expect to compete with for market share?
  - Don't forget your market dynamics figure!
- Needs Statement
  - Should be concise (1-2 sentences)
  - Can be integrated into a summary as a closing paragraph to your User Needs
- General
  - Make sure all sections flow well into each other
  - Make sure visuals are readable (reminder: they don't contribute to your page limit!)
  - Keep formatting consistent (same font, consistent font sizes, consistent indenting, etc.)
  - Take special care with properly citing information and validating trustworthy sources, the teaching team checks citations

## Expectations

- Works cited will not count towards the page limit. Start a new page for this
- Figures will not count towards the page limit.
  - If your User Needs ends halfway through a page, then the rest of that page should remain blank and the works cited will start on the next page
- If you feel like you can't fit all of your information into  $5 \pm 0.5$  pages, don't worry! Make sure you save all of your notes. They may be beneficial to later assignments this semester.
- **Invest in this project! The rest of the semester will build upon this initial User Needs inquiry, so work done well now will transfer well to later deliverables.**
- Remember that this is a draft! We expect great work, but don't exhaust yourself for perfection! You will have time later this semester to refine your User Needs before it becomes a part of your DHF