Design Review Case Study – Assignment E – Verification and Validation Studies
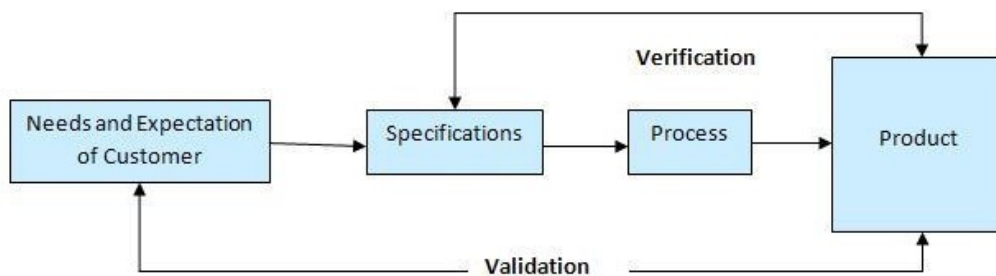
Cell & Tissue Engineering

Introduction

In this section of your case study you will provide information about verification and validation of your selected cell/tissue engineered solution. Verification and validation are two different things.

Instructions

In the design process you start with a user need and from there you construct design criteria or specifications. This is what you laid out in Assignment D. Theses specifications (or design inputs) inform the process (or design outputs); in other words they craft the solution concept that becomes the product. Verification tells you that the product met the specifications or that the design inputs meet the design outputs. Did you make what you said you were going to make. Validation is different. Validation tells you whether the product or solution truly meets the need.

In this assignment we'd like you to find evidence and describe an example of each validation and verification for your product. For verification this will likely be from a bench testing or early phase testing. Does the product work and how do you know! For validation this will be from end user reports – either from patient studies, feedback from clinicians, market-share showing product adoption or the like.

This document is a draft of a section that will be included in your final report. It is intended as a tool for you to get feedback on your progress. It is expected that this document be full-text unless otherwise specified.

Additional Information

- Resources on proper citation and best practices in online research are available online at the JHU Krieger School Writing Center.
- Page limit 2, final point value 20/100, include project topic in header
- Reminder, drafts are worth 50% of the final point value 10/100
- Use MLA format.

Grading Rubric

Points	Component	Description
6	Content 3 pts Verification example 3 pts Validation example	**Verification** Evidence of at least one key verification study, reported data demonstrating the most important aspect for proof of concept **Validation** Evidence of at least one key validation study, how was it conducted, what was the outcome
2	Organization and Structure	Clearly organized content with natural progression and structure. Double spaced. Informative subheading when necessary.
2	Writing	Superior narratives and analyses that are clearly and simply written. References included as appropriate.
10	**SUM**	