<u>Bioengineering Day Poster Addendum (ABET questions)</u>

1. List two to four **Desired Needs** of your project that led to your final design objectives.
   Answer in two to four bullet points or concepts within a sentence or two.
   - **Anatomical and Physiological Realism:** There is a critical need for an *in vitro* platform that accurately replicates vaginal geometry and thermal conditions (37°C).
   - **Cost and Time Efficiency:** The system must allow for quick setup and rapid swapping of components, facilitating high-throughput testing with minimal downtime.
   - **Dynamic Rotation:** The system must simulate various body angles through controlled rotation to track movement effects on internal processes.

2. List the major **Constraints** on your design/project
   a) **Safety/Regulatory Affairs:** The device must comply with standard laboratory safety protocols, specifically regarding the low-voltage electrical components used for heating and rotation.
   b) **Risks**: The primary technical risks include potential leakage at the modular clamshell interfaces and material fatigue of the synthetic silicone canal over repeated use, both of which could compromise the physiological accuracy and reproducibility of the drug retention data.
   c) **Global Impact**: By providing a low-cost, reusable alternative to animal models, this device increases accessibility for researchers in budget-constrained settings.
   d) **Manufacturability**: The assembly is designed for easy replication using common 3D-printing techniques and off-the-shelf mechanical components.
   e) **Quality Control**: Regular calibration is necessary to ensure the platform provides a reliable and standardized baseline for every test performed.

3. List the major **Engineering Standards** on your design/project
   c) standards that could be developed from your project
   - This project could establish a new standard for simulating dynamic body movement during drug testing, defining specific rotation angles and speeds to ensure data consistency across different benchtop models.
   - My work could help define a standard protocol for the maintenance and validation of reusable testing platforms, ensuring that repeated use does not compromise the accuracy of drug deposition measurements.
   - This research could contribute to a standardized "Reference Material" profile for synthetic vaginal simulants, creating a universal benchmark for friction and elasticity in non-clinical testing environments.

4. Explain **Ethical, Environmental, or Societal concerns** for practical applications of your project.
   - **Ethical**: By providing a high-fidelity benchtop alternative, this project supports the ethical "3Rs", Replacement, Reduction, and Refinement, by reducing the need for animal models in early-stage pharmaceutical testing.
   - **Environmental**: The reusable modular design significantly reduces laboratory waste compared to single-use models. The use of durable silicone and 3D-printed components allows for cleaning and long-term use rather than frequent disposal.
   - **Societal**: This low-cost, reusable platform increases global accessibility to drug-testing tools, helping to accelerate the development of critical therapeutics for women's reproductive health in both high- and low-resource settings.

5. Describe **Active Teamwork** and **Leadership** in your design group
   a) **collaboration** and inclusion of diverse opinions?
   - As the sole student on the project, I actively sought and integrated diverse technical perspectives through weekly consultations with my PI, Dr. Erika Cyphert, and PhD mentor,

Yumie Lee. I incorporated their feedback on anatomical accuracy and drug-delivery protocols to ensure the benchtop model met professional research standards.

b) **delegation** of leadership on subprojects?

- I functioned as the lead project manager, delegating technical research tasks to myself across multiple domains. I managed the independent development of the mechanical rotation hardware, the integration of the electrical thermal control system, and the fabrication of the modular silicone components.

c) establishing and reaching **goals and deadlines**?

- I established a rigorous individual project timeline to manage milestones for the Final Design Review and Bioengineering Day deadlines. By maintaining a structured workflow, I ensured that a functional, validated prototype was completed for testing according to the pre-set academic schedule.

d) received or given **constructive feedback**?

- I participated in regular review sessions where I received and implemented constructive feedback from Dr. Erika Cyphert and Yumie Lee.

6. What were the most significant motivating factors that led you to

a) acquire **new knowledge**

- The primary motivation for acquiring new knowledge was the technical requirement to create a fully autonomous physiological environment. To achieve the 37°C thermal stability and controlled rotation needed for valid drug-retention testing, I independently studied closed-loop control logic and sensor integration, moving beyond my core curriculum to implement these hardware features.

b) be **self-initiating**

- I was self-initiating in the design of this system because of the urgent need for accessible, low-cost tools in reproductive health testing. I led research on synthetic material properties and additive manufacturing to develop a modular clamshell assembly, ensuring the platform was not only functional but also reusable and efficient for high-throughput laboratory use.

c) **persist** against challenges and setbacks.

- My persistence through technical setbacks was driven by the goal of lowering the barriers to entry for drug-retention testing. Knowing that a successful benchtop model could save significant time and money in the development of life-saving therapeutics for women motivated me to iterate on the mechanical design until the platform reached consistent, reproducible performance.

7. What are your most **innovative and/or entrepreneurial ideas** for this project

- The most innovative idea is to turn this platform into a standardized "plug-and-play" kit for labs. Instead of every researcher building their own custom setup, they could use this consistent, reusable model to get results that are easily comparable across the industry.
- From an entrepreneurial standpoint, the device's biggest value is its ability to "fail fast." By using a reusable benchtop tool instead of expensive animal models, pharmaceutical companies can test many different drug versions quickly and cheaply to find the best one before moving to clinical trials.
- There is a significant business opportunity in creating tools specifically for women's health, a field that has been historically overlooked. This device fills a specific niche by providing a specialized, low-cost solution for testing reproductive health therapeutics that currently don't exist on the market.
- The design allows for a "subscription" style business model. While the main machine is a one-time purchase, the lab can sell different types of replaceable silicone inserts to simulate various physiological conditions, ensuring the device stays useful for many different types of studies.