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.
   - No affordable, accessible point of care tool exists prior to insulin usage
   - Rapid identification of insulin patient vials
2. List the major **Constraints** on your design/project
   a) Safety/Regulatory Affairs
   - FDA approval outside current project scope but all design choices made in anticipation of future compliance

   b) Risks
   - Improper fitting of components and inaccurate results

   c) Global Impact
   - ~38.4 million Americans and hundreds of millions globally live with diabetes, so insulin potency verification is a worldwide unmet need

   d) Manufacturability
   - Main manufacturability risk: silicone stopper dimensional consistency across large batches; mold tolerances must be tightly controlled

   e) Quality Control/Marketability
   - Cycle reliability tested over 10–20 simulated use cycles tracking vial alignment and draw completion time
3. List the major **Engineering Standards** on your design/project
   a) affected the components used in the device

   - ISO 10993-1:2018 Biocompatibility risk framework; drove selection of medical-grade stainless steel for the needle entering the insulin vial

   b) standards that could be developed from your project
   - Standards using DLS classification of insulin potency could be developed from our project.

4. Explain **Ethical, Environmental, or Societal concerns** for practical applications of your project.
   - Ethical concerns that could be raised is the integrity and protection of the data of the patients that will be stored within the database.
5. Describe **Active Teamwork** and **Leadership** in your design group
   a) **collaboration** and inclusion of diverse opinions?
      - Weekly meetings and design reviews conducted by all team members.

   b) **delegation** of leadership on subprojects?
      - Subprojects were delegated based on technical background. Mechanical assembly, Arduino firmware, and software design had team members assigned.

   c) establishing and reaching **goals and deadlines**?
      - Milestones were tracked using a Gantt chart and biweekly meetings with mentors.

   d) received or given **constructive feedback**?
      - Mold failures were documented and systematically addressed with multiple iterations, web app would need synthetic data for analysis.

6. Motivating Factors

- New Knowledge: We worked through academic literature and patents to develop a signal processing pipeline from scratch.
- Self-Initiating: Recognizing that commercial DLS instruments cost $15,000+, we independently sourced a 532 nm diode laser and avalanche photodetector at under $300 total and designed the optical path around them.
- Persisting Against Challenges: Early prototypes produced inconsistent autocorrelation curves due to stray light. We systematically blackened all interior surfaces and added a spatial filter, resolving the issue without supervisor intervention.

7. Innovative and Entrepreneurial Ideas

- Integrate a Bluetooth-connected smartphone app to log test timestamps and Z-average results, enabling longitudinal tracking of insulin quality across a patient's supply.
- Extend the optical design to detect aggregation in GLP-1 receptor agonists (e.g., semaglutide), expanding the addressable market as injectable biologics proliferate.
- License the sealed-sample quartz tube cartridge as a single-use consumable paired with a reusable reader unit — a razor-and-blade model that reduces upfront cost while sustaining recurring revenue.