Evalin: DLS-Based Insulin Quality Testing Device

1. Desired Needs

- Rapid, non-destructive verification of insulin in prefilled vials.
- A portable, low-cost device accessible to patients and clinic staff.
- Quantifiable output that can flag degraded insulin before it is administered to a patient.

2. Major Constraints

- **Safety/Regulatory Affairs:** Future FDA 510(k) pathway would require validation against reference methods.
- **Risks:** Mechanical misalignment of the cam mechanism could introduce vibration noise into the measurements.
- **Global Impact:** Insulin degradation is a leading cause of dosing failure in patients injecting insulin at home; a low-cost quality check could prevent hypoglycemic or hyperglycemic events worldwide.
- **Manufacturability:** Spring-loaded plunger and quartz tube assembly were prototyped with off-the-shelf components. Scaling to injection-molded parts would require redesigned tolerances and material validation.
- **Quality Control/Marketability:** target market includes home users, pharmacies, and humanitarian aid organizations.

3. Engineering Standards

- **ISO 13321/ISO 22412:** govern measurement of particle size distribution and polydispersity index.
- **USP <797> and ICH Q1B:** pharmaceutical photostability and container integrity standards led to the quartz tube selection.
- **Standards that could be developed:** a device-specific performance standard for insulin verification, defining accurate output ranges and required measurement repeatability.

4. Ethical, Environmental, and Societal Concerns

- **Ethical:** A false-negative result (device clears degraded insulin) carries direct patient harm risk. We addressed this conservatively by setting detection thresholds based on literature-reported sizes of clinically harmful fibrils (>200 nm).
- **Environmental:** Prototype uses minimal materials. Commercial scale should consider recyclability of the single-use cartridges.
- **Societal:** Broader access to insulin quality testing could reduce preventable complications for the ~9 million insulin-dependent patients globally who lack reliable refrigeration infrastructure.

5. Active Teamwork and Leadership

- **Collaboration:** Weekly design reviews included all team members. Decisions on component material and geometry were made by consensus after testing.
- **Delegation:** Subprojects were assigned by technical background: mechanical assembly, Arduino firmware, and web app design each had a dedicated owner.
- **Goals and Deadlines:** Milestones were tracked against the course design history document (DHD); Prototype was fully completed before the cam mechanism was tested.
- **Constructive Feedback:** Midpoint tests found that the silicone material was too weak for the stopper component, the web app was going to need synthetic data instead of device data, and an extra luer needed to be made for the needle to tube connection.

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.