

1. Desired Needs

- Designing an accurate, reliable, and automatic fluid draw mechanism for insulin to ensure proper fibrillation detection during optical analysis
- Creating a software application to analyze optical results and display them in a user-friendly interface

2. Major Constraints

- Safety/Regulatory Affairs: Class II medical device under FDA
- Risks: Incorrect results can lead to patient hyperglycemia (false negative), wasted insulin (false positive), and reduce the user's trust in the device. Also a risk of user error and injury on the needle of the device, and potential contamination.
- Global Impact: A low-cost quality check of insulin before injection could prevent wasted insulin and hospitalizations, especially in areas without reliable refrigeration.
- Manufacturability: Cartridge assembly was prototyped with off-the-shelf components. Scaling to injection-molded parts would require new 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) could potentially harm users.
- Environmental: Prototype uses minimal materials. Commercial scale should consider recyclability of the single-use cartridges.
- Societal: Broader access to insulin quality testing could reduce complications for insulin-dependent patients who lack reliable refrigeration infrastructure.

5. Active Teamwork and Leadership

- Differing backgrounds from BTECH, BENG, software backgrounds, subprojects chosen and lead on interest and time, flexible weekly deadlines, team and mentor feedback weekly.

6. Motivating Factors

- Reading academic literature and patents to develop a deep understanding of the constraints and goals. Improving upon prototypes through trial and error. Adapting to challenges with creative solutions (developing synthetic data to test software applications when real device data was not available).

7. Innovative and Entrepreneurial Ideas

- Developing a cheap, fast, at home alternative to testing insulin instead of needing a specialized testing facility. It doesn't require a large quantity of insulin to get results, and the cartridge is single-use to minimize contamination.