Project 21 Addendum Sophia Lin

1. Desired Needs
   - Low cost, automated sorting and quality control platform to be accessible to research labs
   - Preserve organoid viability and sorting accuracy
2. Major Constraints
   a) Safety & Regulatory Affairs
      - Prevent pressure build up or leakage that can break device
      - Future clinical/commercial applications as laboratory device requires FDA 21 CFR Part 820
   b) Risks
      - Shear-induced organoid damage during sorting and handling
      - Inaccurate sorting can lead to inconsistent and unreliable experiments
   c) Global Impact
      - Improved organoid quality consistency benefits research relevant to neurological disorders affecting millions worldwide
   d) Manufacturability
      - PDMS cast on resin-printed molds enables rapid, low-cost iteration and manufacturing
      - Modular architecture with separate components allows independent replacement or upgrades
   e) Quality Control/Marketability
      - Sorting accuracy validated using bead phantoms of known diameter and sphericity
      - Flow conditions validated against analytical shear stress calculations before biological use
      - Target market: academic organoid labs, neurological disease research centers
3. Engineering Standards
   - ISO 10993 (Biocompatibility of Medical Devices): material selection for all fluid-contact components
   - ISO 22916 (Microfluidic Devices)
4. Ethical, Environmental & Societal Concerns
   - Ethical: Device reduces reliance on animal models for neurological research, aligning with FDA initiatives to phase out certain animal testing.
   - Environmental: Mineral oil and uncured resin require proper chemical waste disposal. Resin mold reusability reduces per-device material waste. PDMS is chemically inert but is not biodegradable.
   - Societal: Improved organoid sorting consistency accelerates drug discovery and disease modeling.
5. Teamwork & Leadership
   - The team held regular meetings to share progress across subprojects ensuring integrated design decisions and inclusion of all perspectives.
   - Leadership was distributed by subproject while contributing to shared fabrication and testing tasks.
   - Project milestones were tracked against course deliverable deadlines with iterative design cycles informed by experimental results and advisor feedback.
   - Constructive feedback was exchanged during design reviews and meetings, incorporated throughout the fabrication and validation process.
6. Motivating Factors
   - The biological application, fabrication techniques utilized, and building a device from scratch motivated self-directed learning.
7. Innovative/Entrepreneurial Ideas
   - Integrating real-time morphological imaging and automated valve actuation into a single less than $200 millifluidic platform, making organoid quality control accessible to labs