

SHIVANGI SARKAR

ssarka29@asu.edu | 480-823-9015

<https://www.linkedin.com/in/shivangi-sarkar/> | <https://github.com/shivisark> | <https://www.shivangisarkar.com/>

EDUCATION

Master of Science in Biomedical Engineering

Arizona State University, Tempe, AZ

Bachelor of Science in Biomedical Engineering

Barrett Honors College & Arizona State University, Tempe, AZ

EXPERIENCE

Mayo Clinic | *Graduate Engineering Intern*

May 2024 – May 2025 | Rochester, MN

- Drafted IQ protocol for PVD system used in microfabrication; led validation documentation efforts for device readiness.
- Designed and implemented SOPs for software validation (Preform); aligned efforts with ISO 13485 and FDA guidance.
- Reduced software-related testing errors by 25% by performing processes like risk management (FMEA).
- Conducted internal audits of QMS; ensured compliance with FDA (21 CFR 820) during cross-functional reviews.
- Performed component-level validation on additive-manufactured implants (Ti-6Al-4V); used ANSYS for stress testing.
- Actively collaborated with Quality, Manufacturing, Regulatory, and R&D teams.

Desert Platforms | *New Product Development Intern*

Sep 2023 – Dec 2023 | Phoenix, AZ

- Managed Design History Files (DHF) to ensure compliance regulatory standards.
- Drafted and edited test protocols in compliance with ISO 13485 QMS standards.
- Co-authored SBIR and AFWERX grant proposals emphasizing feasibility, quality, and compliance strategies.

KEY PROJECTS

Automated DHF Generator (ECG Patch)

Jun 2025

- Python tool that automates creation of DHF, linking design inputs/outputs/risk/FMEA.
- Automated traceability matrix and Word-based DHF report generation.
- Integrated risk-based prioritization and verification tracking.

Air Quality and Motor Skill Study

May 2025

- Linked PM2.5 exposure to cognitive/motor performance in human participants.
- R-based data cleaning, spatial joins (geosphere), visualization (ggplot2).

Heart Disease Prediction with ML

May 2024

- Developed multiple classification models on patient datasets; 92.6% accuracy (Random Forest).
- Used Python (pandas, scikit-learn, matplotlib) for model building and validation.

Blood-Brain Barrier-on-a-Chip – Curcumin for TBI

May 2024

- Fabricated a PDMS microfluidic chip to model BBB under TBI.
- Applied laser-induced shockwaves to mimic mechanical injury.
- Measured TEER, FITC-dextran permeability, and qPCR-based inflammation markers.

Senior Capstone: Brain Cooling Non-Invasive Device

May 2023

- Designed a passive cooling helmet using Peltier modules and aluminum heatsinks.
- Ran thermal and airflow simulations in COMSOL.

SKILLS

Quality: CAPA, FMEA, 8D, Risk Analysis, IQ/OQ/PQ, Protocol Writing, Software Validation, Audit Reports, DHF, Traceability Matrix

Software: Minitab, JMP, MATLAB, Python, R, SolidWorks, COMSOL, Mimics, 3-matic, SQL (in progress)

CERTIFICATIONS

IRB Biomedical, Social/Behavioral, Board Member (Group 1–4 Certified)

May 2025-May 2029

Google Data Analytics (In Progress)

Jun 2025-Present