

Sheila Lo

sheilalo.com | contact@sheilalo.com

EDUCATION

Northwestern University

M.S. Engineering Design Innovation (Human-Centered Design)

Sept 2016 – Dec 2017

California Institute of Technology

B.S. Mechanical Engineering

Oct 2012 – Jun 2016

EXPERIENCE

Roche

Regulatory Affairs Specialist

Jul 2019 – Present

- Develop regulatory strategies in compliance with US, EU, and other international regulations for 8 clinical decision support software products launched in 22 countries and 3 products in development. Contributed to 4 releases in 2019 and 31 releases in 2020.
- Collaborate with human factors team to conduct summative studies with patients and physicians and to author usability engineering files for 4 Software as a Medical Device (SaMD) products.

Genentech

Regulatory Project Management Intern

Oct 2018 – Jul 2019

- Designed and conducted in-person simulation of new label development process that reduced document review time by 400+ hours.
- Led usability tests to evaluate new internal regulatory strategy tool for 800+ users. Analyzed user feedback and metrics to evaluate post-launch effectiveness.

Udacity

User Researcher (Contract)

Sept 2018 – Oct 2018

- Collaborated with user research team to conduct 109 remote, semi-structured interviews with students to understand barriers to success in online education.

Proteus Digital Health

Human Factors & Usability Engineering Intern

Jun 2018 – Aug 2018

- Led a remote unmoderated usability study for a patient-facing registration portal.
- Conducted a study with customer support agents to improve workflow and patient data portal.

Medtronic

Biomedical Engineer Summer Associate, Atrial Fibrillation Solutions

Jun 2017 – Aug 2017

- Designed and machined a modular *in vitro* test apparatus that leverages MRI and CT scans from previous clinical trials to support testing of next generation cryoballoon catheter technologies. Apparatus moved early catheter testing from swine to lab.

Niagara Bottling

Research & Development Intern

Jun 2015 – Aug 2015

- Designed, prototyped, and tested 3D printed water bottle designs to improve bottle strength for future designs.

CERTIFICATIONS

California Emergency Medical Technician (E108835)

Sept 2014 – Present

National Registry of Emergency Medical Technicians (E3153737)

Aug 2014 – Present