

# Shreyansh Sheth, M.S., M.Tech., B.Eng.

## Biomedical Engineer and Regulatory Affairs Professional

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### Profile

A highly skilled Regulatory Affairs professional with a Master of Science in Regulatory Affairs and a Master of Technology in Biomedical Engineering. Proven track record of working in the hospital setting and medical device industry. Strong desire to contribute to the field of medical science and technology through utilizing my extensive skill set.

### Experience

#### Regulatory Affairs Team Leader (XN-Project Leader)

April to July 2023

*Breegi Scientific (Boston, MA, USA)*

- Orchestrated clinical trials Phase-I for a neonatal incubator by leading a group of five.
- Demonstrated adept project management and coordination, achieving the project delivery within a challenging deadline.
- Developed Consent Forms, Case Report Forms, and Investigator's Brochure in accordance with ISO 14155 & ICH guidelines.

#### Regulatory Affairs Specialist

June to Sept. 2022

*Neuro-Spinal Innovation Inc. (Mississauga, ON)*

- Led Risk Management efforts, ensuring adherence to ISO 14971, ISO 24971, and IEC 60601 guidelines for medical devices.
- Collaborated with cross-functional teams to guarantee quality, safety, performance, and regulatory compliance.
- Conducted device testing with maintaining Design History File (DHF) and Device Master Record (DMR).

#### Teaching Assistant and Peer Mentor

Sept. 2021 to April 2022

*Northeastern University (Toronto, ON)*

- Mentored and supported graduate students in academic and social transitions.
- Managed administrative tasks, including scheduling, event coordination, and record-keeping.
- Acted as the Class Delegate, facilitating communication between professor and students.

#### Research Assistant

May to Aug. 2021

*International Institute of Information Technology (Raipur, India)*

- Spearheaded groundbreaking experiment focused on harnessing smartphone sensors for advanced diagnostic applications.
- Applied cutting-edge statistical data analysis and signal processing to refine vital physiological data from sensor inputs.
- Demonstrated exceptional research acumen by extensively reviewing and synthesizing insights from scientific papers.

#### Biomedical Engineering Technologist

June to Sept. 2019

*Sterling Hospitals (Ahmedabad, India)*

- Conducted inspections and testing of various diagnostic, therapeutic, and life support medical equipment.
- Performed preventive maintenance and periodic checking of devices, ensuring safety and usability.
- Documented and maintained comprehensive records of equipment maintenance activities, adhering to strict standards.

### Education

• MS in Regulatory Affairs – Northeastern University – Toronto Campus

July 2023

• MTech in Biomedical Engineering – Vellore Institute of Technology

June 2022

• BEng in Biomedical Engineering – Gujarat Technological University

August 2020

### Certifications

- Human Anatomy Specialization – University of Michigan, Ann Arbor
- BCI & Neurotechnology Spring School – g.tec medical engineering GmbH

### Projects and Publications

- **MDEL and MDL submissions for CooperVision Biofinity (Project- Canadian RA)** – Performed complete MDEL and MDL submissions for an FDA approved device to be licensed in Canada.
- **Foreign Risk Notification (FRN), Health Canada** – Developed a FRN submission for the change performed in labeling of the product (notifiable action).
- **Stress Identification System - ISC-2021 Conference** – Developed a stress identification system using LabVIEW and EEG signals.
- **Analysis of P300 ERPs and PSD - ICAICTSEE-2020 Conference** – Analyzed EEG-based P300 Event-Related Potentials using MATLAB.

### Summary of Skills

- **Software:** Proteus Circuit Design Suite, NI Multisim, MATLAB, NI LabVIEW, Arduino, R Studio, Keil µVision
- **Programming Languages:** MATLAB, Python, C, R, Arduino.
- **Regulatory Affairs:** FDA CFR, Health Canada, ICH, ISO, IEC, EMA, EU MDA, Ethics Submission, GCP, Clinical Trials.