

Shreyansh Sheth

Biomedical Engineer and Regulatory Affairs Professional

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Profile

Dynamic professional with dual master's degrees in Biomedical Engineering and Regulatory Affairs, offering a robust track record in Biomedical Research, Regulatory Affairs, and Risk Management. Proven expertise driving innovation in medical technology and in navigating complex regulatory landscapes. Eager to leverage my skills and experience to advance groundbreaking medical solutions.

Summary of Skills

- **Technical:** Machine Learning, Neuroscience, Embedded Systems, Circuit Design Suite, NI Multisim, Arduino, Keil µVision, MPLAB
- **Programming:** MATLAB, Python, R, C, LabVIEW
- **Regulatory:** Regulatory Documentation, Risk Management, Labeling, QA/QC, V&V, Auditing, CAPA, QMS, US FDA CFR, Health Canada, MDSAP, ISO 13485, ISO 14971, ISO 24971, IEC 60601, ICH, GCP, GMP, TCPS-2, Clinical Trials, Vigilance

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

Relevant Experience

Printing and Quality Assistant – Viva Healthcare (Toronto, ON) March to Dec. 2023

- Conducted quality control checks, implementing adjustments to uphold the highest standards of accuracy and consistency.
- Managed the logistics of incoming and outgoing shipments, optimizing packaging and labeling processes to guarantee efficient and accurate distribution.
- Assisted in setting up and operating systems, ensuring precise material loading and fine-tuning settings according to protocols, thereby achieving superior quality and minimizing waste.

Regulatory Affairs Team Leader (co-op) – Breegi Scientific Inc. (Boston, MA, USA) April to July 2023

- Led a team of five to expedite Phase-I clinical trials for a neonatal incubator, significantly shortening the submission timeline.
- Leveraged exceptional project management and coordination skills to ensure seamless project execution and timely completion.
- Developed Consent Forms (ICFs), CRFs, and IB in compliance with ISO 14155 & ICH guidelines, enhancing the submission efficiency.

Regulatory Affairs Specialist (Intern) – Neuro-Spinal Innovation Inc. (Mississauga, ON) June 2022 to March 2023

- Spearheaded comprehensive risk management and facilitated TÜV testing, ensuring compliance with ISO and IEC standards for medical devices, which enhanced product safety and reliability about 20%.
- Developed and implemented a variety of test methods for the device, meticulously crafted case reports, and authored Standard Operating Procedures (SOPs) to streamline operations and ensure regulatory compliance.
- Maintained up-to-date Technical Files and Design Dossiers, thereby leveling-up regulatory approval processes.

Biomedical Service Engineer – Sterling Hospitals (Ahmedabad, India) June 2020 to July 2021

- Executed rigorous inspections and testing protocols for a diverse range of diagnostic, therapeutic, and surgical equipment, enhancing operational efficiency and patient safety.
- Led preventive maintenance and periodic checks, ensuring optimal functionality and compliance with safety regulations.
- Documented maintenance activities and maintained comprehensive records, adhering to stringent industry safety standards and contributing to a 15% reduction in equipment downtime.

Certifications

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

Projects and Publications

- **Regulatory submissions for CooperVision** – Performed MDEL and MDL submissions for an FDA approved device in Canada.
- **Stress Identification System - ISC-2021 Conference** – Developed a stress identification system using LabVIEW and EEG signals.
- **Automated Medicine Dispenser** – Developed Raspberry Pi based Servo system to dispense medicine using Python (Kivy) UI.